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# THE EFFECTS OF PARTIAL BODY WEIGHT SUPPORT FOR GAIT FOR PATIENTS WITH NEUROLOGICAL DYSFUNCTION—A CASE STUDY APPROACH

by

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A Scholarly Project Submitted to the Graduate Faculty of the Department of Physical Therapy
School of Medicine
University of North Dakota

in partial fulfillment of the requirements for the degree of

Master of Physical Therapy

Grand Forks, North Dakota May, 2003 This Scholarly Project, submitted by LaRae Haas, Beth Millage, and Becky Sorenson, 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 Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

Mulule Labreque (Faculty Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)

## **PERMISSION**

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The Effects of Partial Body Weight Support for Gait for

Patients with Neurological Dysfunction—A Case Study

Approach

Department

Physical Therapy

Degree

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## **ABSTRACT**

The purpose of this study was to determine the effects of partial body weight support during gait for individuals with neurological dysfunction. Body weight support (BWS) training provides a safe environment in which the individual can perform and practice mechanics of normal gait at a variety of speeds with or without body weight support, depending on the level of function. The subjects who participated in this study were community ambulators older than 20 years of age with a neurological diagnosis. Each subject was tested initially and at the conclusion of the study to compare data using a battery of balance and gait tests. Each subject participated in body weight support treadmill gait training using the LiteGait™ three times a week for up to six weeks. Each subject was to begin with 40% body weight support (BWS) and a treadmill speed of .5 mph, progress to 20% BWS and a speed of .7 mph, and finally to 0% BWS and a speed of 1.0 mph. All three subjects made improvements when comparing initial to final testing results. Many factors may have limited the results of our study including the tester, sensitivity of the tests performed, or sudden changes in medical status.

## CHAPTER 1

## INTRODUCTION

Following a neurological insult to the body, many people will have a decreased ability to ambulate or will exhibit abnormal gait patterns. For many of these people, their rehabilitation goals will include normalizing their gait pattern, increasing endurance, and increasing their ability to perform activities of daily living (ADL's). It is from these goals that therapists have tried a variety of techniques in order to restore normal gait and increase endurance for ambulation and ADL's.

Gait training, in general, serves to normalize gait by trying to facilitate the appropriate muscles to move the limbs efficiently. Muscle facilitation during gait can be done through manual contacts or through use of devices such as functional electrical stimulation timed to fire the appropriate muscles. 

Additionally, gait training works to improve speed in gait and improve balance. 

These areas are often decreased as an indirect result of a neurological disorder.

Body weight support gait training, such as LiteGait<sup>TM</sup>, has been used for a number of years because of the many benefits it provides to people with neurological diagnoses and to the therapist. Using a body weight support device in rehabilitation is useful in gait training because it supports the individual in

normal postural alignment, unweights the body to decrease the work of ambulation, and provides the individual with a safe environment in which to practice gait.<sup>2</sup> With the safer environment, it is possible to start gait training sooner, which often provides a psychological boost for the individual. Utilizing this type of gait training allows the therapist to provide the individual with manual contacts for facilitation of proper gait pattern and to manually move the individual's limbs without having to support them to prevent a fall.

Body weight support gait training can be performed on a treadmill or over even terrain. Using a treadmill is beneficial in promoting proper timing for stepping and improving gait speed.<sup>3</sup> Also, the moving belt of the treadmill may help facilitate stepping by causing a quick stretch of the hip flexors in people who have difficulty initiating movement.<sup>3</sup>

## Problem Statement

Loss of independence in gait is common following a neurological incident. This study will investigate whether or not the use of body weight support gait training over a treadmill can improve quality of gait, postural control, and gait speed. There is always a need to improve current physical therapy interventions for gait training, and body weight support gait training may be another way to improve function for individuals with neurological diagnoses.

## Purpose of Study

The purpose of this study is to see if body weight support gait training will improve balance, quality of gait, postural control, and increase the speed of gait.

# Significance of Study

This study will provide further information and increase awareness of body weight support gait training as an alternative and/or additional tool for use in gait training during physical therapy. This study will also add to the body of research in body weight support gait training with a variety of neurological dysfunctions.

# **Research Questions**

- 1. What is the effect of body weight support gait training on gait kinematics?
- 2. What is the effect of body weight support gait training on postural control and balance?
- 3. What is the effect of body weight support gait training on endurance for activity?

# Hypothesis

Null hypothesis: There is no significant difference in balance scores, gait kinematics, and/or postural control following six weeks of body weight support gait training in individuals over the age of twenty with neurological dysfunction.

Alternate hypothesis: There is a significant difference in balance scores, gait kinematics, and/or postural control following six weeks of body weight support gait training in subjects over the age of twenty with neurological dysfunction.

## CHAPTER 2

#### LITERATURE REVIEW

The following literature review will describe postural control, balance, and components of normal and abnormal gait associated with cerebrovascular accident, malignant brain tumor, and spinal cord injury. Body weight support treadmill training for these diagnoses will also be described.

Postural Control, Stability, and Orientation

Postural control involves trunk control and stability for maintaining the body's position in space for the purpose of steadiness and orientation.<sup>12</sup> Without trunk control, there is an increase in vertical displacement of the center of gravity which creates more work and energy expenditure to compensate for the displacement. Lateral movement of the center of gravity creates linear momentum that must be counteracted by muscular effort and thus increases the amount of work and energy expenditure.<sup>4</sup>

Systems needed for postural control are motor processes, sensory processes, and higher-level integrative processes (central integration).<sup>4</sup> If one or more of these systems are not working properly, postural control is negatively affected. Motor processes can be affected by tone, posture, and movement strategies at the ankle and hip. Movement strategies are effective in controlling

the body's center of gravity relative to the base of support. Sensory processes are affected by visual deficits, somatosensory deficits, and vestibular deficits, whereas central integration is the ability to adapt senses for postural control.

Postural stability, or balance, is the ability to maintain the body in equilibrium or the ability to maintain the center of gravity over the base of support.<sup>5</sup> This is important to prevent loss of balance, especially during dynamic movement.

Postural orientation is defined as the ability to maintain an appropriate relationship between the body segments, the body, and the environment for a task.<sup>4</sup> To achieve this, there must be an equal distribution of coordination, posture, and balance.

Coordination is the working together of muscles and body systems to produce a certain movement.<sup>5</sup> Coordination can be altered by most neurological impairments that occur at the brain or spinal cord. It influences gait because the impairments affect proper timing or sequencing of toe-off, heel strike, and weight shifting.<sup>2</sup> It can also be changed secondary to co-activations of antagonist muscles, delayed muscle recruitment, delayed responses, and problems scaling the amplitude of muscle responses.<sup>4</sup>

Posture is defined as the skeletal alignment accepted as normal that has the least amount of stress and strain on muscles, joints, and ligaments.<sup>5</sup>

Posture may be altered by neurological impairments. It is affected by weakness

or paralysis of muscles, bone abnormalities, osteoporosis, contractures, muscle tone, and/or displaced joints.<sup>2</sup>

Balance can also be affected by neurological impairments. It is usually due to either primary or secondary impairments of the sensory and/or motor systems which greatly impair the ability to ambulate. Primary impairments include parasthesia, hypertonicity, hypotonicity, loss of sensation, and loss of coordination. Secondary impairments may include contractures, muscle wasting/atrophy, and decreased range of motion. Ambulation is often slowed and asymmetric and safety issues arise due to compromised balance while ambulating. This can be compensated by the use of walking assistive devices and balance intervention.<sup>2</sup>

#### Balance

Adequate upright balance is needed in order for safe and efficient gait to occur. Balance is "the condition in which all the forces acting on the body are balanced such that the center of mass is within the stability of limits, the boundaries of the base of support." Since the body's center of gravity is located above a small base of support, a person in the standing position is relatively unstable and will fall without active control of balance. As long as the body is able to maintain its center of gravity over its base of support, a person can resist the destabilizing forces of gravity to actively move the center of gravity and

perform activities. Once the center of gravity falls beyond the base of support, an external support or quick-step is needed to prevent a fall.<sup>6</sup>

There are three components of balance: vestibular, visual, and somatosensory. Vestibular input enables independent and precise control of head and eye movements, when visual and somatosensory inputs are altered. Visual input enables the ability to remain stable on uneven surfaces. Somatosensory input results from contact between the feet and supporting surfaces. These components provide the central nervous system (CNS) with afferent (sensory) input, which can then be followed by the appropriate efferent (motor) response from the CNS. When these systems are functioning correctly, an individual is able to maintain the center of gravity within the base of support with minimal sway. However, with neurological impairment, any one or all of these components may be affected, decreasing a person's ability to maintain balance and perform gait.

In a study by Krebs and Goldvasser et al.,<sup>7</sup> 22 subjects with vestibulopathy and 22 subjects without vestibulopathy were compared for dynamic interfoot distance (IFD) throughout the gait cycle. Interfoot distance was measured as the width between steps. Two trials of each subject's gait at preferred speed and paced gait at 120 steps/minute were analyzed. Gait at preferred speed allowed both groups of subjects to select similar IFD values, but at the cost of a slower gait in the unsteady subjects. When the subjects with

vestibulopathy were required to walk at a "normal" pace of 120 steps/minute,

IFD was increased. This study concluded that wide-based gait alone cannot

differentiate between subjects with and without balance impairments. However,

increased base of support often is a mechanical compensation of individuals with

vestibulopathic instability.

In order for balance to be improved during gait, the practice of individual and composite locomotor tasks is vital. One way this can be accomplished is through walking on a treadmill. Walking on a treadmill has been shown to be a beneficial treatment intervention for individuals with neuromuscular diagnoses. The rationale for its use is to excite innate motor patterns by retraining reciprocal walking motion. The treadmill assists individuals by forcing them to increase the speed of their gait. By doing so, the individual may strengthen the activated muscles at speeds closely associated with over-ground ambulation. A second reason for treadmill training is to gain aerobic endurance without having to struggle with obstacles of over-ground ambulation.

## Normal Gait

Gait can be defined as "rhythmic alternating movements of limbs and trunk resulting in forward movement of the body's center of gravity." Gait analysis involves recognizing any deviations in gait, determining what those deviations are, and using those findings to select an appropriate treatment. In

order to properly analyze gait, it is important to have a thorough understanding of the normal gait cycle.

The gait cycle consists of the activity that occurs between heel strike and a subsequent heel strike on the ipsilateral side. The most common method of dividing the gait cycle is by breaking it into stance and swing phases. The stance phase is the entire period the foot is on the ground, and it accounts for 62% of the gait cycle.<sup>9</sup> The swing phase begins when the foot comes off the ground, and it accounts for 38% of the gait cycle.<sup>9</sup> The Ranchos Los Amigos Classification breaks the gait cycle down into eight subdivisions to be observed during normal gait.<sup>9</sup> Table 1 describes a summary of these subdivisions.

Table 1- Normal Gait Analysis Terminology 9

	it Analysis Terminology
Initial contact	The moment when the foot of the leading extremity contacts the ground. Accounts for 0% of the gait cycle.
Loading response	Occurs immediately following initial contact and continues until the contralateral extremity lifts off the ground at the end of the double-support phase. It is the first period of double-limb support. Accounts for 0-12% of the gait cycle.
Mid-stance	Begins when the contralateral extremity lifts off the ground and continues to a position in which the body has progressed over and ahead of the supporting extremity.  Accounts for 12-31% of the gait cycle.
Terminal stance	The period from the end of mid-stance to a point just prior to initial contact of the contralateral extremity or following heel off of the reference extremity. Progression continues over the stance limb until the body moves ahead of the limb and weight is transferred onto the forefoot. Accounts for 31-50% of the gait cycle.
Pre-swing	The period following heel off and continuing to toe off. A rapid unloading of the limb occurs as weight is transferred to the contralateral limb. This subdivision is considered the second period of double-limb support. Accounts for 50-62% of the gait cycle.
Initial swing	Begins when the toe leaves the ground and continues until maximum knee flexion occurs. The thigh begins to advance as the foot comes off the floor. Accounts for 62-75% of the gait cycle.
Mid-swing	The thigh continues to advance as the knee begins to extend as the foot clears the ground. This is the period immediately following maximum knee flexion and continues until the tibia is in a vertical position. Accounts for 75-87% of the gait cycle.
Terminal swing	The period from the point at which the tibia is in the vertical position to a point just prior to initial contact. Accounts for 87-100% of the gait cycle.

Gait can also be divided into four separate attributes that combine to form a normal and functional gait pattern. Table 2 lists these attributes. These items were measured with each subject pre- and post-body weight support gait training.

Table 2- Normal Gait Descriptors 9

Stride length	Linear distance between successive heel strikes of the same foot (89% of an individual's height in free walking, and 106% of the individual's height in fast walking).
Step length	The linear distance between two successive points of contact of opposite extremities. This is usually measured from heel strike of one extremity to heel strike of the opposite extremity.
Walking angle	The angle of foot placement. Measured by the angle between the line of forward progression and a line which bisects the midpoint of the heel and the second metatarsal head. At free walking speed this is approximately seven degrees for males. No values reported for females. As speed increases, the walking angle decreases and/or becomes more efficient.
Walking velocity	The distance walked divided by time. Average=82 meters
(10-meter walk time)	per minute.

In addition to these descriptors, another way to view the gait cycle is from a functional standpoint. Using a functional model, gait can be divided into three functional tasks: weight acceptance, single limb support, and swing limb advancement. Weight acceptance includes the phases of initial contact and loading response. This is also the stage where weight is loaded onto an extended lower extremity. The impact of the floor-reaction force is absorbed by the body as it continues in a forward path while stability is maintained. At this point both feet are in contact with the ground.

Single-limb support includes the phases of mid-stance and terminal stance. This is the period when the body progresses over a single, fixed limb. Weight is then transferred onto the metatarsal heads as the heel comes off the ground.

Swing limb advancement includes the phases of pre-swing, initial swing, mid-swing, and terminal swing.<sup>9</sup> This is the period when the limb is unweighted and the foot comes off the ground. Finally the limb is moved in front of the body, reaching out to take the next step.

An example of functional gait is crossing the street. According to Robinett and Vondran<sup>10</sup>, the minimum safe speed for street crossing is 1.12 miles per hour (0.5 meters per second), whereas Perry et al<sup>11</sup> suggested that the speed needed to safely cross the street in the time allotted by crosswalk signals is 1.34 miles per hour (0.65 meters per second).

# Pathological Gait

Ambulation, or gait, is one of the physical functions most commonly affected with a neurological disease process. Gait patterns of individuals with neuromuscular impairments are generally affected by abnormalities in muscle tone, synergistic patterns, diminished balance, decreased balance reactions, and lack of coordination which result in asymmetrical step and stride lengths. Normal posture and motion may be altered and appear as trunk leaning, increased hip

flexion, increased hip extension, diminished dorsiflexion, or increased plantarflexion.

Pathological gait mechanisms develop as a result of the loss of normal function of muscles and/or muscle coordination. A comparison of normal gait patterns with those exhibited by individuals with neurological insult include a decreased walking velocity with a shorter stance phase, decreased weight bearing, and increased swing phase for the involved lower extremity. From a functional perspective, gait abnormalities can be categorized according to the gait cycle. During the stance phase, an abnormal base of support and lower extremity instability may make walking unsafe, energy inefficient, and painful. During the swing phase, inadequate limb clearance or limb advancement may interfere with safety and energy efficiency.<sup>8</sup>

In order to identify and evaluate gait problems properly, the physical therapist must be able to compare normal patterns of gait with what the individual exhibits. Pathological gait mechanisms develop as a result of the loss of normal functioning of muscle and/or coordination. From a functional perspective, gait pathologies can be categorized based on their appearance during the gait cycle and the body segment at which they occur.<sup>12</sup>

Pathological gait patterns can be observed at the foot, ankle, knee or hip.

Tables 3 and 4 list common pathologies found at each body segment.

Table 3- Common Pathological Gait Descriptors of Foot/Ankle/Knee 13

Table 3- Common Pathological Gait Descriptors of Foot/Ankle/Knee		
<u>Foot</u>	The inability to keep the heel in contact with the	
Premature heel-off	ground in any part of initial contact, loading	
	response and midstance.	
	Prolonged heel contact with the floor during terminal	
×	and pre-swing. Delayed heel-off interferes with	
	progression of the body over the forefoot and	
Delayed heel-off	shortens the step length of the contralateral	
	extremity.	
	Simultaneous contact of the forefoot and the heel	
	with the ground. Foot flat provides an immediate	
	base of support for individuals with decreased	
Foot flat contact	balance. No heel rocker is present which decreases	
	the forward momentum of the tibia and the limb's	
	ability to absorb the shock of floor contact.	
	The toes make initial contact with the ground instead	
Forefoot contact	of the heel. It reduces the forward momentum of	
	the tibia and decreases shock absorption.	
	The foot falls to the ground in an uncontrolled	
Foot slap	manner immediately following initial contact, usually	
	caused by a weak tibialis anterior muscle.	
<u>Ankle</u>	Excessive ankle plantarflexion (PF) results in a loss	
Excessive plantarflexion	of forward progression as the tibia is restricted from	
	advancing over the forefoot.	
	Excessive dorsiflexion (DF) indicated conditions	
	where PF is lacking and is functionally more	
Excessive dorsiflexion	significant in stance than swing phases. It is	
	considered abnormal for all phases of gait except	
	midstance and terminal stance.	
<u>Knee</u>	Excessive knee extension provides stability to an	
	otherwise unstable knee during weight bearing.	
Limited flexion/	Limited knee flexion may cause toe drag forcing an	
excessive extension	abnormal substitution pattern in order to advance	
	the limb through the swing phase.	
	Limited knee extension during terminal stance leaves	
Limited extension/	the limb unprepared for initial contact and decreases	
excessive flexion	the step length of the stance limb. Excessive knee	
	flexion places an increased demand on the	
	quadriceps muscles to stabilize the knee.	

Table 4- Common Pathological Gait Descriptors of the Hip 13

Table T Common action gical Gait Descriptors of the Tip	
<u>Hip</u>	Limited hip extension interferes with forward body
	progression, decreases step length, and makes for
Limited extension	an unstable posture during the weight bearing
	stages of gait.
	Limited hip flexion contributes to toe drag and ankle
	PF, which limits limb advancement and causes a
Limited flexion	shorter step length. Substitution patterns are used
	to clear the ground for limb advancement.
	Excessive hip adduction will produce a pelvic drop on
*	the contralateral side. It can increase the limb
Excessive hip adduction	length and cause difficulty with foot clearance. It
	also decreases the base of support.
	Excessive hip adduction increases the base of
	support and length of the limb in the swing phase.
Excessive hip abduction	It causes ipsilateral drop of the pelvis.
	Circumduction is used to advance the limb in the
	absence of adequate hip flexion.

# Gait Speed in Treadmill Training

Individuals with neurological dysfunctions often exhibit decreases in gait speed due to a number of factors including decreased muscle strength, decreased range of motion, increased reaction time, decreased balance, and decreased confidence in his or her ability to ambulate safely. In a study by Sullivan, Knowlton, and Dobkin<sup>14</sup>, subjects with hemiparetic gait were found to have gait speeds 50% below normal. They performed 12 body weight support treadmill training sessions over a four-week period with subjects in three categories. Sessions were 20 minutes long and these categories included: slow speed (.5 mph), fast speed (2.0 mph), and variable speeds (.5, 1.0, 1.5, and 2.0 mph). The overground walking velocity chosen by the subjects was measured

before, during, and after the study. All groups in the study had increases in gait speed following the study and at a three-month follow-up, these speeds were maintained. Although all groups saw increases in speed, the greatest improvement occurred with the "fast speed" group. The researchers concluded that training at speeds comparable to normal walking velocity was the most effective method.

A treadmill is useful for restoring normal gait speed in that it can be set at a constant rate to allow rhythmic input to the individual, assist with a reciprocal gait pattern, and improve coordination.<sup>2</sup> In choosing a treadmill for gait training, it is vital to have one with a wide platform to accommodate the large base of support that some individuals will exhibit. Also, the length of the treadmill needs to be sufficient to accommodate a variety of heights. Taller individuals will have a longer stride and step length with gait. The speed of the treadmill should be slow enough to allow the individual to develop a proper gait pattern first and to focus on quality of movement. Once movement patterns are normalized, the speed should be increased to challenge the individual.

Body Weight Support During Treadmill Training

A review of the literature shows no protocol for determining the percentage of body weight that should be supported in order to obtain the best environment for gait training. However, it is important to remember that at no point should an individual participate in body weight support gait training with all

weight removed due to concern for compromised blood flow to the extremities.<sup>2</sup> A study by Hassid et al<sup>15</sup> found that 15% body weight support provided the greatest step feedback and provided the best symmetrical loading. In a study by Miyai et al<sup>16</sup>, individuals with Parkinson's Disease were observed to have a better gait pattern and a higher subjective comfort rating at 20% of body weight support. Mobility Research, the makers of the LiteGait<sup>TM</sup>, recommend that gait training never occur with more than 40-50% of the body weight supported.<sup>2</sup> They found that greater than 40-50% of body weight support will actually inhibit locomotion. In general, they feel that the individual should be supported to the point where gait is observed to be as normal as possible. This point will depend on the individual's level of impairment, coordination, balance, strength, and function.

## Cerebrovascular Accident

Cerebrovascular Accident (CVA), or stroke, is a sudden onset of neurological impairment due to an abnormality in brain circulation. Stroke is the third leading cause of death and the leading cause of disability among adults in the United States.<sup>1</sup>

A CVA may cause many types of deficits, including changes in consciousness levels and sensory, motor, cognitive, perceptual and language dysfunctions.<sup>1</sup> In order to be classified as a stroke, focal neurological impairments must be present for at least 24 hours. Motor deficits are typically

on the side of the body opposite the brain lesion and consist of either paralysis (hemiplegia) or weakness (hemiparesis).

Strokes are classified into three etiological categories: thrombosis, embolus, or hemorrhage.<sup>1</sup> Thrombosis is the formation of a blood clot within an artery of the brain. Thrombi lead to an artery occlusion and eventual tissue death. Emboli are moving pieces of matter within the bloodstream that become lodged in an artery producing occlusion and tissue death. Finally, hemorrhage is caused by a rupture of a brain vessel with bleeding into the brain. Hemorrhage is known to be the most fatal type of stroke.

Stroke is a partially preventable disease with potentially modifiable risk factors. These risk factors include hypertension, heart disease, diabetes, obesity, smoking, increasing age, gender, race, prior history of stroke, and heredity. Suggestions for decreasing the risk of stroke include: controlling blood pressure, finding out if heart disease or cardiac arrhythmias are present, including exercise in your daily routine, controlling diabetes, smoking cessation, controlling cholesterol levels, moderating alcohol consumption, and a low sodium and low fat diet. Besides decreasing risk factors, effective stroke prevention begins with learning the early warning signs so that treatment may begin early to prevent impairments. Early warning signs include an unexpected, severe headache with no known cause; sudden weakness or numbness of the face, arm, or leg especially on one side of the body; sudden confusion, loss of speech, or difficulty

talking or understanding speech; abrupt dimness or loss of vision; and sudden trouble walking, unexplained dizziness, loss of balance or coordination, or sudden falls. It is important to remember that stroke is an emergency; if you see or have any of these symptoms seek treatment immediately.<sup>17</sup>

Survivors of stroke often experience direct impairments as a result of damage to their neurological system. Sensation is commonly impaired, but is almost never absent on the involved side.<sup>17</sup> The extent of the sensory deficit is related to the extent of the vascular damage in the brain. Pain may also result from indirect impairments such as muscle imbalances, improper movement patterns, and poor body alignment. Pain is often found to be the cause of decreased function, poor concentration, depression, and reduced rehabilitation potential following a CVA. Individuals following a stroke may also experience impairments in vision, depth perception, and other spatial relationships.

Motor deficits are also an obstacle for individuals following a stroke.<sup>17</sup>

During the early stages of a stroke, flaccidity is common due to cerebral shock.

Flaccidity is generally short-lived and is usually replaced by the development of spasticity, hyperreflexia, and synergies. Spasticity is described as tight, stiff muscles that make movement, especially of the arms and legs, difficult or uncontrollable. Spasticity affects approximately 90% of individuals following a stroke and occurs on the side of the body opposite the brain lesion, mostly affecting anti-gravity muscles.<sup>17</sup> Spasticity results in restricted voluntary

movement, static posturing of the extremities, and may lead to muscle contractures. With either spasticity or flaccidity, there may be a decreased ability to stabilize proximal joints and the trunk correctly. Individuals with stroke may experience postural mal-alignment, balance difficulties, and may have an increased risk for falls secondary to changes in muscle control.

Reflexes are distorted and vary depending on the stage of recovery.<sup>17</sup>
Initially, stroke results in hyporeflexia. Hyperreflexia usually appears during the middle stages of recovery where spasticity and synergies are strongest. Stretch reflexes are hyperactive and individuals usually reveal clonus, clasp-knife reflexes, and a positive Babinski.

As the individual goes through stages of flaccidity and spasticity, abnormal synergistic patterns are typically present, and the subject may be unable to move a single limb segment without causing movement in the rest of the limb.<sup>17</sup> The individual is also limited in his/her ability to adapt movements to varying tasks or environmental demands. Initial synergistic patterns are either elicited reflexively as associated reactions or as small, voluntary movements. As the individual progresses into the middle stages of recovery, he/she develops basic limb synergies associated with spasticity. The two main synergy patterns are a flexion synergy and extension synergy. As recovery progresses, the basic limb strategies begin to disappear as more isolated movements are possible and movement control begins to develop.

Paresis, or weakness, is found in 80% to 90% of all individuals following stroke. Paresis is the inability of a muscle or group of muscles to move voluntarily. Due to paresis, individuals are often unable to produce enough force needed to initiate and control movement and posture. Distal muscles are usually more involved than proximal muscles. There are also possible changes in muscle composition, including atrophy of muscle fibers.

Balance is another element often disturbed following a stroke with impairments in steadiness, symmetry, and dynamic stability. <sup>17</sup> Individuals with stroke classically display asymmetry with most of their weight shifted to the uninvolved side during sitting or standing and increased postural sway in stance.

The combination of residual motor weakness, poor motor control, and spasticity directly related to a stroke can result in an altered gait pattern, poor balance, increased risk for falls, and increased energy expenditure during walking. One of the main goals in treatment of survivors of stroke is to restore a proper gait pattern. Intervention normally begins with careful preparation of required muscle activity in the supine position and progresses to working with the individual components of gait while standing. In 50% of survivors of stroke, walking impairments are still observed three months after the injury. As a result, the restoration and improvement of walking ability is a major treatment goal of physical therapy and the individual.

There are numerous physical therapy interventions for gait re-training that can be utilized following a stroke including: Proprioceptive Neuromuscular Facilitation (PNF), Neurodevelopmental treatment techniques (NDT), and partial body-weight support systems. PNF techniques consist of assisted isometric and isotonic leg flexion-extension exercises to improve strength and control of lower extremity musculature in preparation for walking. NDT techniques emphasize spasticity reduction through control of postural symmetry and use of reflex inhibitory movements. A partial body-weight support system allows for task-specific training of complete gait cycles with therapist assistance of the paretic limbs or trunk as needed. These techniques can be used individually or in combination depending on the individual's response.

A study by Miller et al<sup>20</sup>, compared the pre and post-intervention performance of two post-CVA subjects, ages 87 and 93, on a partial-body weight support system. Subject B showed the greatest improvements in the 10-meter walk time (22%) and step length (35% on the right, and 25% on the left), with minimal improvements in overall gait and balance. Subject B was described as more social and alert by her family and nursing staff throughout the duration of the intervention. Subject A demonstrated a faster 10-meter walk time, improved step length, and a 14 point increase on the Berg Balance Scale. The bodyweight support system with treadmill ambulation was well tolerated by both

subjects and proved to be an effective intervention for regaining ambulation and balance skills post-CVA.

In a similar study by Visintin M et al<sup>21</sup>, 50 subjects were trained to walk with up to 40% of their body weight supported by the body weight support system and 50 subjects were trained to walk with 0% body weight supported by the body weight support system. The subjects were assessed on functional balance, motor recovery, overground walking speed, and overground walking endurance. After a six-week testing period, the body weight support group scored significantly higher in all four areas of assessment than the non-body weight support group. A follow-up evaluation three months after the testing revealed the body weight support group continued to have significantly higher scores for overground walking speed and endurance than the non-body weight support group. Both types of training were well tolerated by both groups. This study shows that the partial body weight support system is an effective gait training tool for the treatment of abnormal gait following stroke.

If partial body weight support system equipment is not available or if the individual is not willing to participate, braces, canes, walkers and wheelchairs may also help stroke survivors gain strength and move about more freely.<sup>17</sup> The most commonly used brace is an ankle-foot orthosis (AFO). The AFO starts below the knee and controls the ankle and foot by keeping them in a neutral position. This device is commonly used when an individual is experiencing foot

drop, a common condition during stroke recovery. It occurs when a person's foot or ankle drops down while lifting a leg to take a step. This condition increases the individual's risk for falls if the foot and ankle are not supported by a brace until muscle strength or range of motion increases.<sup>17</sup> Canes, walkers, and wheelchairs can help a person to be more independent at home, work, and in the community. These devices make it possible or easier for individuals to accomplish functional activities that are hard for them and may make them feel more secure.

The goal of rehabilitation is to enable as much independence as possible by improving physical, mental, and emotional functions.<sup>1</sup> Recovery is generally fastest in the first few weeks after onset, with measurable neurological and functional recovery happening in the first one to three months after stroke.<sup>1</sup> Individuals may continue to make functional improvements at a slower rate for up to six months or longer following a stroke.<sup>1</sup> Rehabilitation that begins early in the acute stage increases the individual's potential for functional recovery and should begin as soon as the individual is deemed medically stable.

# Malignant Brain Tumors

Approximately 100,000 Americans are diagnosed each year with primary or metastatic brain tumors.<sup>22</sup> The effects of these tumors vary depending on the type, location, and size of the tumor and vary in their affects on the individual. Half of all primary brain tumors are considered to be gliomas, which can further

be categorized into astrocytomas, ependymomas, oligodendrogliomas, ganglioneuromas, and other types of mixed gliomas. Of particular interest to this case study is information regarding astrocytomas specifically.

Astrocytomas are derivatives of the star-shaped glial cells known as astrocytes.<sup>23</sup> This is the most common primary brain tumor in adults and children. These are typically found in the cerebrums of adults and in the cerebellums of children. Astrocytomas are graded following a biopsy and include the descriptors from the World Health Organization grading system.<sup>22</sup>

Well-differentiated astrocytomas include both grade one and two astrocytomas.<sup>23</sup> Cells contained in these tumors are relatively normal and are considered less malignant. These types of tumors will grow very slowly and can often be completely surgically excised. Tumors in grades one and two are often only life threatening if they are inaccessible to surgery.

Anaplastic astrocytomas include grade three mid-grade astrocytomas.<sup>23</sup>
These tumors will grow more quickly than the well-differentiated type astrocyomas and are considered more malignant. Surgery, in addition to radiation and chemotherapy, are often used to treat anaplastic astrocytomas.

Glioblastoma multiforme includes grade four high-grade astrocytomas.<sup>23</sup> These tumors are highly malignant, grow very quickly, and often diffuse into nearby tissues. This type of tumor is the most common type found amongst

adults. Treatment usually includes a combination of surgery, radiation, and chemotherapy. Chemotherapy can occur before, during, or after radiation.

Other criteria can be used to describe and grade tumors. Physicians may assess atypia which is described as the degree of similarity of the cancer cells to normal cells.<sup>22</sup> Physicians may also determine the mitotic index which is the rate of cell growth. Necrosis in the center of the tumor indicates uncontrolled growth and the margin of the tumor should be assessed to determine the potential for infiltration and the vascularity of the tumor.<sup>24</sup> Often even before a diagnosis is determined from a biopsy, the individual will exhibit a variety of symptoms related to the growing tumor. Increased intracranial pressure may occur due an increased mass or a blockage of the cerebral spinal fluid pathways that can result in irritability, lethargy, vomiting, anorexia, headache, or even a noticeable change in behavior.<sup>25</sup> Depending on the location of the tumor, the effects on the individual may vary. Growth of a tumor in the frontal lobe will present as difficulties with reasoning and thought processing as well as affective behavior and memory.<sup>26</sup> Tumors of the temporal lobe will affect behavior, memory, and hearing and vision pathways. Parietal lobe tumors affect thought, reasoning, memory, and a general dampening of intellect. Occipital lobe tumors will affect speech and motor functioning if located in the dominant side (generally the left hemisphere) and will affect construction of abstract concepts if located in the non-dominant side (generally the right hemisphere) of the brain. A tumor in the

cerebellum is exhibited by ataxia, incoordination, and signs of increased intracranial pressure mentioned above.<sup>27</sup> The cerebellum controls limb, posture, eye/hand coordination, and may also participate in non-motor cognition and attention functions. Any insult to the cerebellum can result in postural instability, gait ataxia, dyssynergia, hypotonicity, fatigue, and headaches. Professionals in physical therapy and occupational therapy become involved in working with these individuals in order to assess his or her level of ataxia and balance. These professionals may suggest assistive devices in order to improve the individual's safety and mobility. Also, all health professionals should be aware of the signs of increased intracranial pressure and notify necessary medical personnel if they are present.

In addition to providing assistive devices and assessing balance, physical therapists may work with individuals who have brain tumors in order to increase strength, balance, and gait.<sup>23</sup> Gait training in individuals with brain tumors is often no different than gait training in other individuals with gait disturbances. Depending on the area of the brain tumor, hemiparesis may result on the contralateral side of the body. Strengthening and gait training will focus on increasing the activity of this weaker side. First, a thorough assessment of the individual's functional limitations related to gait is needed along with objective data of the individual's gait. Next, strength and endurance for activity should be documented as these are important measures of progress.

# Spinal Cord Injury

Half of the population with spinal cord injuries (SCI) are between the ages of 15-30 years old. Young males make up 80% of individuals who sustain a SCI. Every year there are approximately 11,000 new case of SCI's in the United States. SCI's are classified into two types: complete and incomplete. A complete SCI is described as having no motor function or sensation below the level of injury. An incomplete SCI would have some preservation of motor function or sensory function below the level of injury. SCI's are also classified by the neurological level of injury which is determined by the lowest point where there is a decrease or absence of feeling and movement.

SCI's can be further classified into paraplegia or tetraplegia (formerly known as quadriplegia).<sup>30</sup> Paraplegia is the lack of or diminished sensation and movement in the lower parts of the body usually due to an injury in the thoracic, lumbar, or sacral segments of the spine. Tetraplegia is the lack of or diminished sensation and movement in the upper and lower parts of the body, usually due to an injury in the cervical segments of the spine.

The American Spinal Injury Association (ASIA) also sets standards on how to classify SCI's. <sup>28, 30</sup> The scale ranges from A - Complete SCI with no sensory or motor function below the neurological level of injury; B - Incomplete SCI with no motor function below the neurological level of injury; C - Incomplete SCI with motor function preserved below the neurological level of injury, with the majority

of muscles below the level of injury having a muscle grade less than three out of five; D - Incomplete SCI with motor function preserved below the neurological level of injury, with the majority of muscles below the neurological level of injury having a muscle grade greater than or equal to three out of five; and E - Normal sensory and motor function.<sup>28</sup>

Two primary effects of SCI are paralysis and loss of and/or diminished sensation. There are also many secondary effects which include spasticity, bladder and bowel dysfunction, pressure sores, autonomic dysreflexia, postural hypotension, heterotopic ossification, contractures, deep vein thrombosis, and pain. Individuals with incomplete injuries tend to have more severe spasticity than those with complete SCI, which can override voluntary motion. A certain degree of spasticity may be beneficial because it helps to trigger voiding and helps stabilize the body. However, when there is too much spasticity, activities of daily living (ADL's) such as bathing, dressing, and mobility are hard to complete. Spasticity is often increased by environmental temperatures, urinary tract infections, emotional and physical stresses, and bladder or kidney infections. Spasticity can be reduced using various treatments such as muscle relaxants, peripheral nerve blocks, baclofen, intrathecal injections, myotomy, tenotomy, and rhizotomy. It can also be treated through physical therapy intervention with range of motion (ROM) exercises, positioning, casts, splints, and weight bearing activities.30

Other physical therapy interventions tend to focus on strengthening muscles and gait training for individuals with SCI's. 31 It is important to strengthen lower extremities (L/E), upper extremities (U/E), and trunk musculature to aid in ADL's such as walking. Some methods used for pre-gait activities include sit to stand, trunk balance, push ups, weight shifting, dynamic balance while standing, working in kneeling, quadruped, bridging, and modified plantigrade. Aquatic therapy is used for gait training because the water supports a portion of the body weight making walking possible for some individuals who are unable to walk on land. Functional Electrical Stimulation (FES) is also used in gait training to stimulate the muscles to move and thus can help individuals walk. FES tends to fatigue muscles and is a complex device to operate. Therefore researchers have been looking at other ways to improve an individual's gait pattern.<sup>31</sup> One theory that has been tested and shows good results with individuals with SCI's is the body weight support treadmill training. It consists of a treadmill with a harness to unweight part of the subject's body weight. The speed and incline of the treadmill can be adjusted as well as the percentage of the subjects' bodyweight to be supported. This enables the physical therapist to assist with foot placement, and other manual cues while the subject is walking to improve and/or achieve a proper gait pattern.

Gardner et al<sup>32</sup> studied a single subject with a spinal cord injury over a six week period of initial measurements followed by another six week period in

which the subject ambulated on a treadmill three times per week with 32% of his body weight supported. This was followed by a three week period without treatment where additional measurements were taken. Improvements were seen in gait speed during walking, fast walking, and running. Improvements were also made in stride length during running.

Protas et al<sup>33</sup> studied three subjects with incomplete thoracic SCI's (levels T8, T10, and T12). The study was conducted over a 12-week period of training on the treadmill with the assistance of two physical therapists. Subjects were seen five days a week for three months for an hour at each session. Subjects started at 40% body weight support and a speed of .16 mph and the amount of support given was progressively decreased with the speed of the treadmill increasing. Subjects worked up to 20 minutes of continuous walking. Results of the study concluded that the BWS treadmill did increase gait speed and endurance for all subjects.

Norman et al<sup>34</sup> researched how a treadmill apparatus and harness support can be used for evaluation and rehabilitation of gait. They discussed the treadmill structure, speed, and body-weight support system including the harness. They studied two subjects with incomplete cervical SCI's who showed improvement after working on the apparatus. Case Report 1 had significant improvement in treadmill speed and Case Report 2 showed significant improvement in over ground speed as well as treadmill speed.

#### CHAPTER 3

## **METHODOLOGY**

This chapter will describe the testing procedures and research protocol utilized in this study. Information from subjects' history and data from initial evaluations are presented later in the chapter.

## Subjects

Subjects chosen for the study were 20 years of age or older who had a neurological diagnosis, regardless of how long ago the neurological incident occurred. Subjects had to be living in a community in or around Grand Forks, ND and were excluded from the study if they had uncontrolled hypertension (using readings below 160/90 mmHg as a guideline for acceptance). Subjects were recruited through local support groups and personal contacts. This research study was reviewed and approved by the UND Institutional Review Board as well as the Altru Health System Institutional Review Board prior to initiating the study (see Appendix C). Although no pilot study was conducted before this study was carried out, student researchers completed a thorough review and researched equipment and testing protocols.

For this study, three subjects volunteered to participate and were paired with student researchers to undergo a six-week gait training program three times

a week, training with a body weight support system and treadmill. There was no need for group assignment or a control group in this study due to its case study design. Informed consent was obtained through an information and consent form (see Appendix B). All subjects were competent and independent in their decision-making. All subjects signed the consent form to participate in this study, with the exception of subject A whose wife signed the consent form on his behalf. Subjects were given a copy of the form and the original copies will be housed and locked in the UND Physical Therapy Department and will be destroyed three years after the study has ended. Only the principal investigators will have access to this information.

#### Instrumentation

The LiteGait™ body weight support system with the thoracic harness and groin strap was used to conduct this study along with the GaitKeeper™ treadmill (Mobility Research, Tempe AZ). For analysis of gait pattern, the Write Step™ by Abilitations was used. Critikon Dynamap™ 8100 was used to automatically monitor blood pressure and heart rate, along with a blood pressure cuff by Johnson and Johnson. A yardstick, step stool, sturdy chairs (with and without armrests), and a stop watch were used to assess the subject in the Berg, Tinetti, and the Ten Meter Timed Walk Test pre- and post-study.

#### Procedure

All testing and gait training was performed at the Altru Health Institute in Grand Forks, ND by student researchers under direct supervision of a UND Physical Therapy Department faculty member. Subjects initially completed a battery of tests to assess their balance and gait. Testing included the Berg Balance Measure, a Ten Meter Timed Walk Test, the gait portion of the Tinetti Test of Balance and Mobility, and a gait pattern analysis (stride length, step length, and base of support). All tests were performed pre- and post- study.

Berg Balance Assessment<sup>35</sup> (see Appendix E): This test consists of 14 items designed to test subjects' balance. It is scored 0-4 (zero indicating an inability to perform a task to four indicating independently performing a task) with a total score ranging from 0-56. A higher score reflects a better performance and a decreased chance of falling. This test is proven to be reliable with an internally consistent measure with Cronbach's alpha at .96. It has an inter-rater reliability ranging from .71 to .99. This test is also proven to be valid through the manner it was put together.

Tinetti Assessment Tool<sup>36</sup> (see Appendix F): This test consists of nine items to observe a gait pattern. The total score can range from 0 to 12.

Individual components of the test score are scored from 0 to 2. A zero indicates the most impairment and a two indicates independence with the activity. This

test is proven reliable with an inter-rater reliability of 85% agreement between testers. The validity of this assessment was not reported.

Ten Meter Timed Walk Test: Each subject was instructed to walk at his or her normal pace for ten meters. The ten meters had previously been measured and marked off with tape. The amount of time it took for the subject to walk from start to finish was recorded initially and at the final evaluation to show any improvements, deficits, or if there was no change with the speed of gait.

Gait Analysis<sup>37</sup> (see Appendix G): This was performed by having the subject walk across a template that recorded each subject's footprints. Each subject was instructed to walk at a normal speed across the template. Stride length, step length, walking angle, and base of support were measured and recorded. Stride length is the distance from initial contact of one extremity to the next initial contact of the same extremity. Step length is the distance from initial contact of one extremity to the initial contact of the contralateral extremity. Walking angle (degree of toe out or FIC angle) is the angle of foot placement measured by the angle between the line of forward progression and a line which bisects the midpoint of the heel and second metatarsal head (average is 5-18 degrees). Base of support is the distance between the midpoint of the heel of one foot to the same point on the contralateral foot (average is one to five inches).

Vital Signs: Baseline information on heart rate, blood pressure, and body weight were also recorded. Blood pressure and heart rate were taken by placing a blood pressure cuff on the subjects arm (mid-humerus) at rest while sitting. The machine then inflated and read the pressure readings as well as the heart rate of each subject. All numbers were recorded with each of the three subjects and all were within this study's guidelines. Any subject with a resting blood pressure of 160/90 mmHg or over would have been excluded from this study.

Harness Application: At the start of each session, the harness was applied while the subject was standing in parallel bars for safety. The harness girth was estimated prior to placing around the subject's torso, making sure that the inferior edge of the bottom strap was lined up over the greater trochanter. The three buckles were then snapped starting with the top and working towards the bottom. The three side straps were then tightened, starting with the bottom strap and working up. The straps were pulled taut equally on both sides to ensure proper fit. The harness was tightened as much as possible but within subject comfort. The groin piece was fastened last. The front buckles of the groin strap were fastened prior to placing the harness on the subject; the back buckles were fastened and adjusted last. The groin strap was then tightened so there was no slack. See Figures 1 and 2 for illustration of harness placement. The subjects were then assisted onto the treadmill and hooked up to the

member. The LiteGait™ "lift" was adjusted so the bottom of the buckles were level with the top of each subjects head.



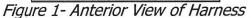




Figure 2- Posterior View of Harness

The buckles were then fastened to the harness with two straps in the front and two straps in the back. All four straps were tightened so that the level of each was equal side to side and front to back. Finally, the percentage of weight supported was set with the subjects' arms at their sides, along with setting the speed of the treadmill. Prior to starting the treadmill, the subjects were given an emergency stop cord and informed that they could stop the treadmill at any time during the session by either telling the researcher or pulling the emergency stop. Once the subjects were ready, the treadmill was started.

Treadmill Protocol: Each session consisted of three bouts of ambulation with a five minute rest period in between each bout. Initially, 40% of the subject's body weight was supported and treadmill speed was set at .5 mph.

Three levels of body-weight support were used (40%, 20%, and 0%) along with three levels of treadmill speed (.5 mph, .75 mph, and 1.0 mph). A decrease in body weight support and an increase in treadmill speed occurred when the subject was able to demonstrate an improved gait technique (fairly symmetrical step length, stride length, cadence, foot clearance, and the ability to weight bear on the affected limb without buckling) and endurance. Endurance was defined as walking at least five minutes in at least two of three bouts. Changes in body weight support and speed were made at the following session after showing these improvements. During the last week of the study, if not before, body weight support was reduced to 0% in order to facilitate transition to overground ambulation without the assistance of body weight support. At the end of the body weight support gait training, all of the initial tests performed were repeated in order to obtain objective data to reflect changes in balance and gait. Each subject was scheduled to complete six weeks of body weight support treadmill training three times a week.

## Data Analysis

Due to the case study design, data was analyzed separately for each subject. Generalizations could not be made due to the variety of diagnoses, age, and prior level of function exhibited by each subject. Initial and final test data were compared to see if any changes had occurred with each subject and are detailed in the Results Chapter.

## Reporting Results

Upon completion of the research project, individual summaries were sent to each of the subjects. A completed copy of the scholarly project will be provided to the preceptor and to the Harley E. French Library of the Health Sciences at UND to be available for interested parties. This scholarly project was completed to fulfill the requirements of the UND School of Medicine and Health Sciences Master of Physical Therapy Program.

## Subjects' Initial Information

The initial session in this study consisted of an interview with each subject to record pertinent medical history and to describe his neurological diagnosis. Following the interview, the subjects were evaluated with a battery of tests to record baseline information for each subject.

## Subject A History

Subject A was a seventy-four year old male who had been diagnosed with a right CVA with resulting left hemiplegia in March 2000. Following physical rehabilitation for his CVA, he fell December 1, 2000 and was in physical rehabilitation again through December 28, 2000. Ever since that time, he had been coming to the physical rehabilitation center three times per week with his wife to continue his exercise program independently. He was also diagnosed with leukemia during this time, but he reported he has been in remission since March 2001. Subject A wore glasses to help his poor eyesight caused by his

macular degeneration. Arthritis affected his knees, back, and hands, but he reported that this was not an obstacle during testing. The subject also exhibited increased tone in his left lower extremity.

Subject A had no frequent assistive device other than a "high stick" he reported using on uneven surfaces. His wife continued to assist him with almost all ADL's, ambulation, and transportation. He described dressing and ambulating stairs as his only difficult activities of daily living. He had three steps to enter his house with a hand railing to assist him. His only complaint initially was not being able to tolerate much walking at one time. He also mentioned his poor eyesight as being a major factor in his quality of gait.

Subject A's last physical therapy intervention was in April of 2002. He was currently doing an exercise program consisting of step-ups, unilateral knee bends, holding a ball with both hands during independent stance, upper extremity range of motion with cane assistance, and arm cradles from side to side. His current medications included aspirin, calcium, and a multi-vitamin. Subject A met all inclusion criteria to participate in this study.

At the initial testing session, details of the study were reviewed with the subject and his spouse who was present for our first session. The subject's spouse read through the consent form and signed it on the subject's behalf due to his poor eyesight. Data was then gathered for blood pressure, resting heart

rate, and body weight. Balance and gait analysis were also performed. Please see Table 5 for initial session data.

Table 5- Subject A Initial Session Data

Resting Blood Pressure	152/81 mmHg
Resting Heart Rate	62 bpm
Body Weight	211 lbs
Berg Balance Score	27/56
Ten Meter Walk Time	50.78 seconds
Tinetti Score (gait portion only)	7/12
Gait Analysis	Stride Length: L=31.01 cm, R=29.72 cm
	Step Length: L=21.99 cm, R=8.41 cm
	Base of Support: 27.62 cm
	Walking Angle: L=14°, R=20.25°

# Subject B History

Subject B was a twenty-year old male who had been diagnosed with a class four astrocytoma (also known as a glioblastoma multiforme) in January of 2001. Prior to diagnosis, he had experienced seizures and headaches. Diagnosis of the tumor occurred after the subject was rushed to the hospital following a period of unconsciousness while swimming. Surgery was performed to remove the tumor and radiation followed. The subject exhibited no residual effects from the surgery at that time. After several months of radiation, a second surgery was performed to remove any remaining tumor and necrotic tissue. It was after this second surgery that the subject began to exhibit left-sided hemiparesis and hypertonicity, most notably in the left upper extremity. The subject had no other significant medical history with the exception of an inguinal hernia at age two. At the initial session, the subject was taking Topamax (topiramate) and

Neurontin (gabapentin), both anti-seizure medications. He commented that these medications tended to make him drowsy but he noted no other side effects. He ambulated into the Physical Therapy department with a single point cane on the right side and reported difficulty with ambulation, especially on stairs. He stated that his left toe often got caught during walking on carpet or when navigating stairs. Subject B reported that he had just started to practice driving again at home, but at this time relied on family and friends for transportation. He had been participating in outpatient physical therapy ever since his second surgery to work on strengthening, balance activities, and gait training. At the time of this study, he was not receiving physical therapy and had not been performing a home exercise program.

At the initial session, details of the study were reviewed with the subject and his mother, and then he read through the consent form and signed it. Data was then gathered and testing was performed as described in the Methodology Chapter. Please see Table 6 for initial session data.

Table 6- Subject B Initial Session Data

Resting Blood Pressure	116/85 mmHg
Resting Heart Rate	83 bpm
Body weight	200 lbs
Berg Balance Score	51/56
10 Meter Walk Time	8.46 seconds
Tinetti Score (gait portion only)	5/12
Gait Analysis	Stride Length: L=102 cm, R=101 cm
	Average Step Length: 45 cm
	Base of Support: 11 cm
	Walking angle: L=4°, R=9°

# Subject C History

Subject C was a 34-year-old male who sustained an incomplete  $C_{3-5}$  spinal cord injury (SCI) 15 years ago. The subject underwent surgery to fuse  $C_{3-5}$  at three weeks post injury. Initially the subject had no voluntary movement of his extremities, but gradually regained movement into all extremities. It took three and one half years post injury for the subject to be able to get on his feet and walk again. The subject has a relevant past medical history of a left ankle triple arthrodesis, current and recurring kidney infections, and smoking half a pack of cigarettes a day, of which he is trying to cut back. The subject is now a independent community ambulator with the assistance of one forearm crutch and an AFO on the left. His medications consist of an antibiotic for a current kidney infection. The subject received physical therapy intervention for four years after his injury. He is currently independent in all activities of daily living (ADL's), but he reports difficulty with long distance ambulation secondary to fatigue. Please see Table 7 for initial session data.

Table 7- Subject C Initial Session Data

Resting Blood Pressure	83/45 mmHg	
Resting Heart Rate	90 bpm	
Body Weight	117 lbs	
Berg Balance Scale	40/56	
Ten Meter Walk Time	13.67 seconds	
Tinetti Score (gait portion only)	8/12	
Gait Analysis	Stride Length: L=71.12 cm, R=81.28 cm	
	Average Step Length: 39.37 cm	
	Base of Support: 15.87 cm	
	Walking Angle: L= -2°, R=2°	

### CHAPTER 4

### RESULTS

Results from this research study are presented for each subject. A weekby-week synopsis of the study will be discussed, and a more detailed session-bysession chart appears in Appendix A.

# Subject A Results

Subject A completed the entire six weeks of the study. Subject A did not report any musculoskeletal problems during the study besides feeling slightly more fatigued, but he was able to complete each ten minute bout without difficulty. Table 8 lists data from final and initial assessment, and Figures 3 and 4 compare initial and final data.

Table 8- Subject A Final and Initial Data Comparison

Assessment	Final	Initial
Resting Blood Pressure	147/78 mmHg	152/81 mmHg
Resting Heart Rate	60 bpm	62 bpm
Body Weight	212 lbs	211 lbs
Berg Balance Score	36/56	27/56
Ten Meter Walk Time	30.52 seconds	50.78 seconds
Tinetti Score (gait portion)	9/12	7/12
Gait Analysis	Stride Length:	Stride Length:
	L=45.72 cm R=45.24 cm	L=31.01 cm, R=29.72 cm
	Step Length:	Step Length:
	L=25.24 cm R=20.88 cm	L=21.99 cm, R=8.41 cm
	Base of Support: 21.11cm	Base of Support: 27.62 cm
	Walking Angle: L=14.75°,	Walking Angle: L=14°,
	R=9.25°	R=20.25°

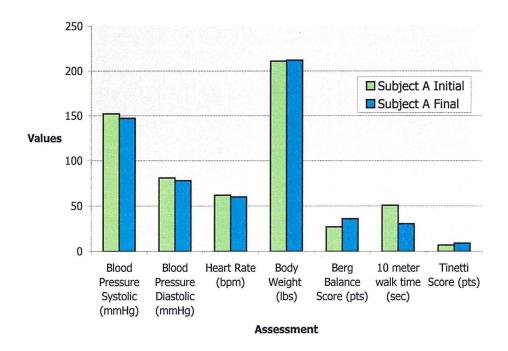


Figure 3- Subject A Testing Results

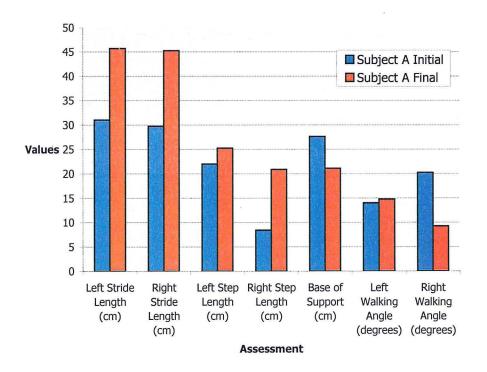


Figure 4- Subject A Gait Analysis Results

### Week One

Subject A completed all initial testing during his first session, but he was unable to begin any treadmill work this first day due to fatigue following his initial testing. He became fatigued with testing and required frequent rest breaks in between tests. The second session of week one began with the subject and his wife walking into the physical therapy department from the front door of the building (approximately 400 feet) prior to treadmill training. For week one, body weight was supported at 40% (equal to 84 pounds for this subject) with a treadmill speed of .5 mph. The subject completed all three bouts of ambulation for the full ten minutes. At his request, he was given a glass of water following each bout on the treadmill for the entire length of the study. He required moderate manual pelvic and left lower extremity assistance, particularly with dorsiflexion, and minimal manual assistance with right lower extremity knee flexion and dorsiflexion. He demonstrated a good base of support, never bringing either lower extremity across midline. Verbal cues were needed to encourage a longer step length on the right. Subject A held onto the handlebars throughout week one; however, when he became fatigued he tended to hold onto the right handlebar more tightly. During the first week, the subject reported a sore left knee and feeling fatigued from the increased amount of activity he was participating in.

### Week Two

During week two, the subject was brought to the physical therapy area in a wheelchair propelled by his spouse, which he continued to do for the rest of the study. He felt that by not walking into the physical therapy area he would be able to conserve most of his energy for his treadmill ambulation. The body weight support remained at 40% with a treadmill speed of .5 mph. The subject completed all three bouts of ambulation for the full ten minutes with reports of less fatigue than previously felt during week one. The subject attempted to walk without use of the handlebars, but was only able to fully accomplish this task by the third session of the second week. The subject continued to need moderate to minimal manual assistance at the pelvis and left lower extremity, particularly dorsiflexion. Verbal cueing was continued to encourage a longer step length on the right. By the end of week two, the subject was demonstrating periodic independent steps with the left lower extremity. Increased tone was a limiting factor in his ability to fully dorsiflex his left ankle throughout the study.

#### Week Three

During the first session of week three, body weight support remained at 40% with a treadmill speed of .5 mph. These parameters were changed to 20% body weight support (equal to 42 pounds for this subject) with a treadmill speed of .7 mph during the second session of week three due to the subjects increasing performance at the first level. At this first level he was demonstrating

independence with pelvic and left lower extremity movements without relying on the handlebars. Subject A completed all three bouts of ambulation for the full ten minutes with a good base of support. The subject continually needed verbal cueing for increased step length on the right. Minimal manual assistance was given for left lower extremity dorsiflexion and occasional knee flexion. Toward the end of week three, the subject was demonstrating periodic independence with the left lower extremity with minimal use of the handlebars. Increased tone was continually a restricting factor for left lower extremity dorsiflexion. The subject did not feel the decrease in weight support and increase in treadmill speed had much of an effect on his fatigue level. The subject stated he felt his endurance had increased since the beginning of this study, and his spouse noticed him being able to walk further distances than he was able to before. He also stated that he was not more fatigued at this level than he was at the previous level.

### Week Four

During week four, the parameters remained at 20% body weight support with a treadmill speed of .7 mph. The subject completed all three bouts of ambulation for the full ten minutes with a good base of support and minimal to no handlebar use. Minimal manual assistance was provided for left lower extremity dorsiflexion less than half of the time, with independence the rest of the time. Intermittent verbal cueing was provided for a longer step length on

the right lower extremity. The subject was making significant progress at this level with independent ambulation the majority of the time. The subject reported feeling more fatigued this week with little energy left for the day.

## Week Five

During week five, the parameters were changed to 0% body weight support and a treadmill speed of 1.0 mph. The subject completed all three bouts of ambulation for the full ten minutes with a good base of support. He was reliant on the right handlebar a majority of the time due to increased body sway produced when not holding on. The subject stated feeling uncomfortable without holding on to the handlebar during ambulation at this speed. Moderate to minimal manual assistance was provided at the pelvis and left lower extremity. Towards the end of week five, the subject demonstrated independent left lower extremity movements a majority of the time. The increased treadmill speed helped improve the subject's quality of ambulation, and intermittent verbal cueing was needed for a longer step length on the right.

#### Week Six

During week six, the parameters remained the same at 0% body weight support with a treadmill speed of 1.0 mph. The subject completed all three bouts of ambulation for the full ten minutes with a good base of support.

Independent ambulation was achieved the majority of the time at session one of week six, and the entire time on session two of week six with the assistance of

the right handlebar. The subject verbalized increased difficulty ambulating without right upper extremity support due to increased body sway. Intermittent verbal cues were needed for longer step length bilaterally. The subject exhibited increased fatigue once completed with each bout on the treadmill. The subject's final session of week six consisted of final testing with data collected and recorded.

# Subject B Results

Subject B completed four weeks of the six-week study, and data was recorded to monitor progress. Subject B began chemotherapy during week three which caused increased fatigue during gait training. The subject also began to experience bilateral knee pain during the third week of the study that increased during the next week. Therefore, the subject decided to leave the study early and continue with outpatient physical therapy as he had done prior to the study. Table 9 and Figures 5 and 6 compare initial and final data.

Table 9- Subject B Final and Initial Data Comparison

Assessment	Final	Initial
Resting Blood Pressure	115/50 mmHg	116/85 mmHg
Resting Heart Rate	79 bpm	83 bpm
Body Weight	196 lbs	200 lbs
Berg Balance Score	52/56	51/56
Ten Meter Walk Time	8.81 seconds, with knee pain	8.46 seconds
Tinetti Score (gait portion)	6/12	5/12
Gait Analysis	Stride Length:	Stride Length:
	L=130 cm, R=133 cm	L=102 cm, R=101 cm
	Average Step Length: 72 cm	Average Step Length: 45 cm
	Base of Support: 11 cm	Base of Support: 11 cm
	Walking angle: L=8°, R=10°	Walking angle: L=4°, R=9°

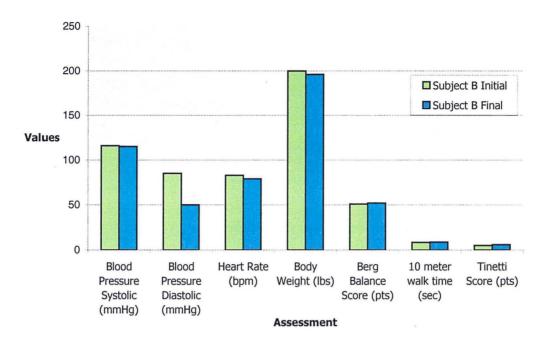


Figure 5- Subject B Testing Results

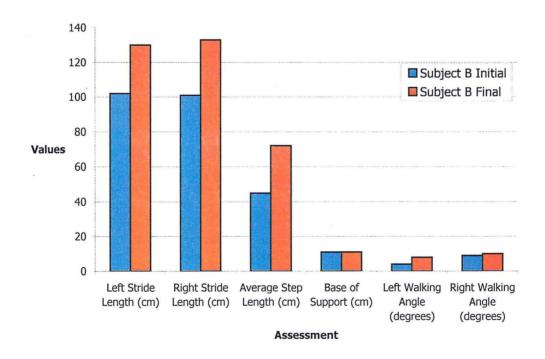


Figure 6- Subject B Gait Analysis Results

### Week One

Subject B completed all initial tests at the first session. He became very fatigued with testing and required numerous rest breaks in between tests. Treadmill training began at the second session, and the subject walked into the physical therapy area from the front door of the building (approximately 400 feet) with use of a single point cane on the right. For the entire first week, body weight was supported at 40% (equal to 80 pounds for this subject) supported with a treadmill speed of .5 mph. The subject completed one of the three bouts of ambulation for the full ten minutes and only partially finished the second and third bouts. The subject required manual facilitation at the hips bilaterally to keep them in neutral alignment and required assistance for left foot placement. The subject needed verbal cues for a longer right step length and had a tendency to bring his right leg across midline close to the left foot. He exhibited hyperextension of his left knee with single leg stance, which he was able to correct with verbal cueing. Additionally, when the subject became fatigued, he exhibited a tremor in his left lower extremity. Throughout the first week, the subject used the right handlebar and relied heavily on it to keep him on the treadmill. The left arm consistently had tone that increased with ambulation on the treadmill. At the end of week one, the subject reported fatigue from the increased amount of activity he was participating in, but he stated that he wished to continue in the study.

### Week Two

During the second week, body weight support remained at 40% and speed at .5 mph as the subject's gait pattern remained abnormal and he had a continued need for assistance with left foot placement. The subject occasionally did attempt to walk without use of the right handlebar, but then required facilitation at the hips to keep them forward in neutral alignment. Also, the left knee continued to hyperextend with single leg stance. The subject continued to adduct his right lower extremity past midline resulting in a very small base of support that sometimes resulted in tandem stepping. Verbal cues were used to increase his base of support to a normal distance. At the end of week two, the subject exhibited good step and stride lengths and an increased ability to advance his left leg, although he needed manual cuing for a heel-toe pattern. The level of tone in the left arm continued to increase with ambulation. The subject continued to report fatigue with ambulation, but he felt that he was able to walk more now than he had in some time.

## Week Three

During the third week, parameters were changed to 20% of his body weight supported (equal to 40 pounds for this subject) and treadmill speed was increased to .7 mph. The subject was able to complete three bouts of ambulation with a good base of support and rarely exhibited left knee hyperextension. However, he tended to retract his right shoulder and continued

to use the right handlebar for stability. Manual facilitation was provided at the left foot, helping to advance it and promote a heel-toe pattern. Tone in the left arm continued to increase with ambulation, but was observed to be less than at week two. At the beginning of the third week, the subject stated that he felt he had more endurance for activity and less "toe dragging." However, by the end of week three, the subject used his wheelchair to go to and from the Physical Therapy Department instead of ambulation with a cane due to fatigue. The subject also reported decreased endurance for activities at home.

## Week Four

In the fourth week, the subject continued to state that he was becoming increasingly fatigued. He began experiencing slight pain in the left knee slightly superior to the patella. The subject stated he was performing stretching and icing for his knee at home as needed. However, this provided little to no relief and the pain continued to worsen. He was pushed in a wheelchair by his mom or sister to and from the Altru Physical Therapy Department each session. However, one session he did walk from the outpatient physical therapy area (approximately 200 feet) where he had been visiting with a physical therapist. Speed and body weight support remained the same as in week three since no significant changes in gait were observed and the subject began having difficulty completing the three ten minute bouts of ambulation. His left knee began to hyperextend once again with single leg stance throughout the three bouts of

ambulation. The subject was able to correct this after verbal cueing, but he required manual cueing towards the end of the bouts when he began to fatigue. Manual facilitation remained at the left heel helping to encourage use of a heel toe pattern. The subject used the right handlebar throughout each session. During the fourth week, the subject started chemotherapy again and became increasingly more fatigued.

## Week Five

At the first session of week five, it was decided by the subject and his family to withdraw him from the study. All noted that the subject had great difficulty with stairs and transfers secondary to bilateral knee pain. Also, the subject felt it was becoming increasingly more difficult to perform his activities of daily living because of his increased level of fatigue from participating in the study and the start of chemotherapy. The subject was willing to complete final testing that day and data was recorded. Over the course of the study, the subject lost four pounds and showed slight improvements on the final assessments as detailed in Table 9.

## Subject C Results

Subject C completed the entire six weeks of the study. At each session, data was recorded to monitor progress. Below is a week-by-week synopsis of the study and a more detailed session-by-session chart appears in Appendix A. Following the study, he continued to use assistive devices including a left AFO

and left forearm crutch. The subject noted numerous improvements after the study including the following: increased ease in bending his left leg on his own and with better control, increased ability to pick things up from the floor, improvements in recovering after a loss of balance, more efficient stair climbing due to improvement in left knee bending and lifting of the foot, increased endurance for ambulation (both time and distance), and he reported that he can bend his knee up while standing with and without a crutch when tone does not limit this. He also reported that he cut down to three cigarettes per day as compared to one half a pack a day prior to the study.

Table 10- Subject C Final Session Data

Assessment	Final	Initial
Resting Blood Pressure	93/59 mmHg	83/45 mmHg
Resting Heart Rate	85 bpm	90 bpm
Body Weight	109.5 lbs	117 lbs
Berg Balance Scale	48/56	40/56
10 Meter Walk Time	13.5 sec	13.67 sec
Tinetti Score (gait portion)	8/12	8/12
Gait Analysis	Stride Length:	Stride Length:
	L= 91.44 cm, R=86.36 cm	L=71.12 cm, R=81.28 cm
	Step Length: 40.64 cm	Step Length: 39.37 cm
	Base of Support: 16.51 cm	Base of Support: 15.87 cm
	Walking Angle: L=6°, R=8°	Walking Angle: L=-2°, R=2°

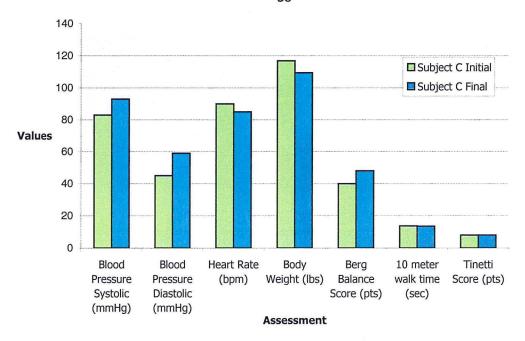


Figure 7- Subject C Testing Results

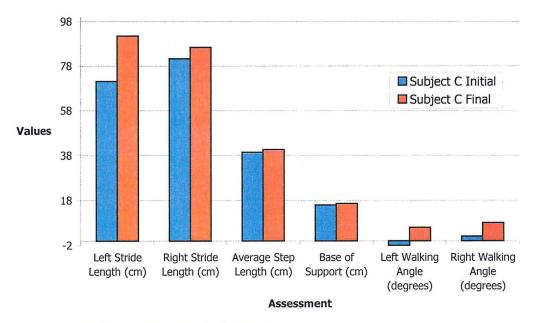


Figure 8- Subject C Gait Analysis Results

### Week One

The initial session consisted of initial testing data, which can be found in subject C's history and initial data. Subject C started out at a walking speed of .5 mph with 40% of his body weight supported (equal to 47 pounds for this subject). The subject held onto the right handlebar throughout all sessions for balance. He required assistance from two people for proper foot placement during ambulation, and minimal assistance was needed on the right foot and moderate assistance on the left foot. The subject needed facilitation at the right foot to keep from toeing in and facilitation on the left foot to achieve foot clearance with dorsiflexion during swing phase. The subject often compensated for this by hiking his left hip to achieve foot clearance on the left. The subject reported stiffness from the initial assessment but stated that he felt better at the third session of the initial week. The subject walked the full ten minutes during the first and third bouts in the first session and 5:50 minutes during the second bout due to fatigue. During the second and third sessions, subject C walked the full ten minutes with each of the three bouts of ambulation.

## Week Two

Subject C continued to walk at .5 mph with 40% of his body weight supported since there were no observed changed in gait pattern. The subject continued to hold on to the right handlebar throughout all sessions for balance. During this week, he only needed one person to assist with his left foot since he

was placing the right foot properly with minimal verbal cuing. Moderate assistance with left foot was still needed to achieve foot clearance and proper dorsiflexion. The subject's left knee "locked up" during the second bout of the second session but continued walking because the pain only lasted through about two strides. He stated he was sore after this occurred. On the third session, his knee locked up again in the third bout; again it didn't persist very long and he kept walking. The subject walked the full ten minutes every bout during all sessions this week.

### Week 3

Subject C started out the week at a walking speed of .5 mph with 40% of his body weight supported but progressed to a walking speed of .7 mph with 20% of his body weight supported during the second session. The subject held onto the right handlebar throughout all sessions for balance. Minimal assistance was needed for foot placement on the left, but subject C was advancing his left leg forward on his own. The subject walked the full ten minutes every bout during the first session. During the second session, subject C walked the full ten minutes during the first and second bouts and walked five minutes during the third bout. Subject C became very fatigued and experienced muscle soreness during the third bout secondary to the increase in speed and decrease in the amount of body weight supported. During the third session, he only walked 5:21 minutes during the first bout due to sudden pain in the back of his knee, and

ambulation was stopped immediately at that time. However, he was able to complete the full ten minutes of ambulation during the second and third bouts. The subject stated that this severe pain in the back of his knee occurred again after the session ended on his way out to the parking lot.

### Week Four

Subject C continued walking at a speed of .7 mph with 20% of his body weight supported. Subject held onto the right handlebar throughout all sessions for balance. Minimal assistance was needed to facilitate dorsiflexion on the left foot during swing phase to achieve foot clearance. During the first session, the subject noted that his left knee began to "feel funny" during the third bout, and he wanted to stop to prevent it from spasming further. At the beginning of the second session, subject C stated that he had been in the emergency room the night before secondary to a kidney infection. He stated that he was now taking medication for the infection, but that he was able to and wished to continue with the study. During the third session, the subject stated that his knee felt "loose" that day. Subject C walked for the full ten minutes during the first and second bouts and only 6:45 minutes during the third bout in the first session of this week due to spasm. In the second and third sessions, he walked the full ten minutes every bout.

### Week Five

Subject C started out walking at a speed of .7 mph with 20% of his body weight supported and progressed to a walking speed of 1.0 mph with 0% of his body weight supported. The subject held onto the right handlebar throughout all sessions for balance. At the beginning of the first session, subject C stated that he had fallen over the weekend and now had a dull ache at his left mid to lower back. He again affirmed that he would like to continue with the study and stated that the harness actually made his back feel better. During the second session, he became fatiqued and his muscles stiffened in his left lea during the third bout due to the increase in speed and decrease in weight support. Also, throughout the third bout, he only received fingertip assist with dorsiflexion and was able to pull the foot and leg through nicely on the left. On the third session, subject C fatigued during the second and third bouts secondary to the decrease in manual facilitation during the second and third bouts. Subject C walked the full 10 minutes every bout the first session. In the second session, he walked 10 minutes the first two bouts and 5:03 minutes during the third bout. In the third session, he walked 10 minutes, 8:54 minutes, and 8:17 minutes.

#### Week Six

Subject C continued at a walking speed of 1.0 mph with 0% of his body weight supported. Subject held onto the right handlebar throughout all sessions for balance. During the first session, he was given minimal assistance with

dorsiflexion on the first bout and required only stand by assistance for three minutes during the second bout. Subject C began fatiguing and catching the left foot on the surface of the treadmill so a return to minimal assistance was used for the remaining time. At the third bout, he received fingertip assist with dorsiflexion. Subject C walked for the full ten minutes during the first and second bouts and 5:20 minutes during the third bout due to fatigue in session one. During the second session, subject C received fingertip assist throughout the first bout and part of the second bout. Fatigue and muscle soreness set in and minimal assistance was given during last part of the second bout and third bouts. In the second session, he walked the full ten minutes every bout. The third session this week consisted of final testing with findings reported in Table 10.

#### CHAPTER 5

#### DISCUSSION/CONCLUSION

The three subjects in our study did show improvements in various areas of this study. Following intervention with body weight support treadmill training, all three subjects showed increases in Berg Balance and Tinetti scores, and they reported that they felt that their walking had improved since beginning the study. Two of the three subjects had improvements in the Ten Meter Walk Test while demonstrating a decreased base of support and increased step and stride lengths.

All three subjects were very motivated to improve their function and gait, with each subject having his own goals for the intervention. The student researchers observed the subjects enjoying their sessions even though the task was tiring at times, especially when parameters were changed.

#### Limitations of the Study

This study was unique in that we used a case study approach with three individuals having different neurological impairments. This study was designed in this matter due to the large amount of time commitment needed on the part of the subject and the student researcher. Additionally, it was difficult to recruit subjects in the area who were able to find transportation to and from the facility

so frequently for the duration of the study. This case study design made it difficult to produce comparisons in data following the study and to find research on body weight support treadmill training with each neurological impairment. We chose to compare each subject pre- and post- intervention and look at the changes that occurred following six weeks of gait training with body weight support treadmill training.

Another potential factor that may have affected outcomes in this study is the time from the onset of neurological impairments to the time of the study. The date of onset varied in each subject, and the available research shows that greater physical improvements tend to occur closer to the time of initial onset. Additionally, the subjects participating in this study have had various amounts of physical therapy intervention in the past which may have been weeks, months, or years before the study and depending on the onset of impairment. This past intervention could have influenced the physical functioning of the subject in the areas studied here such as gait, balance, and postural control. Following the study, it was the individual's responsibility to continue to work on their previous independent home exercise program and gait, and this was discussed with each subject.

Subject A was limited in his ability to ambulate and perform ADL's secondary to poor eyesight as a result of macular degeneration. This naturally caused him to ambulate with a broader base of support and decreased speed

due to an increased fear of falling. Had his poor eyesight not have been a concern for him, subject A may have been able to have greater progress as a result of the body weight support treadmill training. He also relied on his wife to assist him with ambulation at home and in the community, whereas during treadmill training sessions, he was without her assistance for cueing. Instead, prompting and visual cueing came from the student researcher.

Due to increased pain and decreased function, subject B withdrew from our study after completion of week four. Therefore, he did not receive the full six weeks of intervention and the final measurements may not have truly reflected his possible improvements. Additionally, it became known to the student researcher following the study that the subject was found to have regrowth of his brain tumor. This may have prevented improvements due to the active pathology.

Subject C may have been limited in his ability to function secondary to the kidney infection he developed in the fourth week of the study. He also may have been limited in his outcomes of the functional assessments secondary to a fall that occurred in his home over the weekend following the fourth week of the study, where he sustained back pain to his left mid to lower back. On the final day of testing, his back pain had progressed more, to where he was also feeling pain in his left scapular region. This pain may have altered his final testing data.

### Suggestions for Future Research

When designing this study, the student researchers tried to utilize a variety of assessment tools to provide information in multiple areas. Unfortunately, it was difficult to get an accurate objective measure of the subject's own feelings on his individual progress and improvements in activities of daily living. The researchers did try to record any subjective comments from the subjects in the session logs, but more often than not the subjects did not vocalize their feelings or observations unless questioned by the researcher. Therefore, it would have been valuable to have the subjects fill out a standardized questionnaire such as the Short Form 36 (SF-36) to obtain baseline data for comparison upon conclusion of the study. The Short Form 36 is a multidimensional questionnaire that addresses physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health.<sup>38</sup> The SF-36 has been documented in over 1600 publications to be shown useful in, "...monitoring general and specific populations, comparing the burden of different diseases, differentiating the health benefits produced by different treatments, and screening individual patients."<sup>39</sup> In this study, researchers tested subjects pre- and post-intervention. It may be useful in future studies to re-test subjects again months or years later to determine if concrete changes in gait were made rather than only temporary changes.

Additionally, testing outside the clinic environment may show variation in gait and balance scores.

The body weight support system used in this study proved to be very easy to set-up and the harness was easy to apply after locating the proper bony landmarks. The subjects did have to step up onto the treadmill once the harness was attached which was somewhat more difficult due to its position. The student researchers were able to assist the subject onto the treadmill and prevent any loss of balance. Unfortunately, it was difficult for the student researchers to maintain proper body alignment and mechanics during the subject's ambulation due to the position of the treadmill and the location of the subject's body segments, especially distally, needing assistance. Researchers had to sit on a small step stool and often had to rotate their trunk and use excessive shoulder motion in order to facilitate proper lower extremity movements in the subjects. Body mechanics could have been improved if the treadmill was positioned on a raised platform and/or given a larger space in which to work.

#### Conclusions

The purpose of this study was to determine if body weight support gait training would improve balance, quality of gait, postural control, and/or increase the speed of gait. It could be said that the alternate hypothesis was met since all subjects had improvements in these areas. However, no statistical analysis

was performed to determine significance. Further studies with a larger number of subjects with a variety of neurological diagnoses are needed in this area in order to better determine effectiveness of this intervention. A larger sample size in a statistical-based study would be highly effective for determining if statistical differences in balance, gait, and postural control are present utilizing body weight support treadmill training.

#### Physical Therapy and BWS Treadmill Training

Body weight support treadmill training can be utilized as a method for performing gait training. It provides a safe environment in which the individual can perform and practice mechanics of normal gait at a variety of speeds with or without body weight support, depending on the level of function. Additionally, the therapist is better able to facilitate the individual, observe gait patterns, and provide verbal cueing to achieve a normal gait while the harness is in place.

A variety of physical therapy interventions can and should be used in conjunction with body weight support treadmill training. Range of motion, strengthening, and pre-gait activities are all vital for achieving a normal gait and should be incorporated into every treatment plan.

APPENDIX A

## **Intervention Documentation Chart for Subject A**

		4/30/02	5/02/02	5/03/02	5/06/02	5/9/02	5/10/02	5/13/02	5/15/02
	% BW support	Initial Testing Day	40%	40%	40%	40%	40%	40%	20%
	Speed		.5 mph	.5 mph	.5 mph	.5 mph	.5 mph	.5 mph	.7 mph
	Time (walk 1)		10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes
	Time (walk 2)		10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes
	Time (walk 3)		10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes
	Distance Walked (in feet)	_	1. 440 2. 440 3. 440	1. 440 2. 440 3. 440	1. 440 2. 440 3. 440	1. 440 2. 440 3. 440	1. 440 2. 440 3. 440	1. 440 2. 440 3. 440	1. 616 2. 616 3. 616
71	Quality of ambulation		-Mod. pelvic & L L/E assist -BOS good -verbal cues & min. assist at R L/E -Mod. ankle DF assistance	-Mod. pelvic & L L/E assist -BOS good -verbal cues to correct R L/E step length -Mod. ankle DF assistance	-Mod. pelvic & L L/E assist -BOS good -verbal cues to correct R L/E step length -Min ankle DF assist	-Mod. pelvic & L L/E assist -verbal cues to correct R L/E step length -BOS good -Min ankle DF assist	-BOS good -Min. pelvic & L L/E assist with periodic indep. with L L/E	-BOS good -Indep. with pelvic & L L/E -cues to increase step length bilaterally	-BOS good -Min. L L/E assist with indep. in last 2 min. -verbal cues for increased R step length
	Comments		Wt=211lbs -211(.40)= 84 lbs. BW support -Pt. used R handlebar	-pt. c/o a L sore knee -pt. used R handlebar	-feeling fatigued -pt. used R handlebar	-difficult start, but improved with walking -minimal handlebar use	- No handlebar use	-No handlebar use	-42lbs. BW support -minimal handlebar use

# **Intervention Documentation Chart for Subject A (Continued)**

	5/17/02	5/20/02	5/22/02	5/23/02	5/28/02	5/29/02	5/30/02	6/03/02	6/05/02	6/06/ 02
% BW support	20%	20%	20%	20%	0%	0%	0%	0%	0%	Final Testing Day
Speed	.7 mph	.7 mph	.7 mph	.7 mph	1.0 mph	1.0 mph	1.0 mph	1.0 mph	1.0 mph	
Time (walk 1)	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	
Time (walk 2)	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	
Time (walk 3)	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	
Distance Walked	1. 616 2. 616 3. 616	1. 616 2. 616 3. 616	1. 616 2. 616 3. 616	1. 616 2. 616 3. 616	1. 880 2. 880 3. 880	1. 880 2. 880 3. 880	1. 880 2. 880 3. 880	1. 880 2. 880 3. 880	1. 880 2. 880 3. 880	
Quality of ambulation	-BOS good -Min. L L/E assist with periodic indepverbal cues for increased R step length	-BOS good -Min. L L/E assist with indep. half of the time -verbal cues for increased R step length	-BOS good -Min. L L/E assist with indep. the majority of the time -verbal cues for increased R step length	-BOS good -L L/E indep. the entire time with min. verbal cues -verbal cues for increased R step length	-BOS good -Mod. L L/E assist -Min. pelvic assist -verbal cues for increased R step length	-BOS good -Min. L L/E assist with indep. the majority of the time	-BOS good -Min. L L/E assist with indep. the majority of the time	-BOS good -Min. L L/E assist with indep. the majority of the time	-BOS good -Amb. indep. with min. verbal cues for R and L L/E step length	
Comments	-minimal handlebar use	-minimal handlebar use	-No handlebar use	-No handlebar use	-held handlebar with R U/E entire time	-held handlebar with R U/E majority of time	-held handlebar with R U/E majority of time	-difficulty amb. without R U/E support of handlebar	-difficulty amb. without R U/E support of handlebar	

### **Intervention Documentation Chart for Subject B**

	6/3/02	6/4/02	6/6/02	6/10/02	6/11/02	6/13/02	6/17/02	6/18/02
% BW support	Initial Testing Day	40%	40%	40%	40%	40%	20%	20%
Speed		.5 mph	.5 mph	.5 mph	.5 mph	.5 mph	.7 mph	.7 mph
Time (walk 1)		10 minutes	10 minutes	10 minutes	10:17 minutes	5:40 minutes	10 minutes	10:10 minutes
Time (walk 2)		10 minutes	10 minutes	10 minutes	10 minutes	10:02 minutes	10 minutes	10:04 minutes
Time (walk 3)		5:56 minutes	7:36 minutes	10 minutes	10 minutes	10:01 minutes	10 minutes	10 minutes
Distance Walked (in feet)		1. 440 2. 440 3. 261	1. 440 2. 440 3. 334	1. 440 2. 440 3. 440	1. 452 2. 440 3. 440	1. 249 2. 441 3. 440	1. 616 2. 616 3. 616	1. 626 2. 620 3. 616
Quality of ambulation		-hyperext L knee -BOS good -tendency to drift to R	-no hyperext today -R foot drifted to midline, verbal cues to correct	-hips needed verbal cues to stay forward -R foot drifted to midline	-hyperext at L knee - R foot drifted to midline	-no hyperext today -very small BOS, verbal cues to correct	-pt. had tendency to retract R shoulder -BOS good	-continued to retract R shoulder as well as R hip, vc's to correct
Comments		Wt=200lbs -facilitation at L foot and hips -Verbal cues for R foot -pt. used handlebar on R -tremor in L leg with fatigue	-facilitation at L foot -pt. used handlebar on R	-facilitation at L foot -pt. used handlebar on R	-facilitation at L foot and hips -pt. did not hang on for most of ambulation	-facilitation at L foot -pt. did not use handlebar at all during session **pt. VERY FATIGUED today	-facilitation at L foot and at R shoulder -pt. used R handlebar throughout **Pt. subjective report of increased endurance with ADL's and less "toe dragging"	-facilitation at L heel only -decreased tone in L arm today **Pt c/o fatigue from ambulation, rode in w/c to and from session

### **Intervention Documentation Chart for Subject B (Continued)**

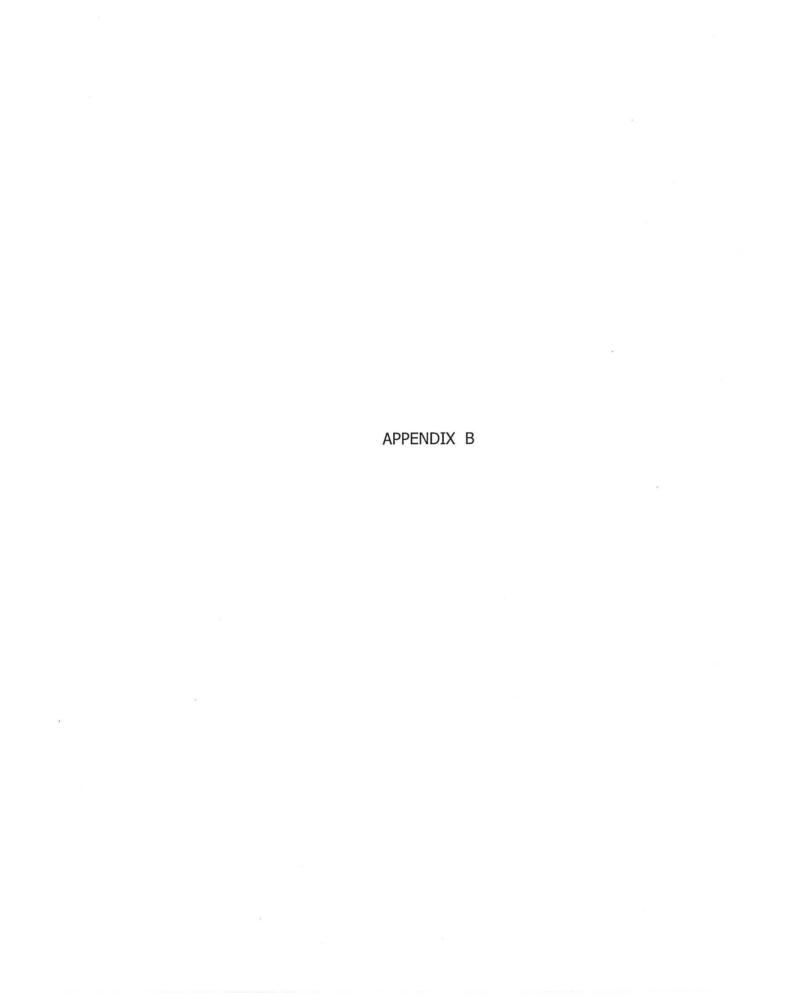
	6/20/02	6/24/02	6/25/02	6/27/02	7/1/02
% BW support	20%	20%	20%	20%	Final Testing Day
Speed	.7 mph	.7 mph	.7 mph	.7 mph	
Time (walk 1)	10 minutes	10:01 minutes	12:12 minutes	10 minutes	
Time (walk 2)	10:09 minutes	10 minutes	8:30 minutes	10 minutes	
Time (walk 3)	10 minutes	10 minutes	10 minutes	10:25 minutes	
Distance Walked (in feet)	1. 616 2. 625 3. 616	1. 617 2. 616 3. 616	1. 751 2. 523 3. 616	1. 616 2. 616 3. 641	
Quality of ambulation	-hyperext atL knee today	-L knee hyperext -L leg tremor	-L knee hyperext -R foot drifted to L, verbal cues to correct	-L and R knee hyperext, verbal cues to correct -R foot drifted to L, verbal cues to correct	
Comments	-facilitation at L heel -tone in L arm increased with ambulation	-facilitation at L heel -light grip on R handlebar **pt. c/o slight pain in L knee, recommended icing **w/c to and from session	-facilitation at L heel -light grip on R handlebar  **pt. walked in today, had OP therapy prior to session today **still had c/o L knee pain, slightly relieved with ice at home **pt. started on chemother today	-facilitation at L heel -occasionally used light grip on R handlebar **pt. c/o R knee pain today and increased fatigue	

## **Intervention Documentation Chart for Subject C**

	6/5/02	6/6/02	6/7/02	6/10/02	6/12/02	6/14/02	6/17/02	6/19/02	6/21/02
% BW support	Initial Testing	40%	40%	40%	40%	40%	40%	20%	20%
Speed		.5 mph	.5 mph	.5 mph	.5 mph	.5 mph	.5 mph	.7 mph	.7 mph
Time (walk 1)		10:06 minutes	10 minutes	10 minutes	10:02 minutes	10 minutes	10 minutes	10 minutes	5:21 minutes
Time (walk 2)	_	5:50 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes
Time (walk 3)		10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	5 minutes	10 minutes
Distance Walked (in feet)		1. 444 2. 255 3. 440	1. 440 2. 440 3. 440	1. 440 2. 440 3. 440	1. 441 2. 440 3. 440	1. 440 2. 441 3. 440	1. 440 2. 441 3. 440	1. 616 2. 616 3. 308	1. 329 2. 616 3. 616
Quality of ambulation		-R Intoeing -L knee ext during swing phase. Hikes R hip (compensate) -Little L DF	-Intoeing on R -Keeps L knee ext. Hikes R hip to compensate -Little DF on the L during toe off.	Demos good R foot alignmentAssistance with L knee flexion and L DF	-Assistance with L dorsiflexion (DF) during toe-off	-Assistance with L DF	-Assist with L DF	-Assistance with L DF	Assistance with L DF
Comments		-2 person Mod assistance -Facilitation at R and L feet and L kneeSubject reported stiffness from day beforeUsed R handlebar	-2 person Mod assistance -Facilitation at R and L feet and L kneeSubject stated felt less stiff today -Approximating L foot decreases tone and helps flex L kneeUsed R handlebar	-1 person Mod assistance -Facilitation at L foot. -Used R handlebar	-1 person Mod assistance -Facilitation at L footSubject's left knee locked up in bout 2 for about 2 strides. He stated he was sore after this episodeUsed R handlebar	-1 person Mod assistance Facilitation at L footSubject's left knee locked up in bout 3 for about 3 stridesUsed R handlebar	-1 person Min assistance Facilitated at L foot. -Used R handlebar	-1 person Min assistance -Facilitation at L footSubject fatigued and L muscle soreness on 3 <sup>rd</sup> bout -Used R handlebar	-1 person min assistance -Sharp pain in back of L knee on 1 <sup>st</sup> bout. This happened again after the session had endedUsed R handlebar

# Intervention Documentation Chart for Subject C (Continued)

	6/24/02	6/26/02	6/28/02	7/1/02	7/2/02	7/3/02	7/8/02	7/10/02	7/12/02
% BW support	20%	20%	20% 20% 0% 0%		0%	0%	0%	Final Testing	
Speed	.7 mph	.7 mph	.7 mph	1.0 mph	1.0 mph	1.0 mph	1.0 mph	1.0 mph	
Time (walk 1)	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	
Time (walk 2)	10 minutes	10 minutes	10 minutes	10 minutes	10 minutes	8:54 minutes	10 minutes	10 minutes	
Time (walk 3)	6:45 minutes	10 minutes	10 minutes	10 minutes	5:03 minutes	8:17 minutes	5:20 minutes	10 minutes	
Distance Walked ( in feet)	1. 616 2. 616 3. 415	1. 616 2. 616 3. 616	1. 616 2. 616 3. 616	1. 616 2. 616 3. 616	1. 880 2. 880 3. 444	1. 880 2. 783 3. 728	1. 880 2. 880 3. 469	1. 880 2. 880 3. 880	
Quality of ambulation	Assist with L dorsiflexion (DF)	Assist with L DF	Assist with L DF	Assist with L DF	Assist with L DF	Assist with L DF	Assist L DF	Assist L DF	
Comments	-1 person Min assistance -L knee started to feel funny on 3 <sup>rd</sup> bout so subject stopped to prevent spasm -Used R handlebar	-1 person Mod assistance -Subject had been in ER night before for kidney infection. Demoral administeredUsed R handlebar	-1 person min/mod assistance -Subject stated knee felt loose -Used R handlebar	-1 person Min/contact assist to achieve toe- offSubject fell this weekend. Dull ache L mid lower back -Used R handlebar	-1 person Min assist -3 <sup>rd</sup> bout subject fatigued and muscles stiffenedOn 3 <sup>rd</sup> bout, subject received finger tip assist with DF -Used R handlebar	-1 person Min assistance -Subject fatigued in 2 <sup>nd</sup> and 3 <sup>rd</sup> boutsOn 2 <sup>nd</sup> & 3 <sup>rd</sup> bouts, finger tip assist with DF -Used R handlebar	-1 person Min assist -2 <sup>nd</sup> bout no assist. (SBA) for last 3 min. 3 <sup>rd</sup> bout fingertips assist for 5:20 minutes -Used R handlebar	-1 person finger touch assist on 1st and 2nd bout (1st half), and min assist on last ½ of 2nd bout and 3rd bout due to muscle fatigue.	



#### 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 C

	EXPEDITED REVIEW REQUESTED UNDER ITEM	<i>1</i> 3,	(NUMBER[S]) OF HHS REGULATIONS
X		7	
	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 WHI	CH NOTICE OF APPROVAL SHOULD BE SENT: Cindy Flom-Meland or Michelle LaBrecque Box 9037 PT
SCHOOL/COLLEG	E: Medicine DEPARTMENT: Physical Therapy PROJECT DATES: 04-02 to 05-03  (E.g., A&S, Medicine, EHD, etc.) (Month/Day/Year)  The Effects of Partial Body Weight Support for Gait for Patients with Neurological Dysfunction – A Case Study Approach
FUNDING AGENCI	ES (IF APPLICABLE):
	T (Check ALL that apply):
X NEW PROJEC	DISSERTATION OR
CHANGE IN F	PROCEDURE FOR A PREVIOUSLY APPROVED PROJECT
DISSERTATION/TH	HESIS ADVISER, OR STUDENT ADVISER:
PROPOSED PROJ	ECT: INVOLVES NEW DRUGS (IND) INVOLVES NON-APPROVED USE OF DRUG INSTITUTION
IF ANY OF YOUR S	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)
MATERIAL, OR PL	T INVOLVES ANY HUMAN TISSUE, BODY FLUIDS, PATHOLOGICAL SPECIMENS, DONATED ORGANS, FETAL ACENTAL MATERIALS, CHECK HERE
	T HAS BEEN\WILL BE SUBMITTED TO ANOTHER INSTITUTIONAL REVIEW BOARD(S), PLEASE LIST NAME 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 ac Subjects performed by personnel conducting such activities under the auspices of the University. No ac without prior review and approval as prescribed by the University's policies and procedures governing the SIGNATURES: SAMHAMMERS, Amanda Cliam, Mandy Schumach Bucky Fuhier, Bucky Fuhier, Willia Herring	tivities are to be initiated the use of human subjects.
And the Burn July Marie 1 ( )	acount name
sur circan , Ducky tukie , Willia Holiving	
Cindy Flom-Meland, Muhlly LaBreigne Principal investigator	4-9-03
Principal/Investigator	Date
Cincle Florn-Meland, Michelle ZaBregue Project Director or Student Adviser	4-9-03
Project Director or Student Adviser	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<sup>1</sup>

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
The Effects of Partial Body Weight Support for Gait for Patients With Neurological

which this release pertains is 
Dysfunction – A Case Study Approach

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.

4-9-03

Date

Signature of Student Passarcher

### 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 March, Research 4-2-62  Title Date

word\research\prmsnfrm



### 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	IC			
Address to which notice of approval should be sent: UND Department of Medicine, P.O. Box 9037 PT, Grand Fo	rks			
Research Coordinator: Phone # 780-1751				
Project Title: The Effects of Partial Body Weight Support for Gait for Patients with Neurological Dysfunction –	Α.			
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.	ıot			
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.	1			
Project approved. <b>EXPEDITED REVIEW NO.</b> 3,7 Next scheduled reviewed is on				
Project approved. <b>EXEMPT CATEGORY NO.</b> Stated in REMARKS SECTION.  No periodic review scheduled unless so				
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  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 Cincly +
Rever
4/12/02

### LEAD IRB DESIGNATION SHEET

I have reviewed the proposal received from <u>Cindy Flom-Meland and Michelle La Brecque</u> 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 University of North Dakota Institutional Review Board be the lead IRB			
because subjects will be accrued at their institution.			
John P. Madden	Dan J. Liter		
John P. Madden, Ph.D., Chair	Kevin J. Tveter, M.D., Chair		
University of North Dakota Institutional Review Board	Altru Health Systems Institutional Review Board		
3-11-02	Yhrlor		
Date	Date		

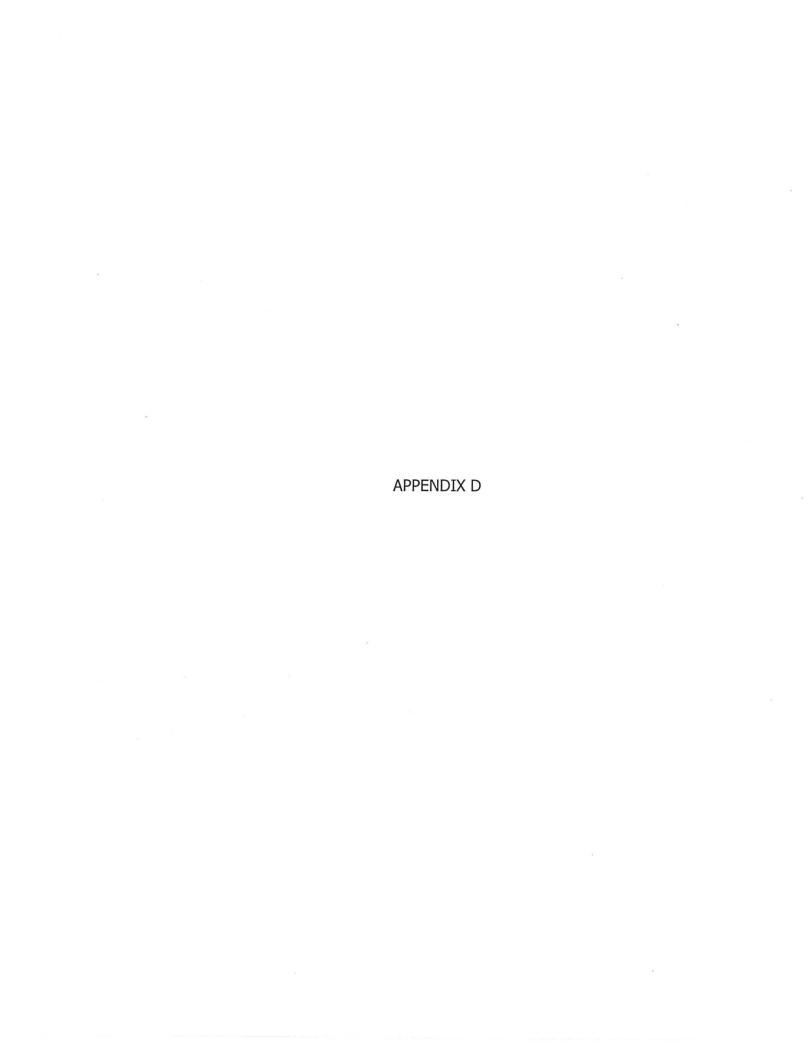


# APPLICATION TO CONDUCT RESEARCH AT ALTRU HEALTH SYSTEM FACILITIES

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 Cial E	Flore Modern 1
Address 513 Ex	Flom-Meland Date 3-19-03
Telephones numbers	Work 777- 4130 Home 775-2474
	Physical Therapy UND
In Gait &	or Patients with Neurological Parkynetion: a Case
(	or Patients with Neurological Dippunation: a Case Study approach
	(check all that apply):
Altru physician	n/staff member
Student	Department PT (Flex-time) Advisor Steve Rock
	Relationship to Altru, if any
	Coursework Thesis Dissertation
Other	
_X_Faculty	College/Department UND/ Physical Therapy
	Relationship to Altru, if any Flex - time employee
041	Overviewiew
Other	Organization Position
	Relationship to Altru, if any
	reductionship to rintu, if any
Please answer the f	following questions:
	, , , , , , , , , , , , , , , , , , ,
1. Describe the nature	e and extent of involvement expected of Altru staff with your project
	members by name and/or title, specific activities requested of them and an
estimate of the amour	at of their time that would be required).
None. My 5	tudents and myself will be evaing the Litebait devices.
and tread	tudents and myself will be evaing the Litebut device.
tract are lo	cated within the department of PT at AHI.
z. Describe the nature	e of patient contact required by your project, if applicable (i.e. access to
medical records, pane	ent interviews, etc.) The subjects for this project will withough altre, but through the
107 120	Comments altre, but streets, in
Carree FOCK	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
ichentifying 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
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). Name,
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
6. Projected start of project activities at Altru March 2002 (as 500n as given appr
Projected completion of project activities at Altru August 2002
Projected completion date of entire project May 2003
7. Source of funding sought or received Not applicable
8. Other information/comments
Please see IBB form & consent form that were
previously sent.
Cincly Flom-Meland Signature of Applicant  Cincly Flom-Meland Signature of Faculty Advisor

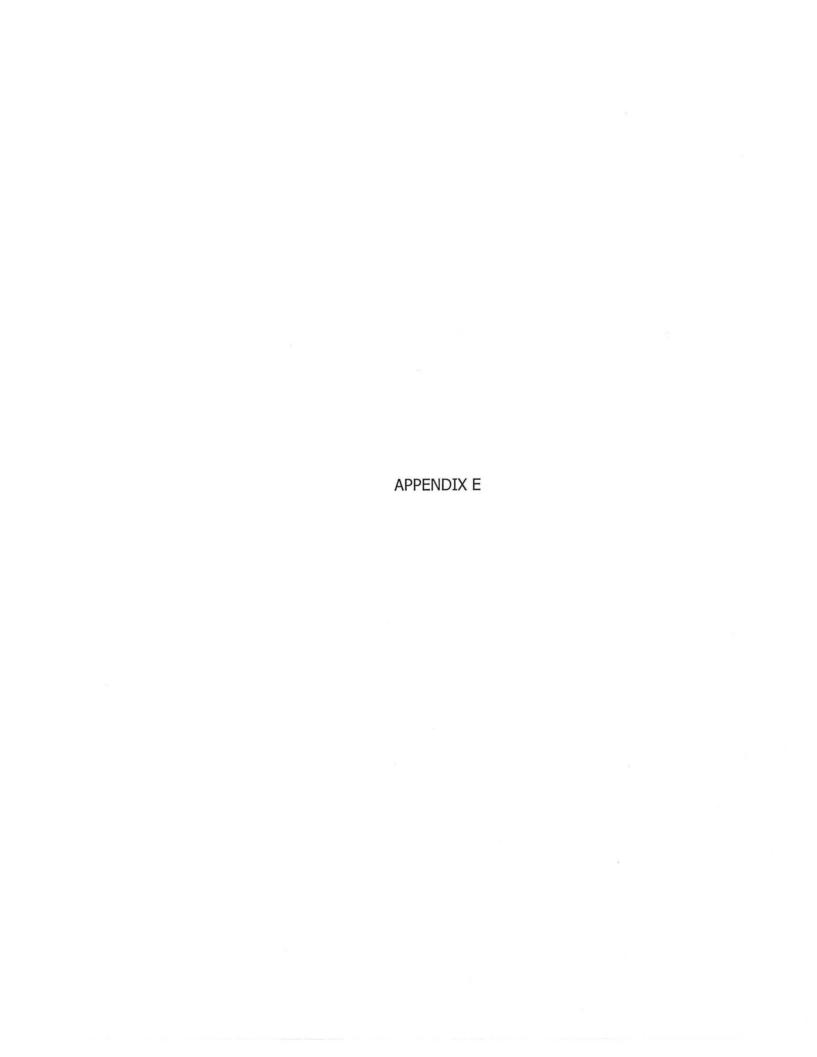


### **Initial Evaluation Form:**

Subjective information:      Date of evaluation:			
Consent form reviewed and signed? Yes No			
Pt. number: Pt. age: Pt. diagnosis:			
Pt. Relevant Past Medical History:			
Current Medications:			
Current Functional Status:  -Uses assistive device? Yes No  If yes, what?  -Problems with ADLs? Yes No  If yes, what?  -Problems with ambulation? Yes No  If yes, what?			
Prior Physical Therapy intervention? Yes No If yes, please describe here:			
Other comments:			
Objective information:			
Resting BP: Pt. weight:			
Berg Balance Score: 10 meter walk time:			
Tinetti Score (gait portion only):			
Gait Analysis:  -Stride length -Step length -Base of Support -angle Other comments:			

### **Final Evaluation Form:**

Date of evaluation:/ Evaluator Name:			
Pt. number:	Pt. diagnosis:		
-Problems with ADLs? Yes No If yes -Problems with ambulation? Yes	, what? , what? No , what?		
Other comments:			
Objective information:			
Resting BP: Resting HR:	Pt. weight:		
Berg Balance Score:	10 meter walk time:		
Tinetti Score (gait portion only):	_		
Gait Analysis: -Stride length -Step length -Base of Support -angle			
Other comments:			



### **Berg Balance Scale**

(from: 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.)

*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.

1.	Sitting to standing
	Instructions: Please stand up, try not to use your hands for support.
	( ) 4 able to stand without using hands and stabilizes independently
	( ) 3 able to stand independently using hands
	( ) 2 able to stand using hands after several tries
	( ) 1 needs minimal aid to stand or stabilize
	( ) 0 needs moderate or maximal assist to stand
2.	Standing unsupported
	Instructions: Please stand for 2 minutes without holding
	( ) 4 able to stand safely 2 minutes
	( ) 3 able to stand 2 minutes without supervision
	( ) 2 able to stand 30 seconds unsupported
	( ) 1 needs several tries to stand unsupported 30 seconds
	( ) 0 unable to stand 30 seconds without support
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 with supervision
	( ) 2 able to sit 30 seconds
	( ) 1 able to sit 10 seconds
	( ) 0 unable to sit without support 10 seconds
4.	Standing to sit
	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 for a pivot transfer. Ask the patient to transfer one way
	toward a sit without armrests and one way toward a seat with arms. You may use two
	chairs or a bed/mat and chair.
	( ) 4 able to transfer safely with minor use of hands
	( ) 3 able to transfer safely with definite need of hands
	( ) 2 able to transfer with verbal cueing and/or supervision
	( ) 1 needs one person to assist
_	( ) 0 needs two people to assist or supervise to be safe
<b>5.</b>	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 for 3 seconds but stands 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 safely 1 minute
	( ) 3 able to place feet together independently and stand with supervision for 1 minute
	( ) 2 able to place feet together independently but unable to hold for 30 seconds
	( ) 1 needs help to assume the position but can stand for 15 seconds, feet together
	( ) 0 needs help to assume the position and unable to stand for 15 seconds
8.	
	Instructions: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far
	as you can. (Clinician places a ruler at the tips of the outstretched fingers—subject
	should not touch the ruler when reaching.) Distance recorded is from the fingertips with
	the subject in the most forward position. The subject should use both hands when
	possible to avoid trunk rotation.
	( ) 4 can reach forward confidently 20-30cm (10 inches)
	( ) 3 can reach forward safely 12 cm (5 inches)
	( ) 2 can reach forward safely 5cm (2 inches)
	( ) 1 reaches forward but needs supervision
	( ) 0 loses balance when 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 the slipper safely and easily
	( ) 3 able to pick up the slipper but needs supervision
	( ) 2 unable to pick up the slipper, but reaches 2-5cm (1-2 inches) from the slipper and
	keeps balance independently
	( ) 1 unable to pick up and needs supervision while trying
	( ) 0 unable to try/needs assistance to keep from losing balance/falling
10	. Turning to look behind over your left and right shoulders while standing
	Instructions: Turn and look directly behind you over toward the left shoulder. Repeat to
	the right. Examiner may pick an object to look at directly behind the subject to
	encourage a better twist.
	( ) 4 looks behind from both sides and weight shifts as well
	( ) 3 looks behind one side only, other side shows less weight shift
	( ) 2 turns sideways only but maintains balance
	( ) 1 needs close supervision or verbal cueing
4.4	( ) 0 needs assistance while turning
TT	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 cueing
	( ) 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 4 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 assistance
	( ) 0 needs assistance to keep from falling/unable to try

13. Standing unsupported one root 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 and step far enough ahead
that the heel of your forward foot is ahead of the toes of your other foots. (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 stance width.)
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead of the other independently and hold 30 seconds
( ) 2 able to take a 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 >2 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently
( ) 0 unable to try or needs assistance to prevent fall
( ) o unable to try or needs assistance to prevent fair
TOTAL SCORE (Maximum=56)
10 TAL JCOIL (Planificities)

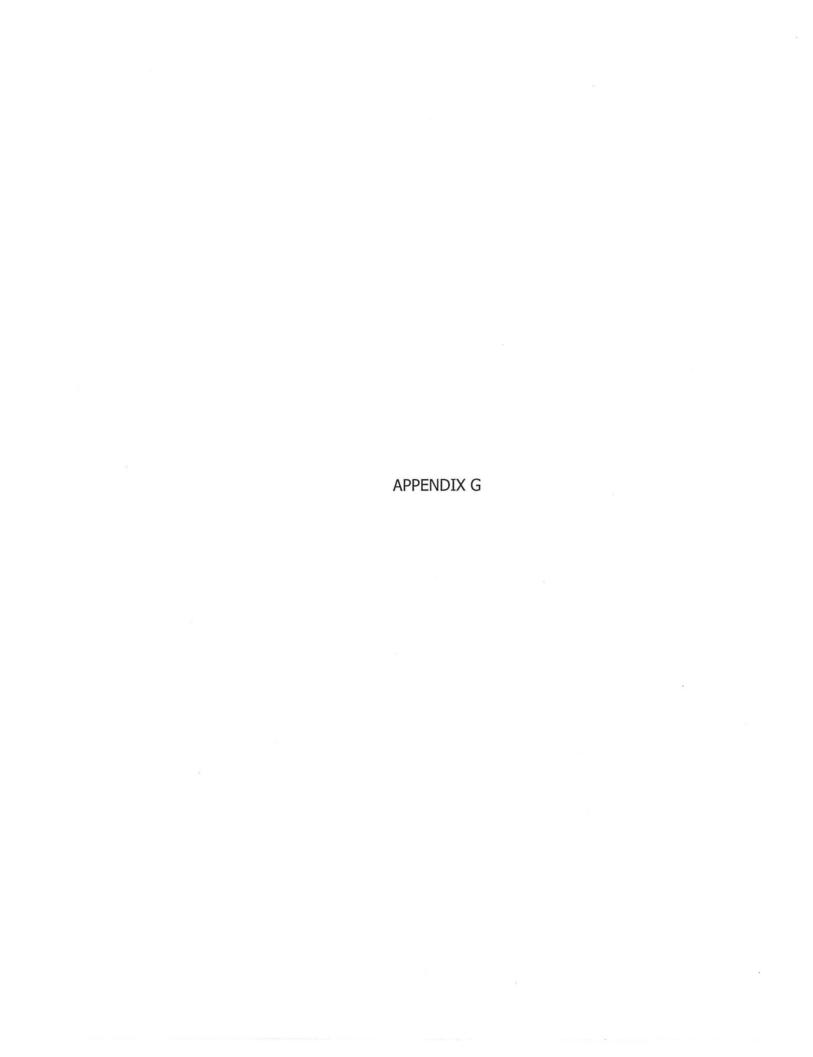
APPENDIX F

### **Tinetti Assessment Tool-Gait Portion**

(from: Tinetti ME. Performance oriented assessment of mobility problems in elderly patients. *JAGS.* 1986; 34(2): 119-26.)

*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)

		Gait Score:	/12
	tance eels apart eels almost touching while walking	=0 =1	
No	o sway, no flexion, no use of arms, and no use of walking aid	=2	
	arked sway or uses walking aid o sway but flexion of knees or back or spreads arn out while walking	=0 ns =1	
over abou Ma Mi	mated in relation to floor tiles, 12-inch diameter; out 10 ft of the course) arked deviation Id/moderate deviation or uses walking aid raight without walking aid	observe excursior =0 =1 =2	
	inuity opping or discontinuity between steps eps appear continuous	=0 =1	
	metry ght and left step length not equal (estimate) ght and left step appear equal	=( =1	
Le	Right foot does not clear floor completely wi Left foot completely clears floor eft swing foot: Does not pass right stance foot with step Passes right stance foot Left foot does not clear floor completely with Left foot completely clears floor	- =( =1	) 
	th and height ght swing foot: Does not pass right stance foot with step Passes right stance foot	=( =:	
Ar	of gait (immediately after told to "go") by hesitancy or multiple attempts to start by hesitancy	=( =:	



#### **ELGAM**

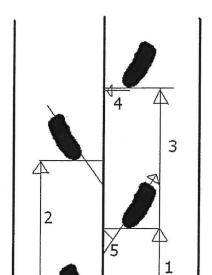
(from: Fried AV, Cwikel J, Ring H, Galinsky D. ELGAM—Extra laboratory gait assessment method: Identification for risk factors among falls among the elderly at home. *International Disabilities Studies*. 1990; 12(4): 161-64.)

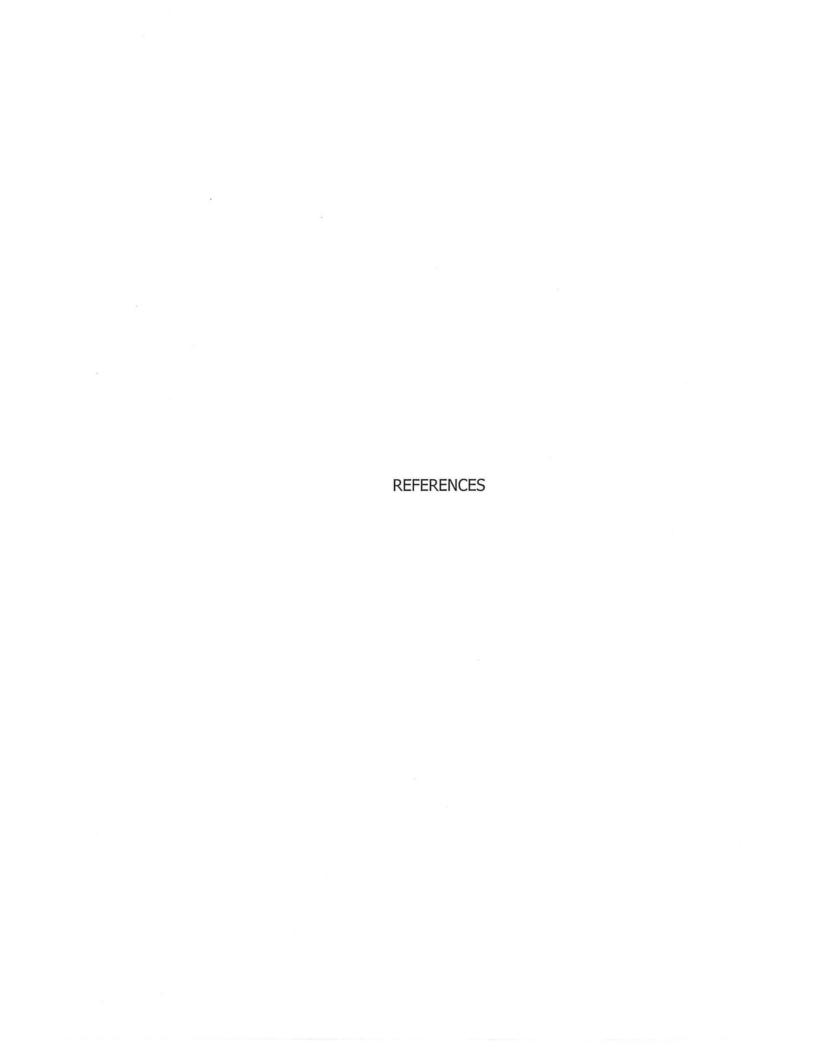
The five parameters of the ELGAM test are independently measured and then may be summed together to form an overall index.

**ELGAM** measures:

1= step length 2= left stride 3= right stride

3= right stride 4= walking base 5= walking angle





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