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

Jill Steinmetz

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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Bachelor of Science, University of Wyoming, 1995
Bachelor of Science in Physical Therapy
University of North Dakota, 1997

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 Jill Steinmetz 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.

M. Lee Denke
(Faculty Preceptor)

K. Weiler
(Graduate School Advisor)

T. Mohr
(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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Signature ____________________________

Date ________________________________
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>LIST OF TABLES</th>
<th>vi</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACKNOWLEDGMENTS</td>
<td>vii</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>viii</td>
</tr>
</tbody>
</table>

## CHAPTER

### I  INTRODUCTION ........................................ 1

- Purpose ........................................ 4
- Clinical Application .......................... 5

### II  REVIEW OF THE LITERATURE ................................. 6

- Static Steadiness ................................. 6
- Symmetry ......................................... 8
- Dynamic Stability ................................ 10
- Fatigue .......................................... 11
- Treatment Time Frames ........................... 12

### III  METHODOLOGY .............................................. 14

- Subjects ........................................ 14
- Questionnaire and Initial Evaluation ........ 15
- Instrumentation .................................. 17
- Procedure ....................................... 18
- Assessment ...................................... 19
- Training ......................................... 23
- Data Analysis ................................... 24
- Reporting Results ................................ 25

### IV  RESULTS .................................................... 26

- Subject Profile .................................. 26
- Data Analysis ................................... 27
LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Descriptives of Subjects</td>
<td>16</td>
</tr>
<tr>
<td>2.</td>
<td>Components of the Tests for Static Steadiness</td>
<td>28</td>
</tr>
<tr>
<td>3.</td>
<td>Components of the Tests for Symmetry</td>
<td>29</td>
</tr>
<tr>
<td>4.</td>
<td>Components of the Tests for Dynamic Stability</td>
<td>31</td>
</tr>
</tbody>
</table>
ACKNOWLEDGMENTS

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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

Multiple sclerosis (MS) has been described as the "great crippler of young adults"1-4 and is becoming an increasing concern for males and females between the ages of 15-50. Multiple sclerosis is a chronic, often progressive disease of the central nervous system (CNS) characterized by demyelination of the white matter in the brain and spinal cord areas.4-6 The disease destroys myelin, a fatty substance surrounding the nerves in the body that aids in electrical transmission of nerve impulses.7 As the myelin is broken down, the destroyed areas become inflamed and result in scar tissue or plaque formation at the involved sites. It is the sporadic nature of the inflammatory areas that classically result in exacerbations and remissions of the disease8 with a multitude of plagues along the CNS giving the disease its name "multiple sclerosis."5 As the disease progresses, small plaques become larger, new plaques form, and adjacent ones conjoin, hence the reason for a chronic state of the disease.6

An estimated one third of a million Americans are afflicted with MS and approximately 200 new cases arise each week. The disease is more prevalent among women than men, at a ratio of 1.8 to 1, and is uncommon in black and Asiatic populations.6,8 The cause of MS is unknown; however, researchers believe it is multi-factorial and that individuals may be predisposed if the
appropriate combination of conditions exist. For example, MS may be caused from a viral infection, an upper respiratory infection, or a gastrointestinal tract infection. The disease may also be the result of a disorder involving the immune system which causes an attack on normal body tissue, in this case, the cells which produce myelin. Heredity may also play a factor with documentation of an estimated 5% of MS patients having a brother or sister with the disease and 15% having a close relative. Finally, the chance of having this disease may be related to geographical area with the risk increasing the farther an individual lives from the equator. The place of residence where the first 15 years of life are spent determines a greater or lesser likelihood of developing the disease with the prevalence increasing for those in the northern United States (US), 100/100,000 cases, versus the southern US, 30/100,000.

There are five types of MS: benign, benign relapsing, chronic relapsing, chronic progressive, and acute progressive. According to Waksman, two-thirds of patients with MS remain ambulatory and function normally, while the remaining one-third need additional assistance for ambulation and self-care activities. Premature death is unlikely with the average life span being 75% of normal life expectancy or approximately 30 years after onset. There is no known cure nor is there any treatment at this time to halt the underlying process of the disease.

Signs and symptoms of MS vary among individuals in terms of severity and CNS involvement. In the early stages of the disease, the individual may experience tingling sensations, numbness, slurred speech, blurred or double
vision, and muscle weakness. As the disease progresses, the signs and symptoms may include pain, spasms, paralysis, inability to coordinate movements, balance difficulties, disturbances in thought/mood, and bowel/bladder dysfunction. More advanced, severe involvement is typically motor in nature, with gait dysfunction becoming a major concern due to general weakness, spasticity, ataxia, balance difficulties, or a combination thereof. A diagnosis of MS may be confirmed by magnetic resonance imaging (MRI), the tool of choice for viewing and identifying plaque areas.

Because MS is a neurological disease affecting the CNS, most patients will experience balance difficulties. Balance is defined as the ability to maintain a weight bearing position either statically or dynamically without a loss of balance (LOB). The body is said to be in a state of balance when the center of gravity (COG) falls within the base of support (BOS) and the result of the external forces acting on the body is zero. Three aspects of balance will be examined in this study and defined. 1) Static steadiness is the ability to obtain a motionless state. 2) Symmetry is the ability to distribute weight evenly between the feet in a weight bearing position. 3) Dynamic stability is the ability to transfer the vertical projection of the COG over the BOS in a dynamic motion. Balance difficulties, which result in disruption of activities of daily living (ADLs) and impede the individual’s safety, require attention by a health care profession. A physical therapist (PT) will commonly evaluate these problems based on objective findings from gait and balance assessments, such as the Tinneti, Berg Balance Scale, Kurtzke's Expanded Disability Severity Scale, and a general assessment
of range of motion (ROM) and manual muscle testing (MMT). Based on the results found, the therapist may chose to use a traditional means of therapy with visual, verbal, and tactile instructions and/or a non-traditional approach including a force platform biofeedback system to analyze and/or retrain the balance system using technological means or a combination thereof.

Recently, there has been a growing acceptance for utilization of a force platform biofeedback system for evaluation and treatment of various neurological and orthopedic diagnoses.9-12 The use of biofeedback as a tool for PTs in treating patients with postural instability can be traced back to the early 1970s. The older biofeedback machines, utilizing audition primarily, have been replaced by current augmented systems that provide visual feedback and objective information regarding the subject’s performance. This latter application of biofeedback has been primarily involved in subjects with peripheral vestibular deficits and those with hemiplegia secondary to a cerebral vascular accident (CVA).11 Currently, there is no research available concerning balance assessments of and retraining for patients with MS using a force platform biofeedback system.5

Purpose

The purpose of this study was to determine if significant changes occur in static steadiness, symmetry, and dynamic stability following a balance retraining program on the NBM®. The research questions that will be addressed are: 1) Is there a significant difference in measures of static steadiness between the
control and treatment groups? 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 the control and treatment groups?

It is hypothesized that there will be a significant difference between the control and treatment groups on measures of balance based on a comparison of the initial to the final balance assessments. The alternate hypothesis states there will be no significant difference between the control and treatment groups on measures of balance based on a comparison of the initial to the final balance assessments.

Clinical Application

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

According to literature by Williams, Roland, and Yellin, little research has been conducted using a force platform biofeedback system to analyze balance in patients with MS. Due to the lack of literature on balance and the MS population, studies which utilized a force platform system for post-CVA subjects will be examined in this review of the literature. Caution must be used in comparing the two neurological populations secondary to the varying signs and symptoms of MS and the natural progression of the disease. The three measures of balance (static steadiness, symmetry, and dynamic stability) will be investigated due to the common reporting of these elements in scientific journal articles. In addition, fatigue in the subject with MS and documentation regarding an adequate time frame for progression in a retraining program will also be examined.

Static Steadiness

Static steadiness has been investigated by numerous researchers utilizing biofeedback on a force platform system to analyze postural steadiness as measured by postural sway. Information on postural steadiness can be found by examining directional displacement of a subject's COG and the total sway area in a static position. Postural control involves use of the sensorimotor
system to coordinate the motor processes for necessary movements and utilization of the somatosensory, visual, and vestibular systems to obtain a state of balance.  

In subjects with hemiplegia, postural sway is often increased with lateral displacement over the non-paretic extremity. General lower extremity weakness, decreased sensory information from the paretic extremity, perceptual problems, and spatial orientation problems contribute to the postural sway abnormalities. Force platform biofeedback systems can measure the vertical ground reaction force and provide a means of computing the center of pressure (COP) of the subject by measuring three or more points on the platform system. A number of studies have used this system to measure a subject's COP and characterize sway both in normal subjects and in a variety of patient populations, including those with neurological sequelae.

Shumway-Cook et al conducted a study which compared postural sway characteristics of subjects with hemiplegia secondary to a CVA and age matched "normal" peers using a force platform biofeedback system. In addition to standard physical therapy (PT), subjects in the treatment group received balance retraining on a platform system for 15 minutes, twice per day for two weeks. Subjects were required to maintain their COG in the center of a small target on the computer screen with emphasis on symmetry and decreased postural sway for equal weight distribution. Retraining involved the use of biofeedback to the subject in order for independent corrections of balance. Subjects in the control group received 15 minutes of standing balance retraining during their regular
therapy sessions which involved verbal, tactile, and visual cues provided by the therapist. Results from this study revealed that those in the treatment group demonstrated greater improvements in decreased lateral displacement over the non-paretic leg than controls who received traditional PT. One-hundred percent of the subjects in the treatment group showed decreased lateral sway displacement over the non-paretic leg versus only 25% of the subjects in the control group. The difference in sway area between groups after treatment was not significant and there was no change in sway following two weeks of retraining for the biofeedback or the traditionally trained subjects.

Symmetry

Symmetry is another measure of balance which has been examined in past literature. Balance retraining for symmetry may be performed on a force platform system with the utilization of feedback on the percentage of body weight per limb. The subject may be required to come to a standing position, reach to the side and return to a symmetrical stance, or perform stride stepping while maintaining the COG in a specified target area on the computer screen.

In an earlier study, Wannstedt and Herman\textsuperscript{14} utilized feedback via an auditory signal provided from a limb-load receptor for patients post-CVA. Of the 30 ambulatory subjects participating in this study, 27 improved their symmetry via the augmented system. This study was performed with the assumption that postural symmetry could be linked to functional ability with an easy transfer to newly learned skills.
Today, current literature has examined force platform systems with visual feedback. In a study conducted by Sackley,² 26 subjects with a post-CVA were randomly assigned to use a visual feedback balance retraining program via a computer (treatment group) or a placebo computer program for balance retraining on a force platform system (control group). All subjects received 12 to 20 minutes of balance retraining in addition to their regular PT sessions three times per week for four weeks. Significant improvements in stance symmetry were found in the treatment group as compared to the control group at the four-week assessment. In a comprehensive review of past literature regarding symmetry, Nichols¹⁵ also found that an increase in stance symmetry was found following training, with the increase being greater in the treatment group (biofeedback) versus the control group (traditional), with reports of maintained stance symmetry one month following training.

In a study by Winstein et al.,¹⁰ standing balance was examined in two groups of 21 matched post-acute hemiparetic adults. The treatment group received standing balance retraining with a visual feedback (VF) system called the standing feedback trainer (SFT), while the other control group received traditional therapy. Subjects trained with the SFT performed significantly better in static standing symmetry (p < .05) following a retraining session for 30 to 45 minutes, five times per week for three to four weeks. Both groups improved significantly in gait velocity, cadence, stride length, and cycle time (p < .01).

Lee¹¹ conducted a study that involved 60 subjects with hemiplegia secondary to a CVA. The treatment group consisted of 30 subjects who
received visual feedback from a force platform system to independently correct their weight bearing symmetry; each session consisted of 20 minutes of biofeedback training daily for three to four weeks. The control group consisted of 30 subjects who received traditional PT for an equivalent amount of time. Differences in symmetry scores from an initial to a final assessment were found using the standing steadiness index (SSI) which is equivalent to the weight borne by the affected leg divided by the body weight minus .5 times 100%. Immediate results from the treatment group were seen after just one day of retraining with significant results found during the final assessment. The implications for this study indicated that visual feedback is superior to traditional therapy.

**Dynamic Stability**

Dynamic stability retraining, the last measure of balance discussed in this review of the literature, refers to movement within the limits of stability (LOS) in which the COG falls outside the BOS. This requires the subject to weight shift to successive targets located on the computer screen which are illustrated as a circle of boxes surrounding a central square. The subject’s task is to shift his/her weight to the lit target within a specified amount of time, usually seven to ten seconds, within 50-75% of their LOS. The transition time, sway path, sway error, and the peripheral sway area are the units used to evaluate subject performance. Subjects with and without balance difficulties who participated in this exercise program were able to extend their LOS and improve dynamic control according to a comprehensive study by Nichols.
A dynamic stability retraining may also improve steadiness, with McRae et al\textsuperscript{16} reporting a decrease in static sway following six weeks of balance retraining on a force platform biofeedback system. Results from this study revealed dynamic balance retraining was strongly reliable in terms of improving measurements of movement time and movement path in repeated tasks. In addition, studies in which multiple exercises are used in a dynamic stability protocol have shown the most consistent results in patient function including transfers, mobility, endurance, and ADLs.\textsuperscript{2,15-17}

Fatigue

Fatigue is a common and sometimes disabling condition which may affect performance in a balance retraining program for a subject with MS. In a study by Sharma et al\textsuperscript{18}, the relationship between muscle fatigue and perceived fatigue were examined. They found that excessive intra-muscular fatigue, as measured by tetanic force (TF), was found in subjects with MS when compared to healthy counterparts. Fatigue was measured by a decline in TF during peripheral nerve stimulation suggesting the cause was not central. This study concluded that the site of impairment for the delayed reaction was apparently within the muscle with excessive peripheral fatigue due to impaired excitation-contraction coupling and abnormal energy metabolism present in MS. Hence, with this information in mind, a subject with MS may need to take several breaks during activity to prevent excessive fatigue.
Treatment Time Frames

While reviewing past literature on balance studies, it is also important to determine appropriate time frames for treatment progression. In a study conducted by Hamman,\textsuperscript{12} 17 healthy subjects ages 20 to 35 were randomly assigned to either of two groups. Group one completed balance retraining sessions one time daily over five days and group two completed one session weekly over a five-week period; both groups utilized a force platform biofeedback system to improve the three components of balance. A standard assessment on the first and last treatment sessions was conducted. An independent t-test revealed no significant difference between groups one and two in pre-test and post-test values for postural sway. The test for dynamic stability revealed that transition time and sway area decreased significantly ($p<.01$) between pre-test and post-test assessments for both groups with path error decreasing significantly for the daily therapy group only. Group two demonstrated similar trends with a significant decrease in transition time and sway area and no significant difference in path error from pre-test to post-test measurements. In conclusion of this study, no difference in performance was found between the daily and weekly therapy groups.

Based on the literature review, a force platform biofeedback system is a commonly used assessment and treatment tool for subjects with neurological problems. Due to the lack of literature involving balance retraining in subjects with MS, a comparison of this study with past studies may be helpful for clinicians. The chance for fatigue among the subjects during retraining will be
controlled by allowing adequate rest periods. A treatment time frame of a daily retraining program versus a weekly retraining program on a force platform biofeedback system should have the same effect on performance.
CHAPTER III
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

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control mean age = 52.4 years

treatment mean age = 49.4 years
Instrumentation

The NBM® (NeuroCom® 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. 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. 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® in the last several years, only recently have reliability and validity issues been addressed. Liston and colleagues 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.12 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 session 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.,12 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 force plates.

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.19

**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 $0^\circ$ and $30^\circ$ 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 $0^\circ$ and one at $30^\circ$.

**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 force plate to the other as quickly as possible. When the monitor displayed the word “GO,” the subject walked to the end of the force plate 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 IV

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>
</tr>
</thead>
<tbody>
<tr>
<td>COG Sway Velocity*</td>
<td>-.572</td>
<td>8</td>
<td>.583</td>
<td>-.4400</td>
<td>.7692</td>
</tr>
<tr>
<td>End Sway*</td>
<td>.144</td>
<td>8</td>
<td>.889</td>
<td>.1200</td>
<td>.8362</td>
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<tr>
<td>Mean Center of Gravity Sway Velocity* (eyes closed)</td>
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<td>.784</td>
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<td>.1371</td>
</tr>
<tr>
<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>
</tr>
<tr>
<td>Mean Center of Gravity Sway Velocity (composite)</td>
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<td>8</td>
<td>.587</td>
<td>4.000E-02</td>
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</tbody>
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* Indicates data were not normally distributed.
Table 3.—Components of the Tests for Symmetry

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<th>Test</th>
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<th>Significance (2-tailed)</th>
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<th>Standard Error Difference</th>
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<tr>
<td>Impact Body Weight (left)</td>
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<td>Impact Body Weight (right)</td>
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<tr>
<td>Lift-up Index Difference*</td>
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<tr>
<td>Left/Right Weight Symmetry</td>
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<td>Lift-up Index Body Weight (right)</td>
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<td>Rising Index</td>
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<td>.2000</td>
<td>.9592</td>
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<td>.207</td>
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<td>Weight Bearing (right) (0°)</td>
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<td>.207</td>
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<td>5.2440</td>
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<tr>
<td>Weight Bearing (right) (30°)</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>
<thead>
<tr>
<th>Component</th>
<th>t</th>
<th>df</th>
<th>Significance (2-tailed)</th>
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<th>Standard Error Difference</th>
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<tr>
<td>Directional Control (composite)*</td>
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<td>Directional Control (back)*</td>
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Table 4.—Components of the Tests for Dynamic Stability (Cont.)

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<th></th>
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<th>Significance (2-tailed)</th>
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<td>Movement Time (left leg)</td>
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<td>Movement Time (right leg)</td>
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<td>On-axis Velocity (forward/backward)</td>
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<td>On-axis Velocity (left/right)*</td>
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<td>.770</td>
<td>.1600</td>
<td>.5278</td>
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<tr>
<td>Reaction Time (backward)</td>
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<td>.853</td>
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<td>.2611</td>
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<td>Reaction Time (composite)</td>
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<td>.235</td>
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<td>.866</td>
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Table 4.—Components of the Tests for Dynamic Stability (Cont.)

<table>
<thead>
<tr>
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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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<tr>
<td>Reaction Time (left)</td>
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<td>.217</td>
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<td>Reaction Time (right)</td>
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<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 V
DISCUSSION

Many studies have used the NBM® for balance retraining in subjects with difficulties in balance as noted earlier in this paper; however, none have been conducted on the neurological population of MS. In this study, dynamic stability retraining was found to be the only significant component of balance to change from the initial to the final balance assessment among the subjects in the treatment group. From the literature review with subjects post-CVA, dynamic stability was also found to be improved following a retraining program on a force platform biofeedback system. Due to the chronic nature of the MS, varying results in balance following a retraining program may exist, thus making comparisons to other studies or future studies difficult.

Significance was found in two of 31 components of the tests for dynamic stability; no significance was found in static steadiness or symmetry. A total of 53 components of balance were analyzed; however, ten (19%) were not considered normally distributed and were disregarded. The results from this study are consistent with past studies on force platform biofeedback systems which have shown significant differences among treatment and control groups in the components of dynamic stability. According to past literature, dynamic stability retraining has shown the most consistent carry-over effects to functional
outcomes in terms of balance for subjects with neurological sequella.\textsuperscript{2,15-17} It has also been proven that dynamic stability retraining improves balance in normal subjects as well.\textsuperscript{15}

Explanation

The main interest of this study was to determine if a force platform biofeedback system is a beneficial tool in balance retraining for subjects with MS. Even though a low number of statistically significant components of the balance tests were found, the results can still be useful for future research. In terms of replicating this study, it is important to look at possible reasons for the overall results: 1) a small sample size, 2) the retraining program, and 3) the natural progression of the disease.

Sample Size

Those subjects who met the requirements for participation in this study resulted in a small sample size (n=10). This variable could not be controlled by the researchers and may have resulted in the low incidence of significant tests found. A larger sample size (n=30) may have allowed for normalcy of data and a greater likelihood of finding significance in the balance components between the treatment and the control groups.

Retraining Program

The actual retraining program for all subjects in the treatment group was chosen by the researchers based on the subject's LOS. Those exercises used in the retraining program were the same for all treatment members with the exception the degree of difficulty, again dependent on the subject's LOS. The
amount of time the subject was allowed to complete each exercise, the surface
on which the subject performed the exercise (foam, tilt board, therapeutic ball),
and the height of the box used during stepping tasks were different for all
subjects based on previous performance and progression over the four-week
period. This selection process, assumed by the researchers, may have hindered
improvement for the subjects. For example, some exercises may have been too
easy, while others were too difficult. An individualized retraining program which
focused on the components of balance most affected by the disease could have
been more beneficial to show significant differences in all the components of
balance, including static steadiness and symmetry.

Natural Progression of the Disease

The chronic progressive nature of MS on the CNS inhibits control over the
human body’s balance system. Exacerbations and remissions characteristic of
MS and the progressive nature of the disease may have accounted for the low
number of significant tests found. The symptoms of MS are variable; hence, a
replication of this study with a different subject pool of MS subjects may show
more significance. In addition, more than one study is needed to represent
reliable findings between researchers among a population pool, such as MS, in
improving balance.

Even though symmetry and steadiness may be closely related to patient
function, these balance components have not demonstrated consistent
findings.\textsuperscript{1,10,12-17} The impact on force platform biofeedback retraining to improve
balance and overall function has been an area of considerable controversy in the
existing literature. The degree to which biofeedback retraining appears to affect function may not only be related to the functional activity evaluated (dynamic stability), but may also be associated with the training protocol used. This can be extremely variable considering the multitude of activities that may be performed on the force platform system and the different levels available for assessment and retraining.

Limitations of Study

This study has several limitations, three of which have already been mentioned: small sample size, the retraining program, and the natural progression of the disease. The precision of data from the balance assessments may have also been limited by 1) the selection of subjects for the treatment group, 2) the way in which each subject was progressed to higher levels in the retraining program, and 3) the possibility for carry-over effects to functional outcomes.

Selection of Subjects

A sample of convenience was chosen based on each subject's desire to participate in an exercise program and his/her ability to comply with the time requirement. This interest in participation may have been related to the degree of balance difficulties. For example, those who considered their balance poor may have been more willing to be in the retraining program (treatment group), while those who considered their balance better were only interested in participating in the balance assessments (control group). According to the questionnaire completed by each subject prior to participation in this study, the
mean number of falls per year for the treatment group was 24.8, while the mean number of falls per year for the control group was only 15.9. These data may support the concern that the treatment group had greater balance difficulties before beginning this study. Even though the subjects in the treatment group may have improved over the four-week period, they did not show a significant difference over those in the control group whose balance generally remained the same.

Progression in the Retraining Program

In the balance retraining program on the NBM®, five levels of difficulty existed. All subjects in the treatment group were progressed to the next appropriate level based on satisfactory achievement in a specific exercise agreed upon by both the researcher and the subject. This rationale for progression may have been premature for some subjects or hindering to others for further progression. Subjects did not need to demonstrate perfection on each exercise in order to advance to a higher level. Thus, the researchers where limited by their own novice experience by the way in which to progress each subject appropriately. A margin of variance among the different components measured in each test was needed to determine the most appropriate time to advance each subject.

Carry-over Effects to Functional Outcomes

Finally, the carry-over effects of the balance retraining exercises may have been a limiting factor in transferring each exercise to a functional one. According to Goodgold-Edwards,²¹ learning is enhanced by practice in
meaningful contexts. All the exercises used in the balance retraining program were not related to functional tasks. Therefore, a verbal explanation on behalf of the researcher needed to be provided in order to inform the subject on the usefulness of each exercise. Learning is also enhanced with repetition and problem solving. Even though the retraining program was repetitious over the four-week period, each exercise was performed only once during the retraining sessions and did not allow for problem solving. The actual menu of exercises available on the NBM® system may have been the limiting factor in the possibility for carry-over effects.

Clinical Implications

This study offers an introduction to future studies regarding balance retraining in subjects with MS. According to Nichols, the goals of a balance retraining program should include: increased static steadiness, decreased symmetry, and improvements in dynamic stability for improvement in overall function. Thus, force platform biofeedback systems may be a useful tool to accomplish such goals in treatment for subjects with balance difficulties. Because a difference was found in dynamic stability components between the treatment and control groups among the subjects in this study, dynamic stability retraining may prove to be beneficial for this population of individuals.

The therapist designing a treatment protocol for a patient with balance difficulties needs to choose the best measure for patient progress. Increased stance symmetry and improvements in dynamic stability among subjects post-CVA have been found in past studies. Static steadiness, as measured by
postural sway, has been inconsistently changed following a retraining program in terms of progression on force platform biofeedback systems. This study offers supportive information regarding improvements in dynamic stability in a population of subjects with MS whose levels of balance difficulties vary greatly.

Conclusion

Assessing and treating balance difficulties to improve function and independence in those with MS is important in the profession of PT. Many studies have been conducted using force platform biofeedback systems in subjects with neurological sequella; however, more research needs to be conducted on other populations pools using the NBM® to determine reliability and validity of this balance retraining machine. The results of this study revealed a change in two of the 31 components of the tests for dynamic stability, while no significant difference was found in the tests for static steadiness or symmetry. These findings suggest that dynamic stability retraining may show a change in balance function following a four-week program. This preliminary study can serve as a vantage point for future research involving a greater sample size for normalcy of data and an introduction to a commonly used biofeedback system, the NBM®.
APPENDIX A
Grand Forks Medical Park

Institutional Review Board

Human Subjects Review Form

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

Jill & Becky, 746-9508

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 suffering from 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.
2. PROTOCOL: (Cont.)

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: ________________________________  ________________________________  ________________________________  
Principal Investigator: ________________________________  Date: ________________________________  
Project Director: ________________________________  Date: ________________________________  
Student Advisor (where applicable): ________________________________  Date: ________________________________
NOTE: EDSS steps 1.0 to 4.5 refer to patients who are fully ambulatory, and the precise step number is defined by the Functional System scores. EDSS steps 5.0 to 9.5 are defined by the impairment of ambulation, and usual equivalents in Functional System scores are provided.

0  -  Normal neurological exam (all grade 0 in FS*).
1.0 - No disability, minimal signs in one FS* (i.e.: grade 1).
1.5 - No disability, minimal signs in more than one FS* (more than one FS grade 1).
2.0 - Minimal disability in one FS (one FS grade 2, others 0 to 1).
2.5 - Minimal disability in two FS (two FS grade 2, others 0 or 1).
3.0 - 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.
3.5 - 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).
4.0 - Fully ambulatory without aid, self-sufficient, up and about some 2 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.
4.5 - Fully ambulatory without aid, up and about much of the day, able to work a full day, may otherwise have some limitation of full activity or require minimal assistance; characterized by relatively severe disability usually consisting of one FS grade 4 (others 0 or 1) or combination of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 300 meters.
5.0 - 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).
5.5 - 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).
6.0 - Intermittent or unilateral constant assistance (cane, crutch, brace) required to walk about 100 meters with our without resting; (usual FS equivalents are combinations with more than two FS grade 3+).
6.5 - Constant bilateral assistance (canes, braces, braces) required to walk about 20 meters without resting; (usual FS equivalents are combinations with more than two FS grade 3+).
7.0 - Unable to walk beyond approximately five meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day; (usual FS equivalents are combinations with more than one FS grade 4; very rarely pyramidal grade 3 alone).

7.5 - Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self but cannot carry on in standard wheelchair a full day; May require motorized wheelchair; (usual FS equivalents are combinations with more than FS grade 4+).

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 grade 4+ in several systems).

8.5 - Essentially restricted to bed much of day; has some effective use of arms; retains some self-care functions; (usual FS equivalents are combinations generally grade 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 eat/swallow; (usual FS equivalents are combinations, almost all grade 4+).

10.0 - Death due to MS

Assessment Index
0  -  Normal gait
1  -  Walks normally but reports fatigue which interferes with demanding activities.
2  -  Abnormal gait or episodic imbalance; gait disorder is noticeable to family; able to walk 25 feet in 10 seconds or less.
3  -  Walks independently; able to walk 25 feet in 20 seconds or less.
4  -  Requires unilateral support; use of cane, single crutch; able to walk 25 feet in 20 seconds or less.
5  -  Requires bilateral support; use of cane, crutches, walker; able to walk 25 feet in 20 seconds or less.
6  -  Requires bilateral support and walks 25 feet in greater than 20 seconds. May use wheelchair on occasion.
7  -  Walking limited to several steps with bilateral support; unable to walk 25 feet. May use wheelchair for most activities.
8  -  Restricted to wheelchair; able to transfer independently.
9  -  Restricted to wheelchair; unable to transfer independently.

(*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**

<table>
<thead>
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<th>Description</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td>1</td>
<td>Abnormal signs without disability</td>
</tr>
<tr>
<td>2</td>
<td>Minimal disability</td>
</tr>
<tr>
<td>3</td>
<td>Mild to moderate paraparesis or hemiparesis; severe monoparesis</td>
</tr>
<tr>
<td>4</td>
<td>Marked paraparesis or hemiparesis, moderate quadriparesis; or monoplegia</td>
</tr>
<tr>
<td>5</td>
<td>Paraplegia, hemiplegia or marked quadriparesis</td>
</tr>
<tr>
<td>6</td>
<td>Quadriplegia</td>
</tr>
<tr>
<td>9</td>
<td>Unknown</td>
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2. **Cerebellar Functions**

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<th>Description</th>
</tr>
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<td>Normal</td>
</tr>
<tr>
<td>1</td>
<td>Abnormal signs without disability</td>
</tr>
<tr>
<td>2</td>
<td>Mild ataxia</td>
</tr>
<tr>
<td>3</td>
<td>Moderate truncal or limb ataxia</td>
</tr>
<tr>
<td>4</td>
<td>Severe ataxia in all limbs</td>
</tr>
<tr>
<td>5</td>
<td>Unable to perform coordinated movements due to ataxia</td>
</tr>
<tr>
<td>7</td>
<td>When weakness (grade 3 or worse on pyramidal) interferes with testing</td>
</tr>
<tr>
<td>9</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

3. **Brainstem Functions**

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<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td>1</td>
<td>Signs only</td>
</tr>
<tr>
<td>2</td>
<td>Moderate nystagmus or other mild disability</td>
</tr>
<tr>
<td>3</td>
<td>Moderate nystagmus, marked extraocular weakness, or moderate disability of other cranial nerves</td>
</tr>
<tr>
<td>4</td>
<td>Marked dysarthria or other marked disability</td>
</tr>
<tr>
<td>5</td>
<td>Inability to swallow or speak</td>
</tr>
<tr>
<td>9</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

4. **Sensory Functions**

<table>
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<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td>1</td>
<td>Vibration or figure-writing decrease only in one or two limbs</td>
</tr>
<tr>
<td>2</td>
<td>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</td>
</tr>
<tr>
<td>3</td>
<td>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</td>
</tr>
<tr>
<td>4</td>
<td>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</td>
</tr>
<tr>
<td>5</td>
<td>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</td>
</tr>
<tr>
<td>6</td>
<td>Sensation essentially lost below the head</td>
</tr>
<tr>
<td>7</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

5. **Bowel and Bladder Functions**

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<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td>1</td>
<td>Mild urinary hesitancy, urgency, or retention</td>
</tr>
<tr>
<td>2</td>
<td>Moderate hesitancy, urgency, retention of bowel bladder or rare urinary incontinence (intermittent self-catheterization, manual compression to empty bladder, or finger evacuation of stool)</td>
</tr>
<tr>
<td>3</td>
<td>Frequent urinary incontinence</td>
</tr>
<tr>
<td>4</td>
<td>In need of almost constant catheterization (and constant use of measures to evacuate stool)</td>
</tr>
<tr>
<td>5</td>
<td>Loss of bladder function</td>
</tr>
<tr>
<td>6</td>
<td>Loss of bowel and bladder function</td>
</tr>
<tr>
<td>9</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

6. **Visual (or Optic) Functions**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td>1</td>
<td>Scotoma with visual acuity (corrected) better than 20/30</td>
</tr>
<tr>
<td>2</td>
<td>Worse eye with scotoma with maximal visual acuity (corrected) of 20/30 to 20/50</td>
</tr>
<tr>
<td>3</td>
<td>Worse eye with large scotoma, or moderate decrease in fields, but with maximal visual acuity (corrected) of 20/60 to 20/99</td>
</tr>
<tr>
<td>4</td>
<td>Worse eye with marked decrease of fields and maximal visual acuity (corrected) or 20/100 to 20/200; grade 3 plus maximal acuity of better of 20/60 or less</td>
</tr>
<tr>
<td>5</td>
<td>Worse eye with maximal visual acuity (corrected) less than 20/200; grade 4 plus maximal acuity better eye of 20/60 or less</td>
</tr>
<tr>
<td>6</td>
<td>Grade 5 plus maximal visual acuity of better of 20/60 or less</td>
</tr>
<tr>
<td>7</td>
<td>Presence of temporal pallor</td>
</tr>
<tr>
<td>9</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

7. **Cerebral (or Mental) Functions**

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Normal</td>
</tr>
<tr>
<td>1</td>
<td>Mood alteration only (does not affect DSS score)</td>
</tr>
<tr>
<td>2</td>
<td>Mild decrease in mentation</td>
</tr>
<tr>
<td>3</td>
<td>Moderate decrease in mentation</td>
</tr>
<tr>
<td>4</td>
<td>Marked decrease in mentation (chronic brain syndrome - moderate)</td>
</tr>
<tr>
<td>5</td>
<td>Dementia or chronic brain syndrome - severely incompetent</td>
</tr>
<tr>
<td>9</td>
<td>Unknown</td>
</tr>
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</table>

8. **Other Functions**

<table>
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<th>Description</th>
<th>Score</th>
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</thead>
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<td>Spasticity</td>
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</tr>
<tr>
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<td>1</td>
</tr>
<tr>
<td>Mild</td>
<td>2</td>
</tr>
<tr>
<td>Moderate</td>
<td>3</td>
</tr>
<tr>
<td>Others</td>
<td>0</td>
</tr>
<tr>
<td>None</td>
<td>1</td>
</tr>
<tr>
<td>Any other neurological findings attribute MS: Specify</td>
<td>9</td>
</tr>
</tbody>
</table>

---

**Neurological Assessment**

**Kurtzke Functional Systems - EDSS**

[Image of Altru Healthcare Systems]
APPENDIX C
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
INFORMATION AND CONSENT FORM #2

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.

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.

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
APPENDIX D
Questionnaire

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?
APPENDIX E
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
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 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


