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The Effects of Balance Retraining Exercises on the Neurocom Balance Master® in Subjects with Multiple Sclerosis

Becky Coy
University of North Dakota

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THE EFFECTS OF BALANCE RETRAINING EXERCISES ON THE NEUROCOM BALANCE MASTER® IN SUBJECTS WITH MULTIPLE SCLEROSIS

By

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An Independent Study
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
1999
This Independent Study, submitted by Becky Coy in partial fulfillment of
the requirements for the Degree of Master of Physical Therapy from the
University of North Dakota, has been read by the Faculty Preceptor, Advisor, and
Chairperson of Physical Therapy under whom the work has been done and is
hereby approved.

(Faculty Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)
PERMISSION

Title The Effects of Balance Retraining Exercises on the Neurocom Balance Master® in Subjects with Multiple Sclerosis

Department Physical Therapy

Degree Master of Physical Therapy

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Date 12/11/98
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ABSTRACT

Multiple sclerosis (MS) is the most common demyelinating disease of the central nervous system (CNS) and is becoming an increasing concern for individuals between the ages of 15 to 50. Multiple sclerosis is a chronic, often progressive disease that may result in difficulties with vision, verbal communication, sensation, bowel and bladder function, balance, and ambulation.

The purpose of this study was to determine if significant changes occurred in static steadiness, symmetry, and dynamic stability in subjects with MS following a retraining program using the NeuroCom Balance Master® (NBM®). Ten subjects (6 females, 4 males) were placed in a control or treatment group. The NBM® was used to assess each subject’s balance at week one and four, and was also used in the retraining program for the treatment group three times per week for four weeks. Results showed a significant difference between groups in two components of the dynamic stability tests: endpoint excursion forward (p = .042) and maximum excursion endpoint forward (p = .029). No significant difference was found in static steadiness or symmetry between groups.

The variability among subjects in the MS population pool, the small sample size, and the four-week time frame may have been limiting factors in this
study. Further research is needed to determine the effectiveness of a balance retraining program using the NBM®.
CHAPTER I
INTRODUCTION AND REVIEW OF THE LITERATURE

Multiple sclerosis (MS) is the most common demyelinating disease of the central nervous system (CNS) and is becoming an increasing concern for individuals between the ages of 15 to 50. Multiple sclerosis is a chronic, often progressive disease that may result in difficulties with vision, verbal communication, sensation, bowel and bladder function, balance and ambulation. Previous studies have utilized a force platform biofeedback system to assess and retrain balance in multiple patient populations, including hemiplegia. No research to date has been conducted utilizing a biofeedback system to assess and retrain balance of persons with MS.

This paper will provide the reader with a description of the etiology and associated signs and symptoms of MS as well as the different categories and course of MS. Diagnosis and treatment of MS will also be covered, with emphasis placed on the treatment of balance impairments so often associated with MS. The three systems necessary for adequate postural stability—visual, vestibular, and somatosensory—will also be discussed.

Multiple Sclerosis

Multiple sclerosis is a chronic, demyelinating disease affecting the white matter of the central nervous system (CNS).\(^1\)\(^-\)\(^6\) It was described as early as six
centuries ago and is considered to be the most common disease affecting the myelin of the CNS. In fact, besides certain mental disorders and neurological injuries secondary to trauma, MS is the most common disease affecting the nervous system of young adults. Multiple sclerosis is most commonly characterized by relapses, or exacerbations, of active disease lasting from 48 hours to several weeks, followed by lengthy periods of improvement, or remission, where symptoms may diminish or even disappear for periods of months to years.

Multiple sclerosis is considered to be a primary demyelinating disease because it attacks the myelin sheaths while sparing the axons. Following the destruction of the sheath, patchy areas of inflammation are found along the CNS. Scar tissue and plaques, or ‘sclerosed’ areas, are then formed where the myelin sheath previously served to protect and insulate the nerve fibers. Because of the destruction of the myelin sheath, the conduction of the nervous impulse is short-circuited, interrupted, blocked, or slowed. With the progression of MS, new plaques form, old plaques expand, and nearby plaques join to form larger sclerosed areas. Remarkably, it is not rare to find plaques two to three centimeters wide and several centimeters long. In active plaques, the sclerosed areas continue to harden and contract, permanently damaging some nerve fibers running through them. In older plaques, astroglia invade the central portion of the scars which were formerly occupied by oligodendroglia, white blood cells, some remains of myelin, and other such remnants from the
inflammatory process.\textsuperscript{1,3} This is of significance because, without oligodendroglia, remyelination will not occur.

An estimated 250 000-350 000 Americans\textsuperscript{5,7} have been diagnosed with MS, with approximately 200 new cases reported every week.\textsuperscript{2} Most patients are between the ages of 15 and 50, with a mean age of 30, when the disease first strikes.\textsuperscript{1,5,7} Women are diagnosed two times more often than men and Caucasians more frequently than Asians or African Americans.\textsuperscript{1,2,5,7} The prevalence of MS in the United States varies from 15 to more than 100 cases per 100 000 persons of all ages.\textsuperscript{1} Interestingly, MS is more prevalent in colder climates\textsuperscript{2} or those places more distant from the equator, such as the Northern U.S., Canada, and Great Britain.\textsuperscript{1,7} In contrast, MS is quite uncommon in those countries near the equator, such as China, Japan, and the Indies.\textsuperscript{5} The incidence of the disease is related to place of residence, especially for the first 15 years of life.\textsuperscript{2,5} For instance, migration from a low- to high-risk area during the childhood or adolescent years is associated with an increase in rate of MS, while migration from a high- to low-risk area during the formative years is related to a decrease in the rate of the disease.\textsuperscript{1} However, adults who immigrate from equatorial countries to more northern ones have a lower incidence of MS than the natives; while adults who immigrate to more equatorial places have a higher incidence of the disease than natives.

Since MS can affect any part of the CNS, initial symptoms can be quite variable.\textsuperscript{3} The signs and symptoms of MS vary significantly from one exacerbation to the next, as well as among individuals.\textsuperscript{2} Symptoms of this
disease most commonly appear, remit, and reappear; often involving other areas, as well as with varying degrees of severity. Certain areas of the CNS are more vulnerable to myelin destruction and subsequent scar formation. Signs and symptoms of MS are the result of the plaques and sclerosed areas along the axon which, in effect, block or distort the conduction of the nerve impulse to and from the various centers in the brain. Early symptoms of MS most often involve sensory rather than motor deficits. For instance, it is not uncommon for an individual to initially experience paresthesias in one or more limbs; bowel, bladder, and sexual dysfunction; diplopia; blurred vision or other such problems associated with optic neuritis; vision loss; loss of proprioception; and vertigo. Of the above, sensory involvement of limbs, gait and balance disturbances, visual loss, and diplopia are most frequently reported as initial symptoms. Balance can be adversely affected by any of the early signs and symptoms associated with MS.

Late symptoms may include dyscoordination; muscle cramps, weakness, and fatigue; spasms; slurred speech; paresis; paralysis; pain; depression or other mood changes; spasticity; loss of balance; ataxia; intolerance to heat; and intention tremor. Of these, balance abnormalities were found approximately 80% of the time throughout the course of the disease. Impaired sensation, fatigue, paraparesis, visual loss, weakness and dyscoordination of limbs, and diplopia were most often reported as symptoms found throughout the course of MS. These symptoms are also very much related to balance. Some patients
experience memory loss and impairment, decreased mentation, depression, and mood swings.\textsuperscript{2,4}

Throughout the course of the disease, it is not unusual to experience multiple symptoms simultaneously; however, with optic neuritis, people commonly present with this singular abnormality.\textsuperscript{5} Symptoms of MS are most often rapid in onset, with variable intensity. Usually early signs and symptoms completely remit after six to eight weeks. The persons’ ability to perform functions of daily life fluctuate from day to day and from attack to attack, and are further influenced by fatigue, temperature, type of MS, and other unknown factors.\textsuperscript{3} An estimated two-thirds of persons with MS are ambulatory throughout the course of the disease, but many require assistive devices to do so.\textsuperscript{2} It is not possible to predict if or when an attack of symptoms will occur; however, exacerbations may be the result of certain external factors, such as infections, stress, pregnancy, trauma, emotional distress, exposure to cold, surgical procedures, and fatigue and over-exertion.\textsuperscript{1,3,6} Nonetheless, for the majority of relapses, no precipitating factor can be found.\textsuperscript{3}

Multiple sclerosis ranges from very mild to intermittent to very severe and rapidly progressive forms.\textsuperscript{2} Since the course of the disease is very unpredictable with an astonishing amount of variability between patients, this disease is classified into several categories based on the severity and degree of neurologic impairment.\textsuperscript{7}

Approximately 20\% to 35\% of patients with MS experience mild symptoms that either remit suddenly or over time or are never even detected. This category
in which people experience no or very few attacks with no recurrence afterward is known as benign MS. With benign MS, onset of symptoms usually include optic neuritis and paresthesias of limbs and trunk. Remission is complete, and severe or permanent disability does not develop.

The majority of patients with MS—some 50% to 65%—have unpredictable attacks followed by bouts of remission lasting months or even years. This category of MS, which is characterized by numerous exacerbations and remissions of signs and symptoms, is known as the relapsing-remitting type. It is not uncommon for some of these patients to have only limited disability even 20 or more years after the diagnosis. Quite often, after the active period of relapse and remission—lasting approximately five years—the pattern of MS changes, resulting in no more acute attacks and more spontaneous recoveries.

A third category of MS is known as relapsing or chronic/progressive, whereby approximately 25% of patients develop significant neurologic disability. Some recovery following attacks is observed, but approximately 15 years after the diagnosis, most will require the use of an assistive device for gait.

The fourth and final type of MS is known as the primary progressive type. Approximately 10% of patients fall into this category and experience a progressive course from the onset of the disease, with the absence of exacerbations and remissions. Interestingly, this group is comprised mainly of older males and usually includes some spinal cord involvement.
In general, patients with MS have a better prognosis if the disease course begins earlier in age, if symptoms are primarily sensory versus motor, and if the person is of the female gender. Ultimately, approximately 50% of persons with MS of the relapsing-remitting, chronic/progressive, and primary progressive types will experience a progressive course. Rao states that the course of the disease is typically one that gradually worsens over an almost normal life span. The life expectancy of people with MS is only slightly less than in the general population—about 75% of normal. Even though the life span is comparable to that of the general population, the quality of life may be quite different than that normally found. For instance, many individuals with MS are unable to walk effectively or to perform other functions of daily life secondary to the common symptoms of weakness, spasticity, dyscoordination, altered balance, and disturbances of the visual and somatosensory systems. Nonetheless, there are many adaptive devices and techniques in addition to environmental modifications that make activities of daily living easier and safer for the person with MS.

What exactly causes MS is unknown, although studies have suggested that a combination of inherited and environmental factors may be to blame. There does appear to be a genetic predisposition in that the rate of MS increases slightly when there is a close relative with the diagnosis. More specifically, research suggests that instead of one or two cases of MS per 1000 in the US, in families where MS is found, the risk increases to three per 100. This is a higher risk, but not a major factor when determining the cause of MS. There is no evidence that MS is directly inherited in the general population;
rather, evidence suggests that persons who develop MS inherit a predisposition to the disease, perhaps with a weakness to an offending agent in the environment. Studies with identical twins—with identical susceptibility genes—show that the second twin develops MS only half of the time. Therefore, even with evidence suggesting a genetic predisposition, other research shows environmental factors are just as important.

Studies have suggested that a person’s genes are related to the susceptibility to and character of MS. Research has found that there is an increase in the chromosome crossover rate in persons with MS. This is an inherited disorder and has that potential to create a disease process.

Moreover, evidence has suggested that exposure, especially in the childhood years, to an offending agent, such as a virus, may cause the MS disease process. Studies have suggested that MS probably begins during childhood and adolescence with signs and symptoms not appearing for a period of years. If such evidence were true, then re-exposure to certain viruses could trigger a relapse. Viral theories are supported by the latitude effect and migration studies; twin, family, and sib-pair studies; and the association between many attacks of MS symptoms and upper respiratory infections.

Another similar theory is that MS is caused by an infectious agent resulting in an allergic response. Studies have suggested that MS may be an autoimmune disease, whereby the body’s immune system (white blood cells) fails to recognize "self" tissue and destroys it as though it were "foreign."
Diagnosis of MS is based on the patient's clinical history, the neurological exam showing signs of progressive neurological dysfunction and the lack of a differential diagnosis. Multiple sclerosis is usually difficult to diagnose because many of the early signs and symptoms come and go or are even indicative of another disease. There is no single neurological or laboratory test that is definitive of MS. To make a conclusive MS diagnosis, however, two factors must be met: 1) evidence of several areas of plaque formation in different areas of the CNS and 2) at least two separate exacerbations of the disease.

Diagnosis of MS is made more certain with the help of neurological tests such as nuclear magnetic resonance imaging (MRI), computed tomography (CT) scan, cerebrospinal fluid (CSF) analysis, evoked potentials, and electroencephalography (EEG). While no definitive test for MS exists, MRI is the most sensitive test—ten times more sensitive than CT—for detecting MS plaques and can locate lesions as the disease progresses. Approximately 95% of patients with MS demonstrate multiple sites of plaque formation in the CNS. Evoked potentials detect abnormalities in the conduction of nervous impulses. Lumbar puncture and CSF analysis, while not specific for MS, do show strong evidence of the disease.

There is no prevention or cure for MS at this time; however, much can be done to aid people in functioning at their optimal level. Some treatment may even result in reducing the frequency and severity of attacks. For instance, several new medications are used to decrease muscle spasms and stiffness; reduce fatigue; control bladder symptoms, sexual dysfunction, and pain; improve
coordination; and control depression and other mood changes. Other medications, such as adrenal hormones and corticosteroids, help shorten relapses, while interferon beta 1a and 1b are used to modify disease activity by decreasing frequency and severity of relapses. Baclofen and dantrolene are used to reduce spasticity that is often found in patients with long-standing MS. Supportive measures for individuals with MS may include physical and occupational therapy to maintain and increase strength and range of motion of involved musculature, in addition to help maintain mobility. Exercise programs, diet, adequate rest, and counseling to combat depression are other measures recommended for persons with MS.

In regard to exercise, it is most effective following an acute attack, during the remitting stage. Vigorous exercise is not recommended during acute relapses or with rapidly and progressing forms of MS. The effects of exercise are dependent on the damage done to the CNS; fatigability; and the severity of spasticity, uncoordinated movements, and weakness. The general goals of exercise include increasing strength, range of motion, endurance, and coordination. When balance deficits are observed, specific balance exercises should be chosen according to the specific needs of the patient. For instance, a patient who is having difficulties with sit to stand transfers should practice specifically on that task. Other persons whose balance is less affected may benefit more from challenged balance activities, such as tandem walking, step up and over, side stepping, braiding, or controlling movements on a tilt board.
Collectively, there are approximately 40 treatments for MS available. Unfortunately, most have little or no effect on the disease, undoubtedly because the cause of MS is still unknown. Other less popular treatments include immunosuppression, transfer factor, antiviral treatment, gluten-free diet, unsaturated fatty acid diet, rest/exercise, and dorsal column stimulation.

Balance

Balance, or postural control, is defined as “the ability to maintain or move within a weight bearing posture without falling.” There are three components of balance: static steadiness, symmetry, and dynamic stability. Static stability is defined as the ability to sustain an upright posture with minimal sway. Symmetry is defined as having equal weight distributed between the weight bearing components. Dynamic stability describes the ability to move within a given posture without a loss of balance (LOB). It is important to understand that static and dynamic balance are greatly affected by vestibular, visual, and somatosensory feedback. These postural components provide the CNS with afferent (sensory) input, which can then be followed by the appropriate and effective efferent (motor) response from the CNS. When these systems are functioning adequately, an individual is able to maintain the center of gravity within the base of support with minimal extraneous movement, or sway. However, if one or more of these systems is compromised, which is often the case in persons with MS, the CNS adjusts by utilizing inputs from the remaining systems to maintain postural control. In other words, the CNS relies more
heavily on the feedback from the remaining systems in order to reduce sway, a measure of postural control, to avoid a LOB.

Visual Input

The optic nerves comprise part of the CNS and are, therefore, susceptible to demyelination and subsequent plaque formation. In approximately 15% of persons with MS, optic neuritis was reported as the initial symptom.\(^3\) Fortunately, vision usually improves within one week. It is also common for people with MS to experience diplopia, blurring of vision, and loss of vision.\(^1\) Persons with MS reported experiencing visual loss or diplopia as an initial symptom 30% of the time. Throughout the course of the disease, however, individuals reported experiencing some type of visual loss or diplopia 98% of the time.\(^6\) Therefore, one can conclude that visual abnormalities, at least sometime throughout the disease process, are a problem for persons with MS. Since visual input is an important component in postural stability, one can then assume that balance may be significantly compromised unless the CNS can rely more heavily on the feedback from the other two components.

Vestibular Input

The vestibular system is responsible for detecting changes in the linear acceleration and deceleration forces acting on the head, as well as angular velocity effects on the head.\(^11,17\) This system also provides feedback necessary to reference the position of the head in response to gravity. Moreover, the vestibular system provides the output necessary for two important reflexes, the vestibulospinal reflex (VSR) and the vestibulo-ocular reflex (VOR). The VSR
allows for head and postural control in order to prevent falls. The VOR controls the eye movements and allows for clear vision during head movements. Vestibular input is also responsible for the righting reflexes which, in turn, are responsible for allowing the body to maintain balance when confronted by sudden movements. The vestibular system is commonly affected by MS, with most persons experiencing episodes of vertigo and dizziness. Vestibular input becomes increasingly important in providing feedback to the CNS when the visual or somatosensory systems are compromised.

Somatosensory Input

The third component important for postural stability is the somatosensory system or proprioceptive component. This input is preferred by most healthy adults for maintaining an upright position. Proprioceptive input from the mechanoreceptors of the foot and ankle provide input to the CNS to promote postural stability and reduce sway. Patients with MS reported experiencing sensory abnormalities of the extremities as an initial symptom of the disease approximately 35% of the time, compared to approximately 70% of the time during the course of the disease. It appears that impaired sensation is quite frequently reported as an early and late symptom of MS. This being the case, one can conclude that the somatosensory or proprioceptive input to the CNS is diminished in persons with MS. Unless the CNS succeeds in integrating input from the other two systems, balance will likely be greatly affected.

It has been reported that balance disturbances are noted 20% of the time as initial symptoms of MS. Abnormalities in balance are reported to occur 80%
of the time throughout the course of the MS disease. Studies have found that instability and increased body sway are associated with vestibular abnormalities, visual problems, loss of vibration sense and lower limb tendon reflexes, and multi-sensory deficiencies in healthy adults.

Recent studies of patients having suffered a cerebrovascular accident (CVA) with resulting hemiplegia utilized force platform systems for assessing and retraining postural control. These systems provide visual and/or auditory feedback to the patients regarding the position of the center of gravity (COG). The NeuroCom Balance Master® (NBM®) is one such piece of equipment that provides the patient with visual feedback of the location of the COG in relation to the limits of stability (LOS). The NBM® consists of a dual-force platform connected to a microprocessor and uses an estimate of the person’s COG projected as a reference point on a computer screen. In addition, numerous training protocols on the NBM® may be utilized to optimize three components of postural stability. These measures of postural control—static steadiness, symmetry, and dynamic stability—are used most often during the balance assessment using the force platform system. Lee et al state that biofeedback, such as that provided by the NBM®, is a most effective method in improving postural instability immediately in hemiplegic subjects as well as for those individuals who can use the visual or auditory feedback. Other studies found that improvements were noticed very quickly and with very little treatment.
Force platform measures of postural sway have been reported to be valid and reliable when using the center of force versus the center of pressure measures.\textsuperscript{10,26} Liston et al\textsuperscript{24} suggested that for CVA patients, complex tests of balance proved to be more reliable than static steadiness or symmetry tests. Dynamic stability measures proved to be more valid measures of functional balance performance than static steadiness measures.\textsuperscript{10,24} However, Liston and colleagues\textsuperscript{24} found that only the LOS test among the dynamic stability measures was highly reliable. Liston and colleagues\textsuperscript{24} recognize that other studies have argued that the majority of the variables tested with the NBM\textsuperscript{r} were found to be valid measures of balance.\textsuperscript{24}

Force platform studies with hemiparetics have shown varied results; however, for the most part, some improvements in postural stability have been observed.\textsuperscript{10,11,22} Studies have suggested that symmetry and dynamic stability measures may provide more accurate information of patient progress.\textsuperscript{10,27} These two measures show consistent improvement with use of visual biofeedback using force plate systems.\textsuperscript{10,27} A study by Shumway-Cook and associates\textsuperscript{12} indicated that hemiplegic subjects improved in measures of static stability when trained with a force platform balance system. Studies showed improvements in stance, weight transference, and in tolerance of imposed forces.\textsuperscript{11,27} While Liston and colleagues\textsuperscript{24} found that standing balance training in hemiparetics improved postural control, that improvement did not carry over to improve locomotor function. These studies suggest that performance is task specific. A study by Panzer et al\textsuperscript{29} concluded that balance retraining of hemiplegics using
the NBM® improved midline positioning, standing mobility, and transfers. Again, these improvements did not translate to improvements in functional mobility, such as gait. In contrast, a case study of two patients with hemiplegia, conducted by Sackley et al., suggested that training effects from visual biofeedback did translate to improved functional skills, thereby increasing activities of daily living (ADL) scores.

When designing a treatment program utilizing the NBM® to optimize effectiveness, one should identify and focus on the particular needs of the patient. It is also important to design a balance program that readily translates to a new learning situation. A study by Maurer and colleagues concluded that a training schedule of 20 minutes three times per week over a period of three weeks was just as effective as a more concentrated schedule. Further, Nichols found that programs which incorporated various training activities have provided consistent changes in patients’ level of function, including transfers, gait, home mobility, endurance, functions of daily life, and gross motor function.

**Purpose of Study**

Recently, there has been a growing acceptance for the utilization of a force platform biofeedback system for evaluation and treatment of various neurological and orthopedic diagnoses. At this time, there is no research available concerning balance assessments of and retraining for patients with MS using a platform biofeedback system. Therefore, the purpose of this study is to determine if significant changes occur in static steadiness, symmetry, and dynamic stability following a balance retraining program on the NBM®.
Research Questions

This research project will answer the following questions: 1) Is there a significant difference in measures of static steadiness between the control and treatment groups utilizing the NBM® for balance retraining? 2) Is there a significant difference in measures of symmetry between the control and treatment groups? 3) Is there a significant difference in measures of dynamic stability between groups with utilization of the NBM® for balance retraining?

It is hypothesized that there will be a significant difference between the control and treatment groups based on a comparison of the initial to the final balance assessment. The alternate hypothesis states that the treatment group will demonstrate improvements in static steadiness, symmetry, and dynamic stability as compared to the control group who should demonstrate either no change in balance or perform slightly worse secondary to the general progressive course of the disease.

Because balance is an integral part of a physical evaluation for a multitude of patient diagnoses, including MS, the significance of conducting this study involved the utilization of the NBM® to assess and retrain patients with MS in an objective and systematic manner. Upon completion of this study, the results can be useful to a clinician eager to use a force platform system with biofeedback to improve balance. As a physical therapist, it is important to examine possible therapeutic treatment modalities that may prove successful in treating various symptoms of MS and be able to apply the tool to other patients.
as well. Finally, this study can be used as a basis for future research involving a larger sample size and/or a longer period of time for balance retraining.
CHAPTER II
METHODOLOGY

An Institutional Review Board form describing the purpose and format for this study was completed by the researchers and approved by Altru Health Systems and the University of North Dakota (see Appendix A). A meeting between the researchers and the neurologist involved in this study was held to discuss selection of subjects and inclusion criteria for participation.

Subjects

A sample of convenience was used from a population pool of MS patients under the care and supervision of a neurologist. Subjects were contacted by telephone and scheduled for an initial assessment. Inclusion criteria for participation in this study consisted of: 1) a diagnosis of MS, 2) a score in the 3.0 to 6.0 range on the Neurological Assessment Kurtzke Functional Systems-EDSS (see Appendix B), 3) an absence of secondary diagnoses that may interfere with this study, 4) no prior experience using the NBM®, and 5) permission from the neurologist associated with this study. Subjects were excluded if: 1) one or more of the above criteria were not met or 2) unable to understand and follow instructions.

Two groups of five subjects (mean age = 50.9 ± 4.5 years) were selected based upon ability to participate in this study. Those subjects who either lived in
rural locations or were unable to participate in the retraining program due to work or other time conflicts were assigned to the control group. The treatment group was composed of those subjects who expressed a desire to participate and were able to commit their time to the four-week retraining program. The control group consisted of five subjects (4 females, 1 male) who performed an initial and final balance assessment on the NBM® only. The subjects in the control group received no balance retraining between testing trials. The treatment group consisted of five subjects (2 females, 3 males) who participated in an initial and final balance assessment and a balance retraining program three days per week for four weeks. The initial and final balance assessments for both groups and the retraining program for the subjects in the treatment group were performed using the NBM®. Refer to Table 1 for descriptive data of subjects.

Questionnaire and Initial Evaluation

Upon arrival at the research site, subjects were given a consent form and a questionnaire (see Appendices C and D, respectively). The questionnaire was given to all ten subjects before beginning the initial assessment on the NBM®. Questions were related to subjective ratings of balance difficulties, number of falls in the last month and year, previous hospitalizations, health problems, medications, sensation, vision, exercise, work schedule, and use of an assistive device. A general screening was performed on each subject prior to beginning the assessment on the NBM® and consisted of manual muscle, range of motion, reflex, and sensation testing (see Appendix E).
Table 1.—Descriptives of Subjects

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Sex</th>
<th>Group</th>
<th>Years</th>
<th>Side Involved</th>
<th>Assistive Devices Used</th>
<th>Balance Difficulties</th>
<th># Times Fallen</th>
<th>Month</th>
<th>Year</th>
<th>Height</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>49</td>
<td>F</td>
<td>C</td>
<td>11</td>
<td>L</td>
<td>cane</td>
<td>mild</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>64</td>
</tr>
<tr>
<td>2</td>
<td>53</td>
<td>F</td>
<td>C</td>
<td>7</td>
<td>L</td>
<td>no</td>
<td>mild</td>
<td>0</td>
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<td>64</td>
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<tr>
<td>3</td>
<td>52</td>
<td>F</td>
<td>Rx</td>
<td>13</td>
<td>R</td>
<td>cane</td>
<td>moderate</td>
<td>5</td>
<td>50-60</td>
<td>68</td>
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<tr>
<td>4</td>
<td>58</td>
<td>F</td>
<td>C</td>
<td>6</td>
<td>R</td>
<td>cane</td>
<td>mild</td>
<td>0</td>
<td>2</td>
<td>62</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>53</td>
<td>F</td>
<td>Rx</td>
<td>6</td>
<td>L</td>
<td>cane</td>
<td>severe</td>
<td>4-5</td>
<td>20-25</td>
<td>65</td>
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<tr>
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<td>52</td>
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<td>Rx</td>
<td>5</td>
<td>L</td>
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<td>moderate</td>
<td>0</td>
<td>1-2</td>
<td>73</td>
<td></td>
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<tr>
<td>8</td>
<td>42</td>
<td>M</td>
<td>Rx</td>
<td>14</td>
<td>L</td>
<td>cane</td>
<td>moderate</td>
<td>3-4</td>
<td>40-50</td>
<td>69</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>47</td>
<td>M</td>
<td>C</td>
<td>9</td>
<td>R</td>
<td>cane</td>
<td>mild</td>
<td>2</td>
<td>20-25</td>
<td>73</td>
<td></td>
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<tr>
<td>10</td>
<td>55</td>
<td>F</td>
<td>C</td>
<td>28</td>
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<td>cane</td>
<td>moderate</td>
<td>5-10</td>
<td>50-60</td>
<td>63</td>
<td></td>
</tr>
</tbody>
</table>

ccontrol mean age = 52.4 years
treatment mean age = 49.4 years
Instrumentation

The NBM\textsuperscript{®} (NeuroCom\textsuperscript{®} International, Inc, 9570 SE Lawnfield Road, Clackamas, OR 97015-9611, Telephone (800) 767-6744) used in this study is composed of two adjacent force platforms (each approximately 155 cm long) resting on four load cells which transfer information from the platform system to a connecting computer.\textsuperscript{14,30} The computer monitor is located at the superior end of the platform and is positioned at eye level to the subject with a cursor representing the center of gravity (COG) as a reference point in relation to the theoretical limits of stability (LOS). The balance master system offers an objective measure of balance and balance-related activities for the patient and clinician by giving continuous visual feedback and statistical information regarding performance on each test and retraining measure.\textsuperscript{14} The machine is sensitive to all types of individuals and accommodates ambulatory and non-ambulatory populations. Objective and quantitative data are available on computerized printouts depicted as graphs, numerical charts, and actual picture representations of the assessment with tracing of the COG movement. Immediate results can be obtained to monitor static steadiness, symmetry, and dynamic stability. Visual feedback is given during retraining with the COG represented as a cursor and movements of the COG depicted as yellow lines indicating linear displacement.

Although there has been a wide acceptance in using the NBM\textsuperscript{®} in the last several years, only recently have reliability and validity issues been addressed. Liston and colleagues\textsuperscript{24} concluded that measurements of dynamic stability in
subjects with hemiplegia were more reliable and valid than those for static steadiness and symmetry. Speculation must be used when interpreting data from this study, in particular, because a generalization cannot be made from one medical diagnosis to another. Therefore, further research is needed to produce normative data to establish reliability and validity values for different populations using the NBM®.

Hamman et al. concluded that a high "learning curve" exists when using the NBM® because significant changes were seen in normal, healthy subjects over repeated retraining sessions. This learning effect was found to increase during the first few training sessions before gradually reaching a plateau. This indicates that a "learning curve" developed within a specific time period. This means that once a threshold has been reached, the body must use higher cortical processing to achieve greater levels of learning. Due to the small sample size in the study by Hamman et al., further research is needed to establish normative data for "learning curves" in neurological populations.

Because MS is a complex disease with a multitude of secondary complications associated with the degree of CNS involvement, difficulty arises in comparing MS subjects to norms of different populations.

Procedure

An introduction to the force platform system for each subject included a general description of the apparatus, how performance is measured, balance strategies utilized to maintain balance, subject expectations, and a warm-up session. Subject data consisting of an identification number, date of birth, and
height were entered into each subject file. Before the initial balance assessment began, each subject was instructed in proper foot placement on the forceplates.

Proper foot placement on the force platform system consisted of aligning the lateral border of each foot parallel to a transverse line and alignment of the medial malleolus perpendicular to this. The feet were symmetrical on the force platform with the exception of allowing the subject to splay the forefoot to a comfortable position. This same foot placement was utilized during the testing procedures and retraining exercises which required subjects to be in an erect, standing position. Subjects were instructed to wear the same shoes worn during the initial and final balance assessments and during balance retraining.

Prior to testing, each subject performed a warm-up on the NBM® which consisted of weight shifting to 25%, 50%, 75%, and 100% LOS. The subject's COG was represented as a cursor located in the center of the screen. Each subject was instructed to lean forward, backward, and side to side; to keep the knees straight; and to pivot around the ankle joints to maximize the ankle strategy. Subjects were placed in level one, two, or three depending on the LOS excursion achieved. The warm-up was also used to orient the subject to the apparatus and to assist the subject in gaining cursor control. Once subjects became comfortable with the force platform system, the balance assessment began.

Assessment

An initial balance assessment was performed three days prior to week one of the study, and a final assessment was performed one day after week four.
Due to the high learning curve associated with the NBM®, a warm-up and two initial and final assessments were completed; however, only the data from the second assessment were used for data analysis.

Adequate rest periods were given between assessments as well as during testing or retraining when needed. Specific instructions describing each test were given, per NBM® manual, to all subjects prior to each assessment test. In this manner, the following balance tests were performed by each group during the initial and final balance assessments: bilateral stance, rhythmic weight shifting, limits of stability, walk, sit to stand, weight bearing symmetry, and step up/over.

After completion of the initial assessments, the control group (n = 5) was scheduled for a final assessment to be performed four weeks from that date. After data from the initial assessment were analyzed, subjects from the control group received a written explanation via mail, while the subjects from the treatment group received a verbal explanation at their next scheduled retraining session regarding their balance performance on the NBM®.

Definitions of the parameters for each assessment test are provided in the glossary. Refer to the glossary in Appendix F. Please refer to the NBM® Operator’s Manual for more detailed information.30

**Static Steadiness Test #1**

The bilateral stance test involved static standing in a predetermined area on the force plates for measurement of mean **COG sway velocity** with eyes
open or eyes closed. A firm surface was utilized for subjects whose LOS was less than 50%, while a foam surface was used for subjects exceeding 50% of their LOS. Standing body sway was recorded for 10 seconds, times three trials. The measured parameter for this test was mean COG sway velocity.

**Symmetry Test #1**

The weight bearing/squat test measured weight distribution between the right and left lower extremities at 0° and 30° of knee flexion. Subjects were required to assume a static position on the specified platform area and the force was recorded. A goniometer was used to accurately measure knee flexion during the squat. The recorded data consisted of percentages that represented the weight borne on each leg to show symmetry of the lower extremities for two trials, one at 0° and one at 30°.

**Dynamic Stability Test #1**

The LOS test involved eight targets arranged in a circular fashion around a central starting box. Depending on the subjects' LOS in the warm-up, the circular arrangement was adjusted to 50% or 75% of the measured limits. Each subject's COG was represented as a cursor positioned in the middle of the computer screen. Subjects were instructed to lean into the direction of the highlighted target as quickly as possible and briefly maintain a static cursor position on the target before returning to midline. Each subsequent target was highlighted in a circular fashion until all eight targets were reached. Parameters
measured for this test were: **reaction time, sway velocity, directional control, endpoint excursion**, and **maximum excursion**.

**Dynamic Test #2**

The rhythmic weight shifting test consisted of two tests: weight shift forward/backward and left/right. Two end-lines represented the distance each subject had to move during the weight shifting test. The subject was required to follow a small moving box which automatically moved between the two end-lines. Auditory and visual feedback was provided by the NBM® to assist the subject in moving the cursor between the points at a three-second transition rate for six excursions. Measured parameters included intentional or **on-axis sway velocity** and **directional control**.

**Dynamic Test #3**

The walk test measured several aspects of gait as the subject ambulated from one end of the forceplate to the other as quickly as possible. When the monitor displayed the word "GO," the subject walked to the end of the forceplate and held steady. This test is performed three times. Measured parameters were **step width, step length, speed**, and **endpoint sway velocity**.

**Dynamic Test #4**

The sit-to-stand test quantified several components of movement as the subject transferred from a seated position on a 20-inch wooden box to a standing position. When the word "GO" appeared on the computer screen, the subject rose as quickly as possible from a seated position without use of the
upper extremities and held steady for 20 seconds. This test was performed three times. Measured parameters were weight transfer time, rising index, COG sway velocity, and right/left weight symmetry.

Dynamic Test #5

The step up/over test required the subject to step up onto a four- or eight-inch high curb (depending on each subject's performance during prior tests) with one leg, to swing the other foot over the curb and onto the floor, and step down with the curb foot. When the word "GO" appeared on the screen, the subject stepped up and over the box as quickly as possible and held steady for five seconds. The measured parameters were lift-up index, movement time, and impact index. The test consisted of six trials, three leading with the left foot and three leading with the right foot.

Training

The treatment group (n = 5) was seen three times per week for four weeks for balance retraining exercises. Subjects in both groups were instructed to maintain their daily activities and to avoid participating in any new extracurricular activities (in addition to this study), as this could skew research findings. All subjects were instructed to report any exacerbation of symptoms during this four-week period.

The balance retraining program for each subject in the treatment group was individualized according to performance and subject progression. Balance retraining exercises included seated circles on a firm 20-inch wooden box,
progressing to a 16-inch firm wooden box with a 6-inch foam cushion, and finally progressing to a medium-sized therapeutic ball. The progression of closed chain exercises consisted of forward/backward, left/right, and figure-of-8 pattern weight shifting with progression from a firm to foam surface and finally a tilt board. Mobility training involved right step, left step, and alternate stepping which was progressed by increasing the step length and decreasing the amount of time each subject was allowed during stepping. The progression of gait was from a wide base of support, to a medium base, to heel-toe tandem walking, as well as decreasing the time available to get from one end of the platform to the other. Stepping activities were progressed from step up, to step up/over, as well as step up/over and back, and increasing the height of the box from 4 inches to 8 inches to 16 inches. Progression to a more difficult level was guided by each subject's performance in the exercise retraining program.

All subjects in the treatment group completed the retraining sessions three days per week. Due to scheduling conflicts, two subjects needed to reschedule their appointments; however, all subjects completed three sessions per week with no absences.

Data Analysis

The data from the initial and final balance assessments for both the treatment and control groups were entered into the SPSS™ software system. With this program, the mean, standard deviation, standard error of the mean, the minimum and maximum scores, t-statistic, degrees of freedom, significance, mean difference, and standard error difference were calculated. These
parameters were used to detect significant changes in components of static steadiness, symmetry, and dynamic stability between groups from the initial to the final balance assessments on the NBM®.

Reporting Results

Upon completion of this study, a summary regarding the results will be completed and sent to each subject and to Altru Health Care Systems. A copy of this independent study will be given to the neurologist involved in this research project, the preceptor, and the University of North Dakota. This study was completed to fulfill the requirements for the University of North Dakota School of Medicine and Health Sciences Physical Therapy Program.
CHAPTER III

RESULTS

An independent measures t-test was used to determine if there were significant changes found between groups in measures of static steadiness, symmetry, and dynamic stability. Two of the 43 components of balance showed significant changes between groups.

Subject Profile

Ten subjects (6 females, 4 males) participated in this study. No subjects were excluded and all data were used. Five subjects (4 females, 1 male) with an age range of 47 to 58 and a mean age of 52.4 years participated in the control group. All testing for this study involved balance assessments on the NBM®. Subjects in the control group were seen twice over a four-week period, once for an initial balance assessment at week one and once for a final balance assessment at week four. Five subjects (2 females, 3 males) with an age range of 42 to 53 and a mean age of 49.4 years participated in the treatment group. Subjects in the treatment group were seen by the researchers for an initial balance assessment at week one, balance retraining three times per week for four weeks, and a final balance assessment after week four.
Data Analysis

The independent variables (IV) in this study consisted of the treatment and the control groups. The dependent variables (DV) were changes between the initial and final balance assessments measured as “gain/loss” scores. The “gain/loss” score was defined as the mean change in performance between the initial and final balance assessments.

Initially, data were examined using analysis of co-variance (ANCOVA). Fifty of the 57 statistical tests did not meet the assumptions underlying the ANCOVA; therefore, all analyses utilized the independent measures t-test. This test was used to determine if there was a significant difference in static steadiness, symmetry, and dynamic stability between the treatment and control groups. Statistical analysis was two-tailed and the level of significance was set at (p < 0.05) for all tests.

**Static steadiness: Is there a significant difference in measures of static steadiness between the control and treatment groups?** Static steadiness was analyzed via five measures as listed in Table 2. Assumptions of the t-test were met in one of the five components. No significant difference was found between the treatment and control groups for any measure of static steadiness.

**Symmetry: Is there a significant difference in measures of symmetry between the control and treatment groups?** Symmetry was analyzed via eleven measures as listed in Table 3. Assumptions of the t-test were met in all
Table 2.—Components of the Tests for Static Steadiness

<table>
<thead>
<tr>
<th>Component</th>
<th>t</th>
<th>df</th>
<th>Significance (2-tailed)</th>
<th>Mean Difference</th>
<th>Standard Error Difference</th>
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<tbody>
<tr>
<td>COG Sway Velocity*</td>
<td>-.572</td>
<td>8</td>
<td>.583</td>
<td>-.4400</td>
<td>.7692</td>
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<td>End Sway*</td>
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<td>.889</td>
<td>.1200</td>
<td>.8362</td>
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<td>.1371</td>
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<td>Mean Center of Gravity Sway Velocity* (eyes open)</td>
<td>1.723</td>
<td>8</td>
<td>.123</td>
<td>.1400</td>
<td>8.124E-02</td>
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<tr>
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<td>.587</td>
<td>4.000E-02</td>
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* Indicates data were not normally distributed.
Table 3.—Components of the Tests for Symmetry

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<th>df</th>
<th>Significance (2-tailed)</th>
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<th>Standard Error Difference</th>
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<td>.307</td>
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<td>.072</td>
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<tr>
<td>Left/Right Weight Symmetry</td>
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<td>8</td>
<td>.084</td>
<td>4.4000</td>
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</tr>
<tr>
<td>Rising Index</td>
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<td>.840</td>
<td>.2000</td>
<td>.9592</td>
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<td>7.2000</td>
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<td>.570</td>
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<td>Weight Bearing (left) (60°)</td>
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<td>.279</td>
<td>-9.2500</td>
<td>7.7822</td>
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<tr>
<td>Weight Bearing (right) (0°)</td>
<td>-1.373</td>
<td>8</td>
<td>.207</td>
<td>-7.2000</td>
<td>5.2440</td>
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<tr>
<td>Weight Bearing (right) (30°)</td>
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<td>8</td>
<td>.570</td>
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<td>Weight Bearing (right) (60°)</td>
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<td>6</td>
<td>.279</td>
<td>9.2500</td>
<td>7.7822</td>
</tr>
</tbody>
</table>

* Indicates data were not normally distributed.
cases. No significant difference was found between the treatment and control groups for any measure of symmetry.

**Dynamic stability:** Is there a significant difference in measures of dynamic stability between the control and treatment groups? Dynamic stability was analyzed via 37 measures as listed in Table 4. The assumption for normal distribution of the independent variable was not met for 6 of the 37 components, and the results were analyzed only with descriptive measures. Thirty-one components met the assumptions of the independent measures t-test. A significant difference, \( t(8) = .042, p < .05 \), two-tailed was found between groups for the component of **endpoint excursion forward**. A significant difference, \( t(8) = .029, p < .05 \), two-tailed was also noted for the component of **maximum excursion endpoint forward**. **Endpoint excursion forward** was greatest for the treatment group, with a mean of 11.4% LOS. The mean for the control group was \(-5.6\%\) LOS which resulted in a mean difference of \(5.8\%\) LOS between the groups. **Maximum excursion endpoint forward** was also greatest for the treatment group with a mean of 4% LOS. The mean for the control group mean was \(-9.4\%\) LOS which resulted in a mean difference of \(-5.4\%\) LOS between groups.
Table 4.—Components of the Tests for Dynamic Stability

<table>
<thead>
<tr>
<th>Component</th>
<th>t</th>
<th>df</th>
<th>Significance (2-tailed)</th>
<th>Mean Difference</th>
<th>Standard Error Difference</th>
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<tbody>
<tr>
<td>Directional Control (composite)*</td>
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<td>.303</td>
<td>6.600</td>
<td>5.9983</td>
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<td>Directional Control (forward/backward)</td>
<td>.294</td>
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<td>.777</td>
<td>4.000</td>
<td>13.6242</td>
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<td>Directional Control (left/right)</td>
<td>1.979</td>
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<td>.083</td>
<td>9.400</td>
<td>4.7497</td>
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<tr>
<td>Directional Control (back)*</td>
<td>.696</td>
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<td>.506</td>
<td>9.200</td>
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<td>Directional Control (composite)</td>
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<td>.755</td>
<td>1.600</td>
<td>4.9598</td>
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<td>.176</td>
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<td>Directional Control (right)</td>
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<td>Endpoint Excursion (back)</td>
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<td>Movement Velocity (composite)</td>
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Table 4.—Components of the Tests for Dynamic Stability (Cont.)

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<th>Significance (2-tailed)</th>
<th>Mean Difference</th>
<th>Standard Error Difference</th>
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<td>-1.557</td>
<td>8</td>
<td>.158</td>
<td>-.8000</td>
<td>.5138</td>
</tr>
<tr>
<td>Movement Velocity (difference)</td>
<td>.427</td>
<td>8</td>
<td>.680</td>
<td>.3400</td>
<td>.7954</td>
</tr>
<tr>
<td>Movement Time (difference)</td>
<td>.525</td>
<td>8</td>
<td>.614</td>
<td>2.6000</td>
<td>4.9497</td>
</tr>
<tr>
<td>Movement Time (left leg)</td>
<td>1.062</td>
<td>8</td>
<td>.319</td>
<td>.1240</td>
<td>.1168</td>
</tr>
<tr>
<td>Movement Time (right leg)</td>
<td>-.151</td>
<td>8</td>
<td>.884</td>
<td>-3.80E-02</td>
<td>.2519</td>
</tr>
<tr>
<td>Maximum Excursion (back)</td>
<td>.044</td>
<td>8</td>
<td>.966</td>
<td>.6000</td>
<td>13.5314</td>
</tr>
<tr>
<td>Maximum Excursion (composite)</td>
<td>-.744</td>
<td>5.644</td>
<td>.487</td>
<td>-2.4000</td>
<td>3.2249</td>
</tr>
<tr>
<td>Maximum Excursion (forward)*</td>
<td>-2.645</td>
<td>8</td>
<td>.029</td>
<td>-13.4000</td>
<td>5.0656</td>
</tr>
<tr>
<td>Maximum Excursion (left)*</td>
<td>.028</td>
<td>8</td>
<td>.978</td>
<td>.2000</td>
<td>7.1764</td>
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<tr>
<td>Maximum Excursion (right)</td>
<td>.346</td>
<td>8</td>
<td>.738</td>
<td>2.4000</td>
<td>6.9397</td>
</tr>
<tr>
<td>On-axis Velocity (composite)</td>
<td>-.266</td>
<td>8</td>
<td>.797</td>
<td>-1.200</td>
<td>.4508</td>
</tr>
<tr>
<td>On-axis Velocity (forward/backward)</td>
<td>-.727</td>
<td>8</td>
<td>.488</td>
<td>-3.4000</td>
<td>.4680</td>
</tr>
<tr>
<td>On-axis Velocity (left/right)*</td>
<td>.303</td>
<td>8</td>
<td>.770</td>
<td>.1600</td>
<td>.5278</td>
</tr>
<tr>
<td>Reaction Time (backward)</td>
<td>-.191</td>
<td>8</td>
<td>.853</td>
<td>-5.00e-02</td>
<td>.2611</td>
</tr>
<tr>
<td>Reaction Time (composite)</td>
<td>1.284</td>
<td>8</td>
<td>.235</td>
<td>.1120</td>
<td>8.726E-02</td>
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<tr>
<td>Reaction Time (forward)</td>
<td>.174</td>
<td>8</td>
<td>.866</td>
<td>3.80E-02</td>
<td>.2185</td>
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</tbody>
</table>
Table 4.—Components of the Tests for Dynamic Stability (Cont.)

<table>
<thead>
<tr>
<th>Component</th>
<th>t</th>
<th>df</th>
<th>Significance (2-tailed)</th>
<th>Mean Difference</th>
<th>Standard Error Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reaction Time (left)</td>
<td>1.339</td>
<td>8</td>
<td>.217</td>
<td>.2240</td>
<td>.1673</td>
</tr>
<tr>
<td>Reaction Time (right)</td>
<td>.840</td>
<td>8</td>
<td>.425</td>
<td>.2300</td>
<td>.2738</td>
</tr>
<tr>
<td>Speed</td>
<td>-.304</td>
<td>8</td>
<td>.769</td>
<td>-1.6600</td>
<td>5.4655</td>
</tr>
<tr>
<td>Step Width</td>
<td>.356</td>
<td>8</td>
<td>.731</td>
<td>.3400</td>
<td>.9555</td>
</tr>
<tr>
<td>Step Length</td>
<td>-.305</td>
<td>8</td>
<td>.768</td>
<td>-.9000</td>
<td>2.9492</td>
</tr>
<tr>
<td>Weight Transfer</td>
<td>.129</td>
<td>8</td>
<td>.900</td>
<td>2.80E-02</td>
<td>.2169</td>
</tr>
</tbody>
</table>

* Indicates data were not normally distributed.
+ Indicates data were significant.
CHAPTER IV
DISCUSSION

This chapter will discuss the findings of this research study in relation to previous research of balance retraining of CVA patients with hemiplegia. Limitations and clinical implications of this study will be addressed with suggestions for future research being made.

Results

Independent samples t-statistic values indicated that there was no significant difference between the control and the treatment groups on measures of static steadiness or symmetry. Significant differences were found between groups on 2 of the 31 components of dynamic stability tests. These two components—end-point excursion forward and maximum excursion end-point forward—were measures of the limits of stability test. Since only 2 of the total 49 components of balance tests were significant, it was concluded that the results failed to support the alternate hypothesis which stated that there was a significant difference between the control and treatment groups on measures of static steadiness, symmetry, and dynamic stability. Even so, it is difficult to make conclusions regarding the results of the static steadiness tests, as only one component of the five met the criteria for a normal distribution.
Explanation

One possible explanation for these findings involves the chronic, progressive course of MS. For example, subjective improvements in balance noted throughout the course of training may not have been demonstrated objectively during the final assessment secondary to a general decline in functional mobility. A second explanation is that balance retraining three times per week for four weeks in addition to regular functions of daily life was simply over-fatiguing the subjects. Several subjects throughout the course of balance retraining did indicate that fatigue was making it necessary for them to take more frequent rest periods during the day. This reported fatigue could negatively affect the subjects' performance during retraining as well as on the final balance assessment.

Another factor that could have skewed the balance performance results is the possibility of non-compliant behavior on the part of the control subjects. It is probable that one or more subjects in the control group did not follow instructions to maintain their present lifestyle. In fact, one subject, upon performance of the final balance assessment, admitted that she had been frequently "practicing" the balance activities performed in the initial assessment to see if she could "improve" on the final assessment. The next issue addresses the probability that the treatment subjects were those who had more severe balance impairments (either subjectively or objectively) and who chose to be in the treatment group because of these deficits. The control subjects may have viewed their balance difficulties as less severe and, therefore, chose to not participate in balance
retraining. This issue is supported by the fewer number of falls reported by the control subjects versus those reported by the treatment subjects. Subjects in the control group reported a mean of 16 falls per year; this compared to a mean of 25 falls per year reported by the treatment subjects. In this scenario, it is possible that, because of the differences in initial balance performance between groups, the treatment subjects did improve from initial to final balance assessments even if these improvements were not observed between groups.

The variable signs, symptoms, and severity of the MS disease among subjects could have influenced the results of this study. It was difficult, at best, to make judgments regarding balance performance as a group, when each subject varies significantly in many areas: strength, range of motion, flexibility, sensation, tone, endurance, balance strategies, overall functional mobility, visual deficits, reaction time, and use of assistive devices. The fact that there was no standard protocol used consistently throughout balance retraining was another factor that could have affected the results. In addition, the training subjects not only were trained at different levels according to the limits of stability (LOS) determined in the warm-up, but also performed various balance retraining exercises depending on the severity of their balance impairments.

Random selection of subjects and subsequent random placement of each subject into either the control or treatment group may have resulted in more statistically significant findings. The researchers' relative lack of experience using the NBM® as well as in evaluating and treating persons with MS could have
further skewed performance measures. Finally, using such a small sample size (five subjects in each group) could have affected results.

Previous Research

Currently, there is no research available regarding balance assessments and retraining for persons with MS utilizing a biofeedback force platform system, such as the NBM®. Therefore, the results of this study will be compared and contrasted with those from previous studies on balance retraining with hemiplegics using a biofeedback system. Previous studies have reported that hemiplegic subjects show more consistent improvement on measures of dynamic stability than other measures of balance when incorporating feedback from a platform system. A study by Nichols¹⁰ reported that dynamic stability and symmetry measures showed consistent improvement in the retraining of hemiplegic patients using biofeedback. A study by Sackley²⁷ also reported improvements in symmetry among hemiplegic patients.

The results of this study with MS subjects showed that no significant differences were found between the control and treatment groups in measures of symmetry. In regard to dynamic stability, this study showed that significant differences between groups were found for only 2 of the 31 components of dynamic stability tests. A study by Shumway-Cook and associates¹² indicated that hemiplegic subjects improved in measures of static stability when trained with a force platform balance system. Such improvements or differences between groups were not observed among the MS subjects of this study.
The results cited in this discussion were based on studies of the effects of balance retraining on cerebrovascular accident (CVA) patients with resulting hemiplegia. A CVA is not a progressive disease; rather, persons having suffered a CVA have the potential to regain some motor and sensory function as well as functional mobility. Individuals with MS typically experience a progressive course and may not regain functional losses. Therefore, any comparisons between the studies with hemiplegics and this study with MS subjects must be made with caution.

Limitations of Study

A major limitation of this study is the small sample size utilized for both the treatment and control groups. For the results of this study to be statistically significant, a larger group of subjects would need to be utilized. A second limitation is the diversity of subjects in regard to their MS diagnoses—type, signs and symptoms, severity, exacerbations/remissions, level of function, and balance deficits. It is difficult to establish a normative sample when the subjects differ so greatly.

The researchers should be proficient and well-practiced in the use of this biofeedback force platform system. Prior to administering the initial balance assessments and retraining on the NBM®, the researchers involved in this study each conducted balance assessments on the same three subjects. The results of these assessments were compared to those of the other two researchers. It was also required that the researchers perform a variety of the balance retraining protocols to gain experience as well as to establish a general protocol for the MS
subjects to follow. This brief training period did allow the researchers to become more comfortable with the NBM®, however, the researchers were completely inexperienced in the assessment and retraining of balance in the MS population.

The fact that the subjects were not selected in a random fashion and were not assigned to groups randomly is yet another shortcoming of this study. For the results to be truly significant, selection would have been performed in a random fashion with subsequent random assignment to the treatment or control group. Another limitation was the limited time frame (four weeks) in which to carry out retraining sessions and final assessments. Perhaps with a lengthened training period (six to eight weeks), statistically significant findings would have been observed with this study. A final limitation was inadequate monitoring of the control subjects’ compliance to maintain their present lifestyle and avoid any changes in physical activity. It is possible that the researchers were not clear in regard to these instructions provided during the initial assessment. Regardless, strict monitoring of control subjects is difficult, at best, especially throughout a four-week time period and in an outpatient type of setting.

Clinical Implications

Balance is an integral part of a physical assessment for a multitude of patient diagnoses, including MS. Therefore, the significance of this study involved the utilization of a biofeedback force platform system to assess and retrain postural stability for persons with MS in an objective manner. When individuals with MS demonstrate improvements in balance, they are able to function more independently and, as a result, gain control over one of the most
debilitating effects of the MS disease process. Improvements in balance and functional mobility also improve the person's emotional and social well-being. Because of the limitations of this study, the results were not as anticipated. Therefore, this study may be used as a basis for future research incorporating a larger sample size and/or a greater period of time for balance retraining.

Future Research

Future research should attempt to eliminate the limitations of this study. Sample size should include more subjects for the data to yield truly statistically significant results. The subjects should be selected in a random fashion and assigned to groups accordingly. The researchers should be experienced in assessment and retraining procedures utilizing the NBM®. It may be of interest to utilize a longer period of balance retraining for MS subjects in the treatment group. Studies could be done to determine the effectiveness of balance retraining using the NBM® for the treatment group versus a home exercise program of conventional balance exercises for a second treatment group in comparison to the control group of MS subjects. Researchers could compare balance performance of persons with MS to the normative data as well as to establish reliability and validity issues in terms of assessing balance in MS patients. Studies could compare the NBM®, Tinetti Gait and Balance Assessment, and Berg balance tests in regard to reliability, validity, and efficiency of balance assessment in persons with MS.
Conclusion

As physical therapists, it is important to examine possible therapeutic treatment modalities that may prove successful in treating various diagnoses, including MS. Balance impairments are common in persons with MS and are often treated with medications or conventional balance exercises. Recently, biofeedback force platform systems—like the NBM®—have been utilized for balance retraining in persons having suffered cerebrovascular accidents with resulting hemiplegia as well as for a variety of other neurological and orthopaedic populations. Force platform studies with hemiplegics have shown varied results; however, for the most part, some improvements in postural stability have been observed.10,11,22

To date, no research has been conducted using a biofeedback force platform to assess or retrain balance in persons with MS. Our study investigated the effects of a balance retraining program with MS subjects utilizing the NBM® force platform system. Results showed that there were no significant differences between the control and treatment groups on measures of static stability and symmetry. Further, only 2 of the 31 components of the dynamic stability tests showed significant differences between groups. Both components were parameters of the limits of stability test and measured the distance at which the initial movement attempt stopped or reversed while moving and the farthest distance the subject reached while moving forward. This finding tends to support studies of hemiplegics which showed significant improvements in dynamic stability. However, the results of this study disagree with those of hemiplegic
studies that found significant improvements in symmetry and static steadiness. Again, one should use caution when making comparisons between studies of balance retraining for persons with hemiplegia and retraining for individuals with MS.
Human Subjects Review Form

For new projects or procedural revisions to approved projects involving human subjects.

Principal Investigator: Biana Zearley, Becky Coy, Jill Phone #: Biana, 775-1061 Date: 3/26/98
Institution: University of North Dakota Steinmetz Department: Physical Therapy
Research Coordinator: Meridee Green Phone #: 777-2831
Proposed Project Dates: 4/8/98
Project Title: The Effects of Balance Training Exercises on the NeuroCom Balance Master in Subjects with Multiple Sclerosis

Funding Agencies (if applicable):

Type of Project: ☐ New Project ☐ Continuation ☐ Renewal ☐ Student Research Project
☐ Dissertation or Thesis Research ☐ Completed Project
☐ Reports (Adverse events, deaths, complications)
☐ Amendments or change in project

Dissertation/Thesis Adviser, or Student Advisor: Meridee Green

Proposed Project: ☐ Involves New Drugs (IND) ☐ Involves Non-Approved Use of Drug ☐ Involves a Cooperating Institution
☐ None of the Above

If any of your subjects fall in any of the following classifications, please indicate the classification:
☐ Minors (< 18 Years) ☐ Pregnant Women ☐ Mentally Disabled ☐ Fetuses ☐ Mentally Retarded.
☐ Prisoners ☐ Students ☐ Abortuses ☐ Control Group

If your project involves any human tissue, body fluids, pathological specimens, donated organs, fetal material, or placental materials, check here ☒.

☒ Expedited Review requested under item 3, 8 (number) of HHS Regulations (see attached explanation)

☐ Exempt Review requested under item (number) of HHS Regulations (see attached explanation)

1. ABSTRACT (Limit to 200 words or less and include justification or necessity for using human subjects. Attach additional sheet if necessary.)

Multiple Sclerosis (MS) is the most common demyelinating disease of the central nervous system and has been referred to as "the great crippler of young adults." The disease commonly affects individuals between the ages of 20-45 and is more prevalent in the geographical areas that are farthest from the equator. Hence, the state of North Dakota lies within the "MS belt" and the occurrence of the disease becomes very prevalent in this area. The symptoms and exacerbations vary greatly among individuals; in addition, the same individual may experience varying signs and symptoms throughout the disease process. According to Shephard et al, who conducted a study on balance disorders in MS patients, balance difficulties tend to be a common problem among MS patients. These difficulties in balance can have severe consequences on an individual's physical and psychosocial well-being. Presently, there is no cure for MS, nor is there a treatment to completely eliminate balance difficulties. However, many patients with MS undergo inpatient therapy, are on a home exercise program, or use an assistive device for their balance difficulties. The purpose of this study is to determine if balance exercises performed on the NeuroCom Balance Master are effective in improving balance for individuals with MS.
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 including data collection instruments where applicable.

2. PROTOCOL: (Describe procedures to which humans will be subjected.)

Background and Objectives

Balance difficulties are a common manifestation of multiple sclerosis. These balance problems are an impairment that may result in a disability or a handicap for the patient. Patients with MS may receive physical therapy, may perform a home exercise program, or may use an assistive device for their balance difficulties. The objective of this study is to determine if an exercise program performed on the NeuroCom Balance Master can improve balance over a four-week period.

Subjects

Ten subjects will be used in this study. Five will be involved in the control group and five will comprise the treatment group. All subjects involved in this study will have MS and will be receiving care under Dr. Teetzen, a neurologist at the Altru Hospital. Patients who are ambulatory, otherwise healthy, and have physician approval will be asked to participate. More specifically, only those patients who are in the 3.0-6.0 category based on the Kurtzke Scale of Multiple Sclerosis Classification will be asked to participate in this study (see attachment). Each subject will be informed of the time-frame, procedure, benefits, and risk factors associated with this study. In addition, all subjects will sign a statement of informed consent.

Instrumentation

The NeuroCom Balance Master has been shown to be a reliable and valid tool in assessing balance impairments and in balance retraining in individuals suffering from cerebrovascular accidents, traumatic brain injuries, orthopaedic disorders, or Parkinson's Disease. There is limited research which utilizes the NeuroCom Balance Master for balance assessment and training in individuals with MS. Therefore, this research project will contribute to expanding research in improving balance in the MS population. Inter-reliability and intra-reliability of the researchers was determined prior to starting the research project by testing three individuals with no experience using the NeuroCom Balance Master. Each individual was instructed and tested in four assessment exercises by the three members of the research team. Due to the high learning curve associated with the NeuroCom Balance Master, each subject was given one practice trial of the assessment to become familiar with the machine, and the data associated with that assessment was disregarded. Each subject was re-tested two days later to establish intra-reliability. Good inter- and intra-reliability was proven by comparing results between each tester and comparing results from retesting. Validity of the NeuroCom Balance Master has been established by the ability to obtain objective, quantifiable measurements from a computerized printout of each assessment. Information in the printout includes diagrams depicting multi-directional movements, deviations in static positions, and tables and bar graphs organizing the data results.

Procedure

This study will consist of two groups of subjects, a control group and a treatment group. All subjects will be given a general evaluation conducted by a member of the research team and will include testing of general lower limb strength, flexibility, sensation, and reflexes. Due to a high learning curve, all subjects will be asked to perform a "trial" initial assessment on the NeuroCom Balance Master. The data obtained in the "trial test" will be disregarded and will be followed by a second initial assessment that will be recorded. The data will be used to determine each patient's current balance difficulties and will be used as a comparison tool to data obtained in the final assessment.
PROCEDURE: (Cont.)

The control group will only be seen twice, initially to be given a general evaluation by a member of the research team and to perform a "trial" and initial assessment, and finally to perform the same assessment after a four-week period. The treatment group will also be given the same general evaluation, "trial," and initial assessment, but this group will be involved in an exercise protocol on the NeuroCom Balance Master three times per week for four weeks. The exercise protocol will be the same for each patient and will only differ in level of difficulty, according to the patient's current level of MS. At the end of the four-week period, the treatment group will also perform a final assessment. These data will be compared to the final assessment of the control group along with the initial assessment of the treatment group to determine if balance was improved with the exercise protocol performed on the NeuroCom Balance Master.

Subjects will be given adequate time to complete all that is asked of them during this study along with appropriate rest periods as determined by the subject. Participation in the general evaluation conducted by the researcher, the initial and final assessments along with the exercise protocol will be pain-free for the patient.

Statistical analysis of the data will consist of descriptive and analytical statistics. A related samples t-test or the most appropriate method of statistical analysis will be used. All data, questionnaires, and consent forms will be kept in a confidential file in Meridee Green's office at the Department of Physical Therapy, University of North Dakota and will be kept for a two-year period.
3. **BENEFITS:** (Describe the benefits to the individual or society.)

Due to the small sample size, this study may not show statistical significance; however, many benefits may still be observed. Upon completion of this study, the NeuroCom Balance Master will be a possible tool used to assist in recording accurate and reliable information for assessment and treating balance dysfunction in individuals with MS. Improvements in balance will increase their functional level and may promote psychological/social well-being. Findings can be used to develop a balance protocol for people with MS that may be used in the clinical setting and can help with support in cost-effective treatment for reimbursement from third party payers. This study can be a foundation for future research involving more subjects to establish normative data of balance parameters for individuals with MS using the NeurCom Balance Master. It will, therefore, contribute to the future for physical sciences and rehabilitation research.

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 insure the confidentiality of data obtained, including plans for final disposition or destruction, debriefing procedures, etc.)

The risks associated with this study are minimal, but those that do exist will be controlled. The physical risks include possible loss of balance during the assessment or training on the NeuroCom Balance Master. However, this risk of falling will be minimized by requiring subjects to wear a gait belt and having at least two members of the research team spotting during all testing and training procedures. In addition, verbal instructions will be given to subjects prior to balance assessment and subsequent training. Also, subjects will be given adequate rest periods to minimize fatigue.

Risks to the subjects' dignity and self-respect will be accounted for and controlled by the research team by 1) scheduling individual testing sessions to promote privacy, 2) giving subjects complete instructions regarding their role in the research project, 3) providing the subjects with a safe and controlled environment in which to work, 4) informing the subjects that all information pertaining to history, performance, and functional outcomes will be disclosed with a number and no names will be used. Finally, the subjects will be notified that they may withdraw from the study at any time should an exacerbation of symptoms or any other problems arise.
5. **CONSENT FORM**: 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 who will be obtaining consent, where signed consent forms will be kept, and for what period of time.

All consent forms, questionnaires, and data reports will be kept in the Physical Therapy Office, Room 1518 of the UND School of Medicine and Health Sciences. Data and information obtained from the study will be kept in Room 1518 for two years following the completion of this study. Please see attached consent form.

6. For FULL IRB REVIEW, forward the signed original of this completed form and, copies as outlined in the attached instructions to:

For EXEMPT or EXPEDITED REVIEW forward a signed original and a copy of the consent form, questionnaires, etc., and any supporting documentation to:

Eleanor Tveit, IRB Secretary
1000 South Columbia Road
Grand Forks, ND 58201
701-780-6161

The policies and procedures on Use of Human Subjects in Medical Park Institutions apply to all activities involving use of Human Subjects performed by personnel conducting such activities. No activities are to be initiated without prior review and approval of the Medical Park Institutional Review Board.

Signatures: [Signature]
Date: 3-26-98

Principal Investigator: [Signature]
Date: 3-26-98

Project Director: [Signature]
Date: 3-26-98

Student Advisor (where applicable): [Signature]
Date: 3-26-98
APPENDIX B
<table>
<thead>
<tr>
<th>EDSS Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>No disability; minimal signs in one FS (i.e., grade 1).</td>
</tr>
<tr>
<td>1.5</td>
<td>No disability; minimal signs in more than one FS (more than one FS grade 1).</td>
</tr>
<tr>
<td>2.0</td>
<td>Minimal disability in one FS (one FS grade 2, others 0 to 1).</td>
</tr>
<tr>
<td>2.5</td>
<td>Minimal disability in two FS (two FS grade 2, others 0 to 1).</td>
</tr>
<tr>
<td>3.0</td>
<td>Moderate disability in one FS (one FS grade 3, others 0 or 1) or mild disability in three or four FS (three or four FS grade 2, others 0 or 1); through fully ambulatory.</td>
</tr>
<tr>
<td>5.0</td>
<td>Fully ambulatory but with moderate disability in one FS (one grade 3) and one or two FS grade 2; or two FS grade 3; or five FS grade 2 (others 0 or 1).</td>
</tr>
<tr>
<td>6.0</td>
<td>Fully ambulatory without aid, self-sufficient, able to walk about 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1); or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 300 meters.</td>
</tr>
<tr>
<td>7.0</td>
<td>Fully ambulatory without aid, up and about much of the day, able to work a full day, may otherwise have some limitation if full activity require minimal assistance; characterized by relatively severe disability usually consisting of one FS grade 4 (others 0 or 1); or combinations of lesser grades usually exceeding those for step 4.0.</td>
</tr>
<tr>
<td>8.0</td>
<td>Ambulatory without aid or rest for about 200 meters; disability severe enough to impair full daily activities (e.g., to work a full day without special provisions); (usual FS equivalents are one grade 5 alone, others 0 or 1; or combination of lesser grades usually exceeding those for step 4.0).</td>
</tr>
<tr>
<td>9.0</td>
<td>Ambulatory without aid or rest for about 100 meters; disability severe enough to preclude full daily activities; (usual FS equivalents are one grade 5 alone, others 0 or 1; or combination of lesser grades usually exceeding those for step 4.0).</td>
</tr>
<tr>
<td>10.0</td>
<td>间歇性或永久性不一致的步态（手杖、拐杖、助行器）要求在没有休息的情况下行走100米；（常见FS等同体包括组合更多的两个FS等级3+）。</td>
</tr>
<tr>
<td>11.0</td>
<td>持续性或永久性不一致的步态（手杖、拐杖、助行器）要求在没有休息的情况下行走20米；（常见FS等同体包括组合更多的两个FS等级3+）。</td>
</tr>
<tr>
<td>12.0</td>
<td>不可能行走超过大约五米，甚至在有辅助的情况下，完全地限制在轮椅上；轮椅的自我或标准的轮椅和转移者单独；上和在轮椅上。</td>
</tr>
</tbody>
</table>

7.5 - Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self or is not able to get on a standard wheelchair a full day; May require motorized wheelchair; (Usual FS equivalents are combinations with more than one FS grade 4+. Very rarely pyramidal grade 3 alone). |

8.0 - Essentially restricted to bed or chair or ambulated in wheelchair, but may be out of bed itself much of the day; retains many self-care functions; generally has effective use of arms; (usual FS equivalents are combinations generally 4+ in several systems). |

8.5 - Essentially restricted to bed much of the day; has some effective use of arms; (usual FS equivalents are combinations generally 4+ in several systems). |

9.0 - Helpless bed patient; can communicate and eat; (usual FS equivalents are combinations, mostly grade 4+). |

9.5 - Totally helpless bed patient; unable to communicate effectively or swallow; (usual FS equivalents are combinations, almost all grade 4+). |

10.0 - Death due to MS |

Assessment Index

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal gait</td>
</tr>
<tr>
<td>1</td>
<td>Walks normally but reports fatigue which interferes with demanding activities.</td>
</tr>
<tr>
<td>2</td>
<td>Abnormal gait or episodic imbalance; gait disorder is noticeable to family; able to walk 25 feet in 10 seconds or less.</td>
</tr>
<tr>
<td>3</td>
<td>Walks independently; able to walk 25 feet in 20 seconds or less.</td>
</tr>
<tr>
<td>4</td>
<td>Requires unilateral support (e.g., cane, single crutch) to walk; uses support more than 80% of the time. Walks 25 feet in 20 seconds or less.</td>
</tr>
<tr>
<td>5</td>
<td>Requires bilateral support (e.g., crutches, walker) and walks 25 feet in 20 seconds or less; or, requires unilateral support but walks 25 feet in greater than 20 seconds.</td>
</tr>
<tr>
<td>6</td>
<td>Requires bilateral support and walks 25 feet in greater than 20 seconds. May use wheelchair on occasion.</td>
</tr>
<tr>
<td>7</td>
<td>Walking limited to several steps with bilateral support; unable to walk 25 feet. May use wheelchair for most activities.</td>
</tr>
<tr>
<td>8</td>
<td>Restricted to wheelchair; able to transfer independently.</td>
</tr>
<tr>
<td>9</td>
<td>Restricted to wheelchair; unable to transfer independently.</td>
</tr>
</tbody>
</table>

("The use of a wheelchair may be determined by a patient’s lifestyle and motivation.

Physician Signature: ___________________________

Date: ___________________________

Neurological Assessment

Kurtzke Functional Systems- EDSS

Altru Health System
1. **Pyramidal Functions**
   - 0 = Normal
   - 1 = Abnormal signs without disability
   - 2 = Minimal disability
   - 3 = Mild to moderate paraparesis or hemiparesis; severe monoparesis
   - 4 = Marked paraparesis or hemiparesis, moderate quadriparesis; or monoplegia
   - 5 = Paraplegia, hemiplegia or marked quadriparesis
   - 6 = Quadriplegia
   - 9 = Unknown

2. **Cerebellar Functions**
   - 0 = Normal
   - 1 = Abnormal signs without disability
   - 2 = Mild ataxia
   - 3 = Moderate truncal or limb ataxia
   - 4 = Severe ataxia in all limbs
   - 5 = Unable to perform coordinated movements due to ataxia
   - 7 = When weakness (grade 3 or worse on pyramidal) interferes with testing
   - 9 = Unknown

3. **Brainstem Functions**
   - 0 = Normal
   - 1 = Signs only
   - 2 = Other cranial weakness
   - 3 = Moderate nystagmus, marked extraocular weakness, or moderate disfunction of other cranial nerves
   - 4 = Marked dysarthria or other marked disability
   - 5 = Inability to swallow or speak
   - 9 = Unknown

4. **Sensory Functions**
   - 0 = Normal
   - 1 = Vibration or figure-writing decrease only in one or two limbs
   - 2 = Mild decrease in touch or pain or position sense, and/or moderate decrease in vibration in one or two limbs; or vibratory (c/s figure writing) decrease alone in three or four limbs
   - 3 = Moderate decrease in touch or pain or position sense, and/or essentially lost vibration in one or two limbs; or mild decrease in touch or pain and/or moderate decrease in all proprioceptive tests in three or four limbs
   - 4 = Marked decrease in touch or pain or loss of proprioception alone or combined, in one or two limbs; or moderate decrease in touch or pain and/or severe proprioceptive decrease in more than two limbs
   - 5 = Loss (essentially) of sensation in one or two limbs; or moderate decrease in touch or pain and/or loss of proprioception for most of the body below the head.
   - 6 = Sensation essentially lost below the head
   - 9 = Unknown

5. **Bowel and Bladder Functions**
   - 0 = Normal
   - 1 = Loss of bowel and bladder function
   - 2 = Loss of stool
   - 3 = Loss of stool
   - 4 = Loss of stool
   - 5 = Loss of stool
   - 6 = Loss of bowel and bladder function
   - 9 = Unknown

6. **Visual (or Optic) Functions**
   - 0 = Normal
   - 1 = Visual acuity better than 20/30
   - 2 = Worse with scotoma with maximal visual acuity (corrected) of 20/30 to 20/59
   - 3 = Worse with large scotoma, or moderate decrease in fields, but with maximal visual acuity (corrected) of 20/60 to 20/99
   - 4 = Worse with marked decrease of fields and maximal visual acuity (corrected) of 20/100 to 0 20/200; grade 3 plus maximal acuity of better of 20/60 or less
   - 5 = Worse with maximal visual acuity (corrected) less than 20/200; grade 4 plus maximal acuity better eye of 20/60 or less
   - 6 = Grade 5 plus maximal visual acuity of better of 20/60 or less
   - 7 = Presence of temporal pallor
   - 9 = Unknown

7. **Cerebral (or Mental) Functions**
   - 0 = Normal
   - 1 = Mood alteration only (does not affect DSS score)
   - 2 = Moderate decrease in mentation
   - 3 = Moderate decrease in mentation
   - 4 = Marked decrease in mentation (chronic brain syndrome - moderate)
   - 5 = Dementia or chronic brain syndrome - severely incompetent
   - 9 = Unknown

8. **Other Functions**
   - a. = Spasticity
     - 0 = None
     - 1 = Mild
     - 2 = Moderate - (minor interference)
     - 3 = Severe - (major interference)
     - 9 = Unknown
   - b. = Others
     - 0 = None
     - 1 = Any other neurological findings attribute MS: Specify
     - 9 = Unknown

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**Neurological Assessment**

**Kurtzke Functional Systems - EDSS**

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**Altru**

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7129-0037-M SEPT '97
INFORMATION AND CONSENT FORM #1

TITLE: The Effects of Balance Training Exercises on the NeuroCom Balance Master in Subjects with Multiple Sclerosis.

You are invited to participate in a study conducted by Becky Coy, Jill Steinmetz, and Biana Zearley, physical therapy students at the University of North Dakota. The purpose of this study is to determine if balance exercises performed on the NeuroCom Balance Master, a machine used to assess balance, are effective in improving balance for an individual with Multiple Sclerosis (MS). Only subjects with MS who are otherwise normal and healthy and have physician approval will be asked to participate.

You will be asked to report to the Physical Therapy Department at the Altru Health Institute Rehabilitation Hospital where a general assessment will be conducted by a member of the research team. We ask that you wear loose, comfortable clothing and tennis shoes when participating in this study. The assessment will include: general lower limb strength, flexibility, sensation, and reflex testing. We will be recording your name, height, and date of birth (all will be confidential). You will be asked to complete a questionnaire concerning balance difficulties, current exercise routine, activities of daily living, and whether or not you use an assistive device for ambulation. You will then be asked to participate in a “practice trial” assessment on the NeuroCom Balance Master which will take approximately 15 minutes. Following this, you will be asked to perform a series of tests on the machine (the actual assessment) and this will take approximately 30 minutes.

You will be asked to return to the Altru Health Institute Rehabilitation Hospital four weeks from the initial evaluation, it is at this time that a final evaluation will be conducted involving the same tests as before. We ask that you continue to assume your regular levels of exercise and activities of daily living during the four week period.

Dr. Teetzen will be overseeing this study and two members of the research team will be present at all times. Throughout the experiment, we will use the NeuroCom Balance Master as an assessment and training tool. This machine is commonly used in physical therapy clinics across the nation and is a clinically accepted measure of balance.

The results from the study will be confidential and your data will be identified by a number known only by the investigators. Whether or not you decide to participate in this study will not jeopardize your future relationship with the Physical Therapy Department or the University of North Dakota. If you decide to participate, you are free to discontinue participation at any time.

The investigators involved are available to answer any current or prospective questions you have concerning this study. Questions may be answered by calling Becky or Jill at (701) 746-9508 or Biana at (701) 775-1061. A copy of this consent form is available to all participants in the study.
In the event that this research activity (which will be conducted at the Altru Heath Institute Rehabilitation Hospital) results in a physical injury, medical treatment will be available, including first aid, emergency treatment and follow-up care as it is to members of the general public in similar circumstances. Payment for any such treatment must be provided by you and your third party payer, if any.

ALL OF MY QUESTIONS HAVE BEEN ANSWERED AND I AM ENCOURAGED TO ASK ANY QUESTIONS THAT I MAY HAVE CONCERNING THIS STUDY IN THE FUTURE. MY SIGNATURE INDICATES THAT, HAVING READ THE ABOVE INFORMATION, I HAVE DECIDED TO PARTICIPATE IN THE RESEARCH PROJECT.

I have read all of the above and willingly agree to participate in this study explained to me by Becky Coy, Jill Steinmetz, and Biana Zearley.

________________________________________
Participant's Signature                     Date

________________________________________
Witness (not the scientist)                 Date
TITLE: The Effects of Balance Training Exercises on the NeuroCom Balance Master in Subjects with Multiple Sclerosis.

You are invited to participate in a study conducted by Becky Coy, Jill Steinmetz, and Biana Zearley, physical therapy students at the University of North Dakota. The purpose of this study is to determine if balance exercises performed on the NeuroCom Balance Master, a machine used to assess balance, are effective in improving balance for an individual with Multiple Sclerosis (MS). Only subjects with MS who are otherwise normal and healthy and have physician approval will be asked to participate.

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Your participation in the study will involve an exercise program that will be conducted on the NeuroCom Balance Master three days a week for four weeks, each session lasting approximately 30 minutes. At the end of the four weeks, an initial evaluation will be conducted to determine the effects of the program on balance. We (the researchers) respect your time and realize this is a big commitment, however, we believe there will be significant improvements in balance and well worth your time and ours.

Dr. Teetzen will be overseeing this study and two members of the research team will be present at all times. Throughout the experiment, we will use the NeuroCom Balance Master as an assessment and training tool. This machine is commonly used in physical therapy clinics across the nation and is a clinically accepted measure of balance.

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I have read all of the above and willingly agree to participate in this study explained to me by Becky Coy, Jill Steinmetz, and Biana Zearley.

Participant's Signature Date

Witness (not the scientist) Date
APPENDIX D
1. Are your balance difficulties?
   - non-existent
   - mild
   - moderate
   - severe

2. How many times have you fallen? Did you sustain an injury, if so please describe it?
   - in last month?
   - in last year?
   - ever?

3. Have you had any previous hospitalizations or surgeries?

4. Do you have any health problems (beyond MS) we should be aware of?

5. Are you taking any medications?

6. How would you describe the sensation in your feet?

7. Do you have any difficulties with vision?

8. How many days/week do you exercise, what type of exercise do you perform (walking, riding bike, treadmill)?

9. What do you do during the day (work, stay home, etc.)?

10. Do you use an assistive device for ambulation, if so what?
MULTIPLE SCLEROSIS INITIAL EVALUATION

Subjects name:
Age:
Height:

MMT:
Sitting
Hip flexion
Knee extension
Knee flexion
Ankle DF

Supine
Hip abduction
Hip adduction

Prone
Hip extension

ROM
Supine
Hip flexion
Knee flexion

Sitting
Knee extension
Ankle DF
Ankle PF

Reflexes
Patella
Achilles

Sensation
Dermatomes
L1 inferior to inguinal ligament
L2 anterior thigh
L3 VMO
L4 dorsum of 1st metatarsal/medial side of foot
L5 dorsum of foot
S1 lateral foot
S2 heel
APPENDIX F
Glossary:

1. **COG sway velocity**: Ratio of the distance traveled by the COG around the center of foot support, expressed in degrees per second.

2. **Directional control**: Comparison of the amount of movement in the intended direction compared to the extraneous movement, expressed as a percentage.

3. **Endpoint excursion**: Distance traveled by the COG on the primary attempt to reach the target expressed in percent LOS. The endpoint is considered to be the point at which the initial movement ceases and corrective movement begins.

4. **End Sway**: The amount of sway occurring after changing from a dynamic to a static position.

5. **Impact index**: The average maximum force transmitted through the lagging leg as it lands on the surface, expressed a percentage of body weight.

6. **Impact index difference**: A comparison of the mean amount of force transmitted through the left and right legs, expressed as a percentage.

7. **Left/right weight symmetry**: The percentage of weight borne by each leg during static and dynamic activities.

8. **Lift-up index**: The average maximum force exerted by the step-up leg, expressed as a percentage of body weight.

9. **Lift-up index difference**: A comparison of the mean amount of force exerted by the left and right legs, expressed as a percentage.

10. **Maximum excursion**: Furthest distance traveled by the COG during the trial, expressed as a percentage.

11. **Mean rising index**: The average amount of force exerted by the legs during the rising phase, expressed as a percentage of body weight.

12. **Mean weight transfer**: The average amount of time between the onset of the cue to move and the arrival of the COG over the feet, expressed in seconds.
13. **Movement time**: The average amount of time to complete the step up/over task, expressed in seconds. Scoring begins with the initial COG shift with the non-stepping leg, and ends with the impact of that leg on the surface.

14. **Movement time difference**: A comparison of the mean movement times over the left and right legs, expressed as a percentage.

15. **Movement velocity**: Average speed of COG movement expressed in degrees per second.

16. **On-axis velocity**: The average COG movement speed in the intended direction, expressed in degrees per second.

17. **Reaction time**: Time in seconds between signal to move and initiation of movement.

18. **Speed**: The rate of ambulation measured in centimeters.

19. **Step length**: Distance between heel contact of one foot to the contralateral foot during ambulation measured in centimeters.

20. **Step width**: Distance between the feet during ambulation in centimeters.
REFERENCES


