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

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

(Faculty Preceptor)

(Graduate School Advisor)

(Chairperson, Physical Therapy)

PERMISSION

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

Department Physical Therapy

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Signature Briana M. Zearley

Date 12-11-98

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ABSTRACT

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

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

The variability among subjects in the MS population pool, the small sample size, and the four-week time frame may have been limiting factors in this

study. Further research is needed to determine the effectiveness of a balance retraining program using the NBM®.

CHAPTER I

INTRODUCTION

Multiple sclerosis (MS) is the most common demyelinating disease of the central nervous system (CNS). The disease process involves breakdown of the white matter insulating the nerves of the balance systems responsible for postural stability.[1-4] It is estimated one-third of Americans have the disease with 200 new cases being diagnosed every week.[2] Eighty percent of the patients with MS have diminished balance[3] and two out of three people may need to modify their previous lifestyle with a cane or other assistive device.[2,5] Within the last decade, there has been a growing acceptance for utilization of a force platform biofeedback system for balance with various neurological and orthopedic diagnosis; however, the problem lies in the limited research available concerning balance assessments and retraining for patients with MS.

The purpose of this study is to determine if significant changes occur in static steadiness, symmetry, and dynamic stability following a balance retraining program on the NeuroCom Balance Master® (NBM®). This research project will answer the following questions: 1) Is there a significant difference in measures of static steadiness between the control and treatment groups utilizing the NBM® for balance re-training?, 2) Is there a significant difference in measures of symmetry between the control and treatment groups?, 3) Is there a significant

difference in measures of dynamic stability between groups with utilization of the NBM® for balance retraining?

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

Since 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 patients with MS in an objective and efficient manner. Another significance to this study relates to the clinical findings that may be statistically relevant to balance retraining in the MS population. Upon completion of this study, results generated can be useful to a clinician who is eager to use a visual, force platform system with biofeedback to improve balance. Finally, this study could be used as a basis for future research with a larger sample size for normalization of data.

CHAPTER II

LITERATURE REVIEW

Chapter II presents a literature review that summarizes the components of balance in relation to the organization from neural controls, biomechanical properties, and balance strategies. The components of balance work together in providing equilibrium so the body can sustain upright postures during various activities. In addition, there is a description of MS which includes a general overview of the etiology, description of the disease process, signs, symptoms, and other debilitating changes associated with it.

Balance

Balance is a critical skill of the human body needed to carry out static, symmetric, and dynamic functional tasks efficiently and independently.[6] Static postures are how much steadiness the body has or the ability of the body to be as motionless as possible[7] during standing, lying, sitting, and kneeling activities.[8] Symmetry is the body's ability to distribute weight evenly between the weight bearing components; i.e., feet in standing position, buttocks in sitting position.[7] The normal ranges of percent body weight on each leg during standing deviates between 43% and 57% respectively.[9] Dynamic postures include the trunk and extremities that are moving to perform walking, running, jumping, throwing, and

lifting;[8] they can also be referred to as the body's ability to transfer its weight around the supporting base through ankle and hip movements.[10]

Many researchers define balance as the ability to maintain equilibrium by maintaining the body's center of gravity (COG) within the base of support (BOS) with minimal postural sway.[1,11,12] The deviation from the vertical, upright position is measured as postural sway. The COG is the point where the total force of gravity is projected onto the support surface,[11] and in humans, it is located anteriorly at approximately the level of the second sacral segment.[8] The BOS is located between the extremities supporting the body weight. In bipedal stance, the BOS is bounded by the length of the two feet with movements in the sagittal plane (anterior-posterior) and the distance between the outside edges of the feet with movements in the coronal plane (left-right).[8,13,14]

Even in quiet standing, postural sway is present,[10,11,15] but people rarely lose balance if movements are within an area around the body defined as the limits of stability (LOS). Limits of stability refers to the maximum angle from vertical that can be tolerated without loss of balance[1] and is pictured as an inverted cone with the apex projecting from the feet. When people are standing with feet four inches apart, the LOS boundaries extend to approximately eight degrees anteriorly, four degrees posteriorly, and eight degrees to each side.[1,7,16-18]

The biomechanical properties that define LOS are similar in standing, walking, and unsupported back seating. As mentioned earlier, the COG can

move forward to back and side to side during standing activities and balance is maintained if movements stay within the LOS boundaries. During walking, the COG advances forward in smooth, rhythmic movements. With initial contact of the foot, the COG is positioned at the back of the LOS. Efficient biomechanical movements of the pelvis, legs, and arms cause the COG to move to the front of the LOS causing the person to step out with the other foot. The whole process begins again with the LOS continuously being reestablished. Unsupported back seating is identical to standing except the base of support is larger and the vertical component of the COG is closer to the BOS enabling more movement of the trunk because the LOS boundaries are increased.[18]

It is unrealistic to think that during everyday life activities the body is always placed in ideal environments where support surfaces are firm and even. Therefore, the body uses strategies called synergies to maintain and recover balance in response to movements of the COG around the BOS during quiet standing, dynamic activities, and/or displacement of the supporting surface.[14,18] The synergies are patterns of leg and trunk muscle contractions that work homogeneously in timing and intensity[1] and are referred to as the ankle, hip, and stepping strategies (synergy).[1,14,15,18,19]

The ankle strategy, one of the first synergies to be identified, is described as shifting the COG through large, slow movements around the ankle joints to maintain balance. The ankle strategy is used in the following situations: 1) when there are small, slow perturbations of the body within the LOS,[1,17] 2) COG alignment is nearly centered within the LOS,[18] and 3) support surface is firm.[14]

The hip strategy involves flexing and extending the hips to control the motion of the COG within the LOS. This strategy is utilized when there are intense, high frequency perturbations.[1] The hip strategy is effective because it produces rapid corrections over relatively shorter distances. In cases where there is an offset of COG alignment for extended periods of time, the ankle strategy is utilized because the hip strategy is used when rapid corrections of balance are needed.[18]

The stepping strategy is used when the perturbation is large and fast enough to move the COM outside the LOS. Rapid stepping or stumbling in the direction of the perturbation is used to realign the BOS under the COG.[1] In the case of a large, fast perturbation, the ankle and hip strategies are no longer adequate in maintaining balance because they cannot generate enough force to move the COG back into the LOS, so the BOS boundaries need to be reestablished by moving the feet.[18]

Numerous sources have researched where the ankle, hip, and stepping strategies originate in the body. According to Gelfand et al,[20] most synergies of maintaining posture are preprogrammed into the subcortical neuron levels of the brain stem and spinal cord. Still questions arise as to whether the strategies arise from the independent stretch of the individual muscles at the coupled joints.[14]

Besides using the synergies, maintenance of balance requires an interaction of the CNS, visual system, vestibular system, musculoskeletal system, and somatosensory system.[1,8,12,14] The integrity of the CNS must be

efficient in receiving and processing information from all of the systems and be able to respond with appropriate output to maintain balance.[8]

The visual system sends information concerning the relationship of the body to objects in the environment.[1,14] When closing the eyes or manipulating the surrounding environment to seem as if it is moving, the visual input has been altered and there is an increase in sway in normal healthy adults.[13,14] Also, the visual system is helpful when there is an advance warning of a disturbance and preliminary action can be taken to minimize the effort of maintaining balance. One example is leaning towards the direction of the external force or widening the BOS.[13]

The vestibular system uses gravity to detect angular and linear acceleration and deceleration forces acting on the head[14] and is responsible for the output of two important reflexes, the vestibulospinal (VSR) and the vestibuloocular (VOR). The VSR relies on inputs from the spinal cord to orientate the position of the head in relation to the body. The VOR controls gaze stability by allowing vision of the eyes to remain fixed on a stationary object when the head is moving.[1,21] The regulation of muscle tone and postural muscle activation is a third function of the vestibular system.[1] In most experiments where balance disturbances lead to muscle stretch input, the result is the stimulation of the vestibular system along with stimulation of the mechanoreceptors of the somatosensory system.[13,15]

The musculoskeletal system consists of the bones, muscles, and other soft tissues in the body. The joints need to have adequate range of motion[8] and

normal biomechanics[14] so the ankle, knee, and hip balance strategies can be used. Also, muscles must have sufficient strength, tone, and be able to contract at appropriate speeds and forces in order to support the body during static, symmetric, and dynamic stability activities.[8]

The somatosensory system provides input from muscles and joint receptors and also uses cutaneous and pressure feedback from body parts in contact with the supporting surface.[14] In addition, it relays information to the CNS about the relationship of body segments to one another. The CNS relies on the inputs of the somatosensory system the most in controlling balance.[14]

Many studies have looked at the hierarchical weighting of sensory inputs by changing the ability and accuracy of visual, vestibular, and somatosensory inputs for standing balance. Nashner[14] and Shumway-Cook[12] have experimented with the body's ability to balance when placed under six different conditions and postural sway was monitored. Conditions 1 through 3 included using a fixed support surface with 1) eyes open, 2) eyes closed, and 3) a dome surrounding the subject showing visually incorrect information by moving with body sway. Conditions 4 through 6 are similar to 1 through 3 except the support surface moves with the body sway. The findings from this protocol show body sway was less when the support surface was fixed, suggesting the CNS relies heavily on somatosensory input. The greatest amount of sway was seen when both the supporting surface and visual system were compromised forcing the body to rely solely on the vestibular system for input.[14]

Multiple Sclerosis

Many different disease processes can affect the ability to balance normally because they may involve breakdown or inhibition of the balance systems. In one of the most common debilitating diseases, MS, balance is frequently decreased or lost completely secondary to breakdown of the CNS (brain, spinal cord, and optic nerves).[22] The disease is often described as the "great crippler of young adults," affecting at least 300,000 Americans.[4,23] The age of onset is between the ages of 15 and 50,[4,23,24] and half the known cases occur before the age of 30.[22] The disease appears more prominently in geographical areas furthest from the equator with an increased prevalence in persons of Northern European heritage.[1,4,24] Multiple sclerosis occurs two times more often in women,[1,4,23] and in whites more frequently than blacks or Asians.[2]

The disease process breaks down myelin or white matter insulating the axons of the nerves and is replaced by plaques (hard, sclerosed areas over the axon).[1] Myelin is important in the process of transmitting rapid nerve impulses throughout the CNS. When part or all of the segment of the axon loses its myelin and is replaced by plaques, the conduction of nerve impulses is slowed, uncoordinated, blocked, or distorted causing areas of the brain and spinal cord to lose their neural chain of communication. The breakdown of the CNS causes a variety of neurological impairments dependent on the precise location of plaques, ranging from a few mild signs and symptoms to complete paralysis.[5] Signs and symptoms of MS include blindness, diplopia (double vision), nystagmus, impaired sensation, weakness, muscle atrophy, spastic paraplegia,

hemiplegia, complete paralysis, ataxia, fatigue, heat intolerance, bowel and bladder dysfunction,[1,4,25] and sexual dysfunction.[23] Most patients experience symptoms throughout their lives, but those who have symptoms that are more sensory in nature, such as numbness, tingling, blurred vision, and dizziness, are more apt to do better than those who suffer more motor and coordination problems.[23]

Speech and cognitive problems have also been documented since the early recognition of the disease. Neuropsychological deficits prevalent in MS include memory impairment, delayed thought processes, visual-spatial difficulties,[26] and intellectual and emotional disturbances (depression and euphoria).[23] Some studies suggest 25% to 50% of patients have some extent of intellectual difficulty.[26]

The cause of the disease is unknown and there is no known cure. Current theories focus on an autoimmune response to the nervous system, slow acting viral infection,[25] or inflammatory reaction to an infectious agent.[1] There is also a clear genetic predisposition to getting the disease. Researchers estimate there is a 3 in 100 chance of getting the disease in families where it already exists compared to a 1 or 2 per 1000 chance in the general population.[4]

The disease course is variable taking on a pattern of recurrent waves of worsening and improvement, although some people exhibit a progressively downhill course with no remissions and others follow a benign course in which few attacks occur.[1,22] In a majority of cases, no precipitating factor can be found to control the fluctuating signs and symptoms, but it is thought that exacerbations

may be influenced by certain external factors, such as infections, pregnancy, trauma, cold/heat, surgical procedures, fatigue, or over exertion.[25]

Four main types of disease courses are recognized.

1) Benign. Approximately 20% to 35% of MS patients are categorized under the benign course characterized by an abrupt onset with a few exacerbations. The exacerbations go into complete or nearly complete remissions.[1,3,23] Prognostic indicators of a more benign disease include no visible plaques in the CNS found on an MRI, earlier age of onset, and female gender.[23]

2) Exacerbating-remitting. Around 65% of patients experience an unpredictable, abrupt onset of symptoms every few months to every three years[5] with periods of partial or complete remissions.[1] Some of these patients only have limited disability even 20 years after diagnosis.[23]

3) Remitting-progressive. Twenty-five percent of patients with MS are included in this group when they display onset of exacerbations, but the remissions following do not always resolve completely leading to substantial neurologic disability.[3] Most patients in this type will require assistive devices to aid in walking by 15 years after diagnosis.[23]

4) Progressive. Researchers suggest this disease type does not follow the typical exacerbating-remitting process of the disease. Ten to fifteen percent of MS patients are affected by this course of disease which is characterized by showing a progressive course of exacerbations with no remissions leading to severe disability. This group is predominantly male and occurs later in life.[1]

The life span of the average person with MS is at least 75% of normal life expectancy with patients living an average of 30 years after their diagnosis. When premature death does occur, it is most often caused by complicating infections, such as bronchopneumonia, and other complications, such as urinary tract infections and infections of the skin.[22]

Although balance is affected 80% of the time in patients with MS,[3] there are no available research articles concerning balance retraining in patients with MS using visual, force platform biofeedback. Numerous studies have been completed using the NBM® in balance rehabilitation of people who have had cerebral vascular accidents (CVA)[19,27] and/or testing normal healthy people.[11,16,17] Shumway-Cook and associates[12] used a force plate feedback apparatus similar to the NBM® in reestablishing balance in hemiplegic patients. The experimental group who had training using the force platform biofeedback for part of their therapy showed greater improvements in decreasing postural sway than did the control group who received only standard physical therapy training of verbal, visual, and tactile cues for part of their balance rehabilitation.

Hamman and coworkers[16] used the NBM® for balance training in normal, healthy subjects who had no history of neurologic or musculoskeletal diseases or injuries. All subjects used the NBM® to complete an initial and final assessment testing static and dynamic stability. Utilization during treatment consisted of moving a cursor around the LOS periphery of a circle in clockwise and counterclockwise directions. The treatment protocol was identical for all subjects in the study with the only difference between the two groups being the training

schedule. For a total of five treatment sessions, one group trained once per day and the other group once per week. Results showed a significant gain in dynamic stability but no significant changes in static stability for both groups.

The differing results of dynamic versus static stability in the Hamman study can be a result of the therapy protocol only focusing on dynamic training involving moving a cursor around the LOS periphery of a circle. Static stability was tested for initial and final assessments, but it was not included in treatment. This supports the concept that performance is task specific; an improvement in skill of one task (static, symmetric, and dynamic) does not carry over to another.[1,19,28] In this case, improvements in dynamic tasks did not carry over for improvement in static tasks. Another reason for the insignificant results of static testing during the Hamman[16] study is working with small scores from the beginning. Since both groups consisted of healthy subjects with no history of balance problems, the pre-therapy scores of postural sway were already low allowing for a small window of improvement when tested during the final assessment.[17] A study conducted by Brandt[29] concluded that over a repeated training course, the amount of improvement from training depends on the amount of initial stability.

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

Subject	Age	Sex	Group	Years	Side Involved	Assistive Devices Used	Balance Difficulties	# Times Fallen		Height
								Month	Year	
1	49	F	C	11	L	cane	mild	0	0	64
2	53	F	C	7	L	no	mild	0	0	64
3	52	F	Rx	13	R	cane	moderate	5	50-60	68
4	58	F	C	6	R	cane	mild	0	2	62
5	53	F	Rx	6	L	cane	severe	4-5	20-25	65
6	52	M	Rx	5	L	no	moderate	0	1-2	73
7	48	M	Rx	5	R	no	moderate	0	0	73
8	42	M	Rx	14	L	cane	moderate	3-4	40-50	69
9	47	M	C	9	R	cane	mild	2	20-25	73
10	55	F	C	28	Equal	cane	moderate	5-10	50-60	63

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.[10,17] (See Figure 1.) 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.[17] 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.

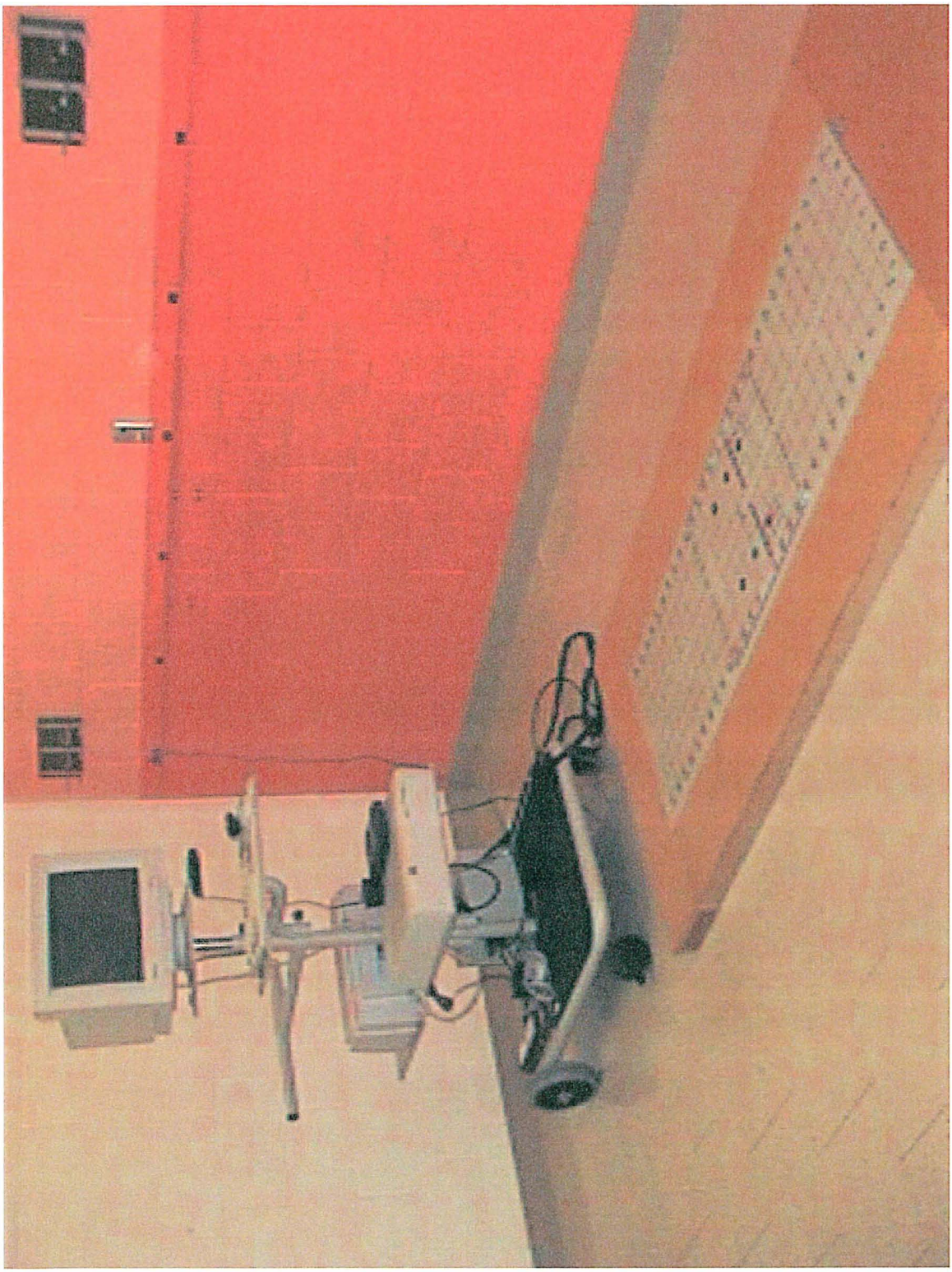

Figure 1. NeuroCom Balance Master Platform System.

Liston and colleagues[19] 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[17] 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,[17] further research is needed to establish normative data for "learning curves" in neurological populations. Because MS is a complex disease with a multitude of secondary complications associated with the degree of CNS involvement, difficulty arises in comparing MS subjects to norms of different populations.

Procedure

An introduction to the force platform system for each subject included a general description of the apparatus, how performance is measured, balance strategies utilized to maintain balance, subject expectations, and a warm-up

session. Subject data consisting of an identification number, date of birth, and height were entered into each subject file. Before the initial balance assessment began, each subject was instructed in proper foot placement on the forceplates.

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

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

Assessment

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

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

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

Definitions of the parameters for each assessment test are provided in the glossary. Refer to the glossary in Appendix F. Please refer to the NBM® Operator's Manual for more detailed information.[10]

Static Steadiness Test #1

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

Symmetry Test #1

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

Dynamic Stability Test #1

The LOS test involved eight targets arranged in a circular fashion around a central starting box. Depending on the subjects' LOS in the warm-up, the circular arrangement was adjusted to 50% or 75% of the measured limits. Each subject's COG was represented as a cursor positioned in the middle of the computer screen. Subjects were instructed to lean into the direction of the highlighted target as quickly as possible and briefly maintain a static cursor

position on the target before returning to midline. Each subsequent target was highlighted in a circular fashion until all eight targets were reached. Parameters measured for this test were: **reaction time**, **sway velocity**, **directional control**, **endpoint excursion**, and **maximum excursion**.

Dynamic Test #2

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

Dynamic Test #3

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

Dynamic Test #4

The sit-to-stand test quantified several components of movement as the subject transferred from a seated position on a 20-inch wooden box to a

standing position. When the word "GO" appeared on the computer screen, the subject rose as quickly as possible from a seated position without use of the upper extremities and held steady for 20 seconds. This test was performed three times. Measured parameters were **weight transfer time**, **rising index**, **COG sway velocity**, and **right/left weight symmetry**.

Dynamic Test #5

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

Training

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

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

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

Data Analysis

The data from the initial and final balance assessments for both the treatment and control groups were entered into the SPSS™ software system.

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

Reporting Results

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

CHAPTER 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

	t	df	Significance (2-tailed)	Mean Difference	Standard Error Difference
COG Sway Velocity*	-.572	8	.583	-.4400	.7692
End Sway*	.144	8	.889	.1200	.8362
Mean Center of Gravity Sway Velocity* (eyes closed)	.292	4.174	.784	4.000E-02	.1371
Mean Center of Gravity Sway Velocity* (eyes open)	1.723	8	.123	.1400	8.124E-02
Mean Center of Gravity Sway Velocity (composite)	.566	8	.587	4.000E-02	7.071E-02

* Indicates data were not normally distributed.

Table 3.—Components of the Tests for Symmetry

	t	df	Significance (2-tailed)	Mean Difference	Standard Error Difference
Impact Body Weight (left)	-.201	8	.845	-1.2000	5.9582
Impact Body Weight (right)	2.088	8	.070	9.0000	4.3105
Impact Index Difference	1.091	8	.307	18.8000	17.2319
Lift-up Index Difference*	2.069	8	.072	16.4000	7.9246
Left/Right Weight Symmetry	-.924	8	.382	-7.0000	7.5750
Lift-up Index Body Weight (left)	-.936	8	.377	-1.8000	1.9235
Lift-up Index Body Weight (right)	1.976	8	.084	4.4000	2.2271
Rising Index	.209	8	.840	.2000	.9592
Weight Bearing (left) (0°)	1.373	8	.207	7.2000	5.2440
Weight Bearing (left) (30°)	.593	8	.570	4.6000	7.7627
Weight Bearing (left) (60°)	-1.189	6	.279	-9.2500	7.7822
Weight Bearing (right) (0°)	-1.373	8	.207	-7.2000	5. 2440
Weight Bearing (right) (30°)	-.593	8	.570	-4.6000	7.7627
Weight Bearing (right) (60°)	1.189	6	.279	9.2500	7.7822

* Indicates data were not normally distributed.

cases. No significant difference was found between the treatment and control groups for any measure of symmetry.

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

Table 4.—Components of the Tests for Dynamic Stability

	t	df	Significance (2-tailed)	Mean Difference	Standard Error Difference
Directional Control (composite)*	1.100	8	.303	6.6000	5.9983
Directional Control (forward/backward)	.294	8	.777	4.0000	13.6242
Directional Control (left/right)	1.979	8	.083	9.4000	4.7497
Directional Control (back)*	.696	8	.506	9.2000	13.2212
Directional Control (composite)	.323	8	.755	1.6000	4.9598
Directional Control (forward)	-1.485	8	.176	-11.2000	7.5432
Directional Control (left)*	-.686	8	.512	-5.8000	8.4581
Directional Control (right)	2.666	4.285	.052	14.8000	5.5516
Endpoint Excursion (back)	-.513	8	.622	-6.4000	12.4643
Endoint Excursion (composite)	-.921	8	.384	-5.0000	5.4295
Endpoint Excursion (forward)+	-2.423	8	.042	-17.0000	7.0157
Endpoint Excursion (left)*	.369	8	.722	5.0000	13.5617
Endpoint Excursion (right)	-.072	8	.945	-.8000	11.1553
Movement Velocity (forward)	-1.286	8	.234	-.8800	.6844
Movement Velocity (back)	-2.068	8	.072	-1.0000	.4835
Movement Velocity (composite)	-1.706	8	.126	-.6600	.3868

Table 4.—Components of the Tests for Dynamic Stability (Cont.)

	t	df	Significance (2-tailed)	Mean Difference	Standard Error Difference
Movement Velocity (left)	-1.557	8	.158	-.8000	.5138
Movement Velocity (difference)	.427	8	.680	.3400	.7954
Movement Time (difference)	.525	8	.614	2.6000	4.9497
Movement Time (left leg)	1.062	8	.319	.1240	.1168
Movement Time (right leg)	-.151	8	.884	-3.80E-02	.2519
Maximum Excursion (back)	.044	8	.966	.6000	13.5314
Maximum Excursion (composite)	-.744	5.644	.487	-2.4000	3.2249
Maximum Excursion (forward)+	-2.645	8	.029	-13.4000	5.0656
Maximum Excursion (left)*	.028	8	.978	.2000	7.1764
Maximum Excursion (right)	.346	8	.738	2.4000	6.9397
On-axis Velocity (composite)	-.266	8	.797	-.1200	.4508
On-axis Velocity (forward/backward)	-.727	8	.488	-.3400	.4680
On-axis Velocity (left/right)*	.303	8	.770	.1600	.5278
Reaction Time (backward)	-.191	8	.853	-5.00e-02	.2611
Reaction Time (composite)	1.284	8	.235	.1120	8.726E-02
Reaction Time (forward)	.174	8	.866	3.80E-02	.2185

Table 4.—Components of the Tests for Dynamic Stability (Cont.)

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

* Indicates data were not normally distributed.
+ Indicates data were significant.

CHAPTER V

DISCUSSION

Since there were no significant increases or decreases of balance in the treatment group following four weeks of retraining sessions, the "gain-loss" variable was used to determine if significant changes occurred between the control and treatment groups. The "gain-loss" variable does not specify if increases or decreases in performance occurred or in which group it occurred. It only reports if a significant change occurred between the groups.

The findings of this study showed significant changes in only two out of 31 components of dynamic balance. There were no significant changes in balance components of static steadiness or symmetry between the control and treatment groups.

A significant change in dynamic balance was found in the distance the subject traveled in the forward direction toward the target boxes set up at 50% and 75% LOS before corrective attempts were made. This means there was a change in anticipatory (feedforward) movement planning of the CNS indicating learning where in space to go and how to get there.[10] Another finding of this study indicated there was also a significant change in the distance traveled in a forward direction to the target boxes. There may have possibly been a change in muscle strength and/or ankle joint range of motion allowing for a change in

excursion. Other causes for the change in distance traveled may have been caused from subjects in the treatment group having a decrease in fear and perceptual limitations.[10] This could be due to experience using the NBM® and feeling safer when performing excursions during retraining sessions because two researchers were standing on each side of them. Subjects may have taken more of a risk in moving to the boundaries of LOS because they knew someone was there to catch them if they lost their balance. The changes in excursions during retraining sessions in the treatment group may have carried over during the final assessments causing the significance between groups. The significance of these two components of dynamic balance means the LOS boundaries changed in the forward direction in respect to reaching the target boxes on the initial attempt and the distance traveled.

Finding significance for static steadiness was more difficult because four out of five balance components could not be used for reporting results. The only balance component that could be used for reporting results looked at how much steadiness is present in static standing with eyes open. Steadiness during standing with eyes open was tested during standing on either a firm or foam surface depending on which level subjects were tested.

The level at which subjects were tested determined which balance systems dominated in decreasing postural sway. Three subjects in the control group and four in the treatment group reached the 50% LOS boundary. Therefore, they were assessed at Level I for the respective test which involved using a firm surface with eyes open. Using a firm surface with eyes open

focused more on the function of the visual and somatosensory systems. Two subjects from the control group and one from the treatment group reached the 75% LOS boundary. Therefore, they were assessed at Level II that used a foam surface to stand on with eyes open. Testing using the foam surface decreased the use of the somatosensory system because proprioceptor inputs were hindered from decreased feedback. Subjects tested at Level II relied more heavily on the function of the visual and vestibular system.

The degeneration of the visual system weighs more for the insignificance of change in sway because both Level I and II relied on this balance system for postural control. Three out of five subjects in the treatment group reported involvement of the visual system which may have accounted for the insignificance in changes found in this particular balance component test. The decreased function of the visual system might have caused subjects to inadequately compare the surrounding environment for reference of the body to vertical and horizontal alignments.

Measurement of balance symmetry was tested during both static and dynamic tasks. Most people with MS are more involved on one side of the body compared to the other (5 subjects were more involved on left, 4 more involved on right, 1 equal involvement). Previous studies have shown that visual force platform feedback is effective in retraining balance symmetry in CVA subjects.[7,9,19,28] Results from these studies cannot be readily compared to subjects with MS because the breakdown of the CNS occurs differently between the two subject populations. Multiple sclerosis is a progressive deterioration of

the CNS resulting in irreversible sclerosed areas in the spinal cord or cerebral cortex or both causing permanent inhibition in the neural transmissions of the balance systems. Whereas, CVA is not a progressive disease. Instead, it involves breakdown of the CNS cells (cerebral cortex, brainstem) from occlusion of blood vessels or hemorrhaging.

The insignificance of the majority of the data shows the study was not effective in retraining balance systems due to the permanent degeneration of the CNS. Other possible causes of the insignificance of results is that the NBM® was not effective in the treatment group for improving strength and sensation to promote equal weight bearing in sitting and standing activities.

Limitations of Study

Besides debilitating changes in the communication of balance systems of the CNS, neuropsychological deficits can also hinder balance performance when using the NBM®. Studies have found that subjects with MS have deficits in verbal and nonverbal learning, memory impairment, and decreases in sustained attention.[30] Also, deficits in retention and retrieval were more pronounced for visuospatial information than for verbal information.[26] This can have detrimental effects on assessment and retraining sessions. Subjects may not be able to adequately process visual input on the screen; for example, the box stating the word, "GO." This may cause a delayed reaction and will affect assessment findings.

The decreases in cognitive ability can cause the learning curve associated with the NBM® to shift to the right. This effect concludes that 12 balance

retraining sessions during this study may not have been enough to cause a lasting effect in balance. More retraining sessions may have been required in subjects with MS to get the same training effect in subjects without the cognition and neuropychological deficits.

Since depression is present in 27% of people with MS,[30] it may play a role in the research findings. Studies have shown the incidence of depression is significantly more common in subjects with MS when compared to matched control subjects with some other neurological disease.[26] Symptoms of depression include pessimism, fatigue, difficulty making decisions,[31] difficulty concentrating or thinking clearly, change in sleep and eating habits,[31,32] change in self-esteem, and loss of energy.[32] It has been found that depression is caused by an external factor in people with MS.[30] Since all subjects reported some degree of balance difficulty (4 mild, 5 moderate, and 1 severe), the focus of this study was on balance retraining. Participation in this study could have made subjects more aware of the debilitating effects of MS on their balance. The increased awareness in the deterioration of balance could have directly induced depression or, if depression was already present, increased their levels of depression creating a downward spiral of decreased balance.

Motivation could be directly related to depression levels. If subjects were feeling "down and blue," they are more than likely going to feel tired and avoid participating in activities.[33] Pre-morbid motivation status would also be an important indicator of post-morbid motivation. If subjects were not very

motivated individuals before the debilitating effects of the disease set in, they are more than likely not going to change and become more motivated.

Fatigue can be a significant cause of disability in the individual with MS. It is one of the most commonly reported problems of MS brought on by muscle weakness and strain, depression, and elevated body temperature.[1] The loss of energy and limited tolerance to exercise secondary to fatigue contributes to a decrease in physical performance. All subjects in the study were instructed not to participate in any extracurricular activities outside the study so a treatment effect could be accredited solely to the NBM®. Although this was taken into account, activities immediately before the assessment and retraining sessions were not controlled. Individuals with MS can have adverse reactions to hot baths, hot packs, heat from the weather, fever, and exercise. The result is worsening of the clinical signs and symptoms of MS causing increased fatigue and reduced function. This could have a big impact on retraining effects and results. Subjects in the treatment group who were engaging in activity that increased body temperature may not have been able to perform at optimal levels when retraining using the NBM®. This would cause the final assessment scores of the treatment group to have less of a change and, therefore, result in insignificant data when compared to the control group.

This study did not address how participation of the treatment group in the study affected their function at home and in the community. Although there were no significant findings from this study, if subjects reported an increase in function at home or in the community, this study could have been looked at as beneficial.

The ultimate goal of treatment for MS is to enable the subject to take part in a safe and fulfilling lifestyle as much as possible. Future studies should include a functional assessment tool to monitor progress throughout the study. Numerous reliable and valid assessment tools are available like the Rivermead Motor Assessment or Ten Point Activities of Daily Living Scale[9] that measures endurance, transfers, standing mobility, and ambulation. The results from these tools can be used to determine if increases in safety and independence were manipulated from the study.

Participation in this study was dependent upon subjects who received care from the Altru Hospital in Grand Forks, North Dakota. This did not allow for selection of subjects through the process of random selection. Also, the subject's availability to participate in the study was dependent upon proximity and time conflicts. Subjects who lived out of town were not able to comply with the requirements of balance retraining sessions three times per week. Therefore, subjects who lived out of town only participated in the control group and subjects who lived in Grand Forks participated in the treatment group.

The area the study was conducted only allowed for a small number of individuals with MS. The small number of individuals available for the study resulted in a control and treatment group that were not normally distributed. The benefit of a large sample size would allow researchers to perform a matched subject analysis for the control and treatment groups. This would account for age, type of MS, duration of disease, utilization of an assistive device, gender, and side of more involvement. Minimizing the variables at the beginning of the

study through matching of subjects would allow for a clearer interpretation of results and they could be attributed more to the treatment effect of the NBM®.

This study did not limit the subject groups to one particular type of MS: benign, exacerbating-remitting, remitting-progressive, progressive. Although no subjects reported an exacerbation of symptoms throughout the entire course of the study, subtle changes occurring from the progressive nature of the disease in some types of MS could not be accounted for. This would hinder the retraining effects using the NBM® in the treatment group causing insignificant differences in results.

There is a chance subjects from the treatment group could have benefited more from the study if a home exercise program was included in adjunction to the retraining sessions using the NBM®. The effects of exercise could have had an impact on increasing strength, proprioception, and range of motion. As long as the exercises were not performed right before the retraining sessions, the positive effects of exercise would allow for utilization of the ankle, knee, and hip balance strategies from increases in strength and range of motion.

Clinical Implications

Research in the field of physical therapy is limited; therefore, all conducted research is beneficial because it can serve as a starting point for further research. Many changes would be made if this study were conducted again to decrease the variables associated with MS and accredit changes resulting from the study to the NBM®.

CHAPTER VI

CONCLUSION

Problems in balance are a common occurrence in individuals with MS.[1,3,4,23,25] Although balance difficulties are a limiting factor for a majority of the MS population, no research has been conducted using a visually augmented biofeedback platform system in retraining balance with MS subjects. Numerous studies have been completed using visual force platform feedback in the retraining of balance in subjects who have experienced CVA.[9,12,19,28] As mentioned earlier, results from CVA studies cannot be readily compared to studies using subjects with MS because of the different process that occurs in each of the populations during destruction of the CNS. Although studies between CVA and MS subject groups cannot be readily compared, it is beneficial for researchers to read the literature available from the CVA studies because it is a starting point for MS research using the NBM®. The various procedures followed in these studies can be revised and incorporated into effective balance retraining programs for studies with MS subjects.

This study looked at the effects the NBM® had on balance in subjects with MS following a four-week retraining program. Results showed that the device did not have a significant effect on measures of static steadiness and symmetry. In addition, two of 31 dynamic balance components showed significant changes

between groups, endpoint excursion forward and maximum excursion forward. The findings indicate the NBM® had a significant effect on movement in the forward direction with changes occurring in the distance traveled before corrective attempts were made and the furthest distance traveled. Although questions exist as to the effectiveness of this tool for retraining programs of balance, it can still be used in hospitals and clinics for assessments of balance in patients with MS. With the "learning curve" taken into account, the tool provides quick, objective data for documenting changes throughout the treatment program. The quantitative information can be used in conjunction with qualitative information provided from the tester to describe the patient's performance in utilizing balance strategies. A thorough comparison of all the available assessment tools is recommended before purchasing the NBM® as it might not be the most cost-effective choice for assessment testing.

Since this study was conducted using a small sample size and there are no previous studies for comparison, findings cannot totally exclude the NMB® from being an effective therapeutic treatment modality in retraining balance. Future research is needed with a larger sample size to allow for random selection and a normal distribution of groups to determine if the NBM® is an effective tool for retraining of balance.

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.

Principal Investigator: Biana Zearley, Becky Coy, Jill Steinmetz Phone #: Biana, 775-1061 Jill & Becky, 746-9508 Date: 3/26/98

Institution: University of North Dakota 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
☐ Dissertion 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 ____ .

__X__ 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)

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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 assessin balance impairments and in balance retraining in individuals suffering from cerebro-vascular accidents, traumatic brain injuries, orthopaedic disorders, or Parkinson's Disease. There is limited research which utilizes the NeuroCom Balance Master for balance assessment and training in individuals with MS. Therefore, this research project will contribute to expanding research in improving balance in the MS populatio. Inter-reliability and intra-reliability of the researchers was determined prior to starting the research project by testing three individuals with no experience using th 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 tha 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 prin out 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 obtaine 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 curren level of MS. At the end of the four-week period, the treatment group will also perfor a final assessment. These data will be compared to the final assessment of the contro 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 assessmen 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: 3-26-98

Project Director: _____ Date: 3-26-98

Student Advisor (where applicable): _____ Date: 3-26-98

APPENDIX B

NOTE: EDDS steps 1.0 to 4.5 refer to patients who are fully ambulatory, and the precise step number is defined by the Functional System score(s). 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 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1), or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 500 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 if full activity or require minimal assistance; characterized by relatively severe disability usually 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.

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, crutches, 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 5 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 perambulated 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 arm(s); retains some self-care functions; (usual FS equivalents are combinations generally 4+ in several systems).

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

9.5 - Totally helpless bed patient; unable to communicate effectively or 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 (cane, single crutch) to walk; uses support more than 80% of the time. Walks 25 feet in 20 seconds or less.

5 - Requires bilateral support (canes, crutches, walker) and walks 25 feet in 20 seconds or less; or, requires unilateral support but walks 25 feet in greater than 20 seconds.

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

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

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

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

5. **Bowel and Bladder Functions**
   - 0 = Normal
   - 1 = Mild urinary hesitancy, urgency, or retention
   - 2 = Moderate hesitancy, urgency, retention of bowel bladder or rare urinary incontinence (intermittent self-catheterization, manual compression to empty bladder, or finger evacuation of stool)
   - 3 = Frequent urinary incontinence
   - 4 = In need of almost constant catheterization (and constant use of measures to evacuate stool)
   - 5 = Loss of bladder function
   - 6 = Loss of bowel and bladder function
   - 9 = Unknown

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

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

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

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 fourweeks 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 you 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

Name:
Date:

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

MULTIPLE SCLEROSIS INITIAL EVALUATION

Subjects name:
Age:
Height:

MMT:
Sitting
Hip flexion
Knee extension
Knee flexion
Ankle DF

Supine
Hip abduction
Hip adduction

Prone
Hip extension

ROM
Supine
Hip flexion
Knee flexion

Sitting
Knee extension
Ankle DF
Ankle PF

Reflexes
Patella
Achilles

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

APPENDIX F

Glossary:

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

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

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

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

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

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

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