Establishing intra-reliability and normative data in physical functioning assessments: a pilot study

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ESTABLISHING INTRA-RELIABILITY AND NORMATIVE DATA IN PHYSICAL FUNCTIONING ASSESSMENTS:

A PILOT STUDY

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A Scholarly Project
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for the degree of
Doctor of Physical Therapy

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This scholarly project, submitted by Scott Jackson, Ryan Schrock, and Mark Wilson in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Faculty Advisor under whom the work has been done and is hereby approved.

Graduate Advisor

Chairperson
PERMISSION

Title   Establishing Intra-reliability and Normative Data in Physical Functioning Assessments: A Pilot Study

Department  Physical Therapy

Degree  Doctor of Physical Therapy

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ABSTRACT

PURPOSE: Normative data ranges are not available for all functional balance tests for all age groups. The purpose is to establish intra-reliability and normative age-sensitive data ranges in a battery of functional balance-related measures including the modified Clinical Test for Sensory Integration and Balance (mCTSIB), One-legged Stance Test (OLST), Functional Reach Test (FRT), 30-second Sit-to-Stand Test (30STS), 10-meter Walk Test (10MWT), and Activities-specific Balance Confidence Scale (ABC Scale).

METHODS: Ninety-two subjects (n = 92), aged 19-87 years, were tested with each of these balance tests. Participants were randomly assigned the order in which to complete the six balance tests. Intra-rater reliability was established for the FRT, 30STS, and 10MWT using 10 subjects. Data were compiled into normative distributions into three age cohorts for all six tests, 19-39 years old, 40-59 years old, and 60 and older age ranges. Repeated-measure ANOVA was used to compare age cohorts for the FRT, 30STS, 10MWT, and ABC Scale. Bonferroni post hoc analysis was used to assess for statistically significant differences between age groups for the FRT, 30STS, 10MWT, and ABC Scale. Cross tab analysis was used to assess the frequencies of age group performances on the mCTSIB and OLST.
RESULTS: Reliability was established for the FRT (ICC = 0.976), 30STS (ICC = 0.973), and 10MWT (ICC = 0.824). Reliability could not be statistically determined for the mCTSIB, OLST, and ABC Scale. The main findings of this study indicated that the differences in balance between different age categories were apparent among younger cohort groups (19-39 years and 40-59 years) and older-aged group (60-87 years).

CONCLUSION: The results of the present study provide normative values for six balance tests for three age cohorts, 19-39 years old, 40-59 years old, and 60-87 years old. Intra-rater reliability was established for the FRT, 30STS, and 10MWT. Deterioration in balance appears to begin after people turn 60 years and older. The findings from this study can be used by clinicians and researchers when assessing balance capabilities of their clientele.
CHAPTER I
INTRODUCTION AND LITERATURE REVIEW

Balance is required for maintaining a position, remaining stable while moving from one position to another, performing activities of daily living, and moving freely. However, a decline in balance ability has been shown to occur with increasing age. Comprised of vestibular, visual, and kinesthetic systems, balance deficits have a wide range of effects that can result in significant limitations that decrease quality of life. Deficits in balance, functional transitions, and walking can also occur due to a multitude of disease processes that are symptomatic to musculoskeletal, cardiovascular, and neurological disorders. Inactivity and the aging process yield balance and functional pathologies. The maintenance of balance function is essential to stay physically active and to participate in a healthy lifestyle.¹

Functional balance and walking assessments are widely utilized by a variety of health professionals. Clinically, these assessments are used to determine functional limitations, diagnose and localize the severity of injury and disease, provide physical rehabilitation, and used as objective measurements to determine improvement and rehabilitation outcomes. Many standardized functional assessments score individual functional and transitional activities of daily living to compile a composite score, thereby identifying the severity of

¹
functional limitations. Individual tests and measures have been utilized to assess various human balance systems, neural control centers, and abilities. Reimbursement organizations operate on optimal outcomes of treatment. Standardized functional assessments provide objective measurement of outcomes, thereby offering a measure of patient and clinician performance effects.

Functional assessments prove integral from initial contact, throughout treatment, to discharge. Given the current scope of healthcare systems, outcome measures, policies, and reimbursement are dependent on objective functional measurements.² These functional tests are based on empirical evidence. Given the vast number of tests available to the clinician, it is important for the practitioner to select the tool appropriate for both the patient and clinical setting, thus implementing evidence-based treatment.³ The balance tests that are selected by the clinician have to be a valid and reliable source of assessment.

The individual tests used in this study were chosen for the specific objective functional measures they provide, including lower extremity strength, somatosensory-vestibular control, and static and functional movement. These tests include the modified Clinical Test of Sensory Integration and Balance (mCTSIB), One-legged Stance Test (OLST), Functional Reach Test (FRT), 30-second Sit-to-Stand Test (30STS), 10-meter Walk Test (10MWT), and the Activities-specific Balance Confidence Scale (ABC Scale).
Modified Clinical Test of Sensory Integration and Balance

The mCTISB is a static postural test that subjectively measures somatosensory and vestibular control in individuals with neurological deficits, such as multiple sclerosis, Parkinson's disease, or results of aging. There are four static sensory conditions which include eyes open-firm surface, eyes closed-firm surface, eyes open-unstable surface (foam), and eyes closed-unstable surface (foam).

The mCTSIB is not used as a reliability tool of measurement amongst clinicians. However, inter-observer reliability has been seen between computerized and clinician posturography. A study carried out by Loughran et al assessed inter-observer reliability in postural stability and compared it with results obtained by computerized posturography. A total of 81 patients volunteered with a primary complaint of imbalance. Inter-rater reliability between two clinicians and the modified Clinical Test for the Sensory Interaction on Balance as assessed by the Neurocom VSR Balance Master platform was evaluated. The inter-rater reliability scores were high for all conditions of the mCTSIB except eyes open-firm surface. Overall, there was good agreement between observers and the computerized mCTSIB.

The ability to maintain an upright position during quiet standing is a useful motor skill. There has not been a normative data age range for the mCTSIB. A study performed by Cohen et al assessed three groups of neurologically asymptomatic (AS) adults and divided them by age into younger, middle-aged, and older groups. A fourth group was comprised of subjects diagnosed with
vestibular disorders. All groups were assessed under the sensory conditions of the mCTSIB. They found subjects with vestibular disorders were significantly impaired on performance when compared with age-matched AS subjects. Older AS and vestibular impaired subjects had greater variation in their score than did younger AS subjects. The mCTSIB was found to be a useful screening tool for examining static standing.

A study conducted by Raiva et al\textsuperscript{8} was undertaken to identify the effects of age and gender as a preliminary study in community dwelling adults. Also, this study analyzed if the mCTSIB would be useful in the prevention of fall. A total of 120 male and female subjects between the ages of 30-40 years and 60-70 years were assessed using the Neurocom Balance Master 8.0, or human clinical practitioners, during a mCTSIB test. The authors found that the females aged 60-70 years were more stable than the males at the same age. Age and gender were also significant variables that influence postural stability and static balance.

One-legged Stance Test

The OLST is a static balance test that is used to assess lower extremity strength, balance, and coordination by balancing on one leg. The OLST is utilized by clinicians in balance assessments in individuals with multiple sclerosis, Parkinson's disease, and mental retardation. Frzovic et al\textsuperscript{9} determined OLST was significantly decreased in clients with multiple sclerosis, likely due to decreased ankle strategy. Jacobs et al\textsuperscript{10} determined that the OLST, in conjunction with the FRT and the Unified Parkinson's Disease Rating Scale (UPDRS), were significant in predicting ABC scores and concluded that multiple
tests were required to provide optimal assessment in clients with Parkinson's disease.

A study by Goldie et al\textsuperscript{11} utilizing force platforms on 28 healthy elderly and young adults found that the OLST measures postural steadiness unilaterally. This test calls for the client to stand on one leg for 30 seconds. Goldie et al\textsuperscript{11} and Franchignoni et al\textsuperscript{12} determined this test can be performed with either leg and with eyes open and eyes closed. Iverson et al,\textsuperscript{13} studying 54 men aged 60-90 years, determined the OLST was effective as a measure of postural steadiness in older adults.

Franchignoni et al\textsuperscript{12} tested the reliability of measures with the OLST, FRT, Sharpened Romberg, and 30STS. Two independent observers scored the tests which were performed on two successive days. Inter-rater (IRR) and test-retest reliability (TRR) were reliable across the different tests. Intra-class Correlation Coefficients ranged from 0.95 to 0.99 for scoring consistency between rates and from 0.73 to 0.93 within rates, respectively.

Normative data for the OLST has been established for older age groups. Bohannon et al\textsuperscript{14} established normative data for older female age cohorts as follows: 60-69 years = 22.5 seconds and 70-79 years = 14.2 seconds. Literature does not discuss normative age ranges for older males or younger age groups with the OSLT.

Functional Reach Test

The FRT is a measure of balance and the ability to reach outside a fixed base of support. It is a dynamic reach assessment that is used to assess the
risk of falls, such as the elderly and individuals with Parkinson’s disease. It is the difference between arm’s length and maximal forward reach via a fixed base of support.\textsuperscript{4,5} This test indicates the extent the client can move the center of mass in a forward direction to the limit of stability. A study by Kamata et al\textsuperscript{15} was conducted to determine if the FRT can correlate falls in people with Parkinson’s disease. A total of 21 participants with Parkinson’s disease (11 men, 10 women) were recruited. The results indicated that patients with Parkinson’s disease overestimated their ability limits, which may result in falls. Also, this study corroborates that patients with Parkinson’s disease can fall more often as the disease progresses.

A study by Duncan et al\textsuperscript{16} established the FRT as a reliable assessment measure in functional reach mobility. A total of 128 subjects between the ages of 21-87 years were assessed for a test-retest reliability of the FRT. This study found that age and height influence the FRT. The FRT is useful for detecting balance impairment, change in balance performance over time, and in the design of modified environments for impaired older persons. This study also found the FRT to be portable, inexpensive, reliable, precise, and a reasonable clinical approximator of stability.

Another study by Duncan et al\textsuperscript{17} was conducted to determine the validity of the FRT in predicting the risk of recurrent falls in the elderly. A total of 217 elderly, community-dwelling male veterans between ages 70-104 years underwent baseline screening and were followed for six months to monitor falls. Subjects identified with two or more falls during the six month follow-up were
classified as recurrent fallers. The research concluded that the FRT is a simple and easy-to-use clinical measure that has predictive validity in identifying recurrent falls in the elderly population.

Normative data for the FRT has been established for all age groups. Duncan et al\textsuperscript{16} reports age cohort means as follows: 20-40 years = 16.73 inches for men, 14.64 inches for women; 41-69 years = 14.98 inches for men, 13.81 inches for women; 70-87 years = 13.16 inches for men, 10.47 inches for women.

30-second Sit-to-Stand Test

Ascending from sitting to standing is one of the most common daily activities that people do periodically throughout the day. The 30STS test is an example of such a test which assesses an individual’s lower extremity functional strength, balance, sensorimotor, and psychological parameters. Diminished 30STS scores have been found to be a predictor of decline in functional activities including rising from a chair, walking, and stair climbing. The 30STS has been found to be a reliable and valid measure of lower extremity strength in the elderly.\textsuperscript{18}

Normative data have been established in literature. Frattali et al’s\textsuperscript{2} data were created for males and females between the ages of 60-64 years. Jones et al\textsuperscript{19} have established normative data for men and women between the ages of 60-94 years. The average number of sit-to-stand at age 60 was approximately 12-13 sit-to-stand repetitions for both studies. Both studies found that the number of sit-to-stand repetitions decreases by about one sit-to-stand per decade.
10-meter Walk Test

The 10MWT is used to assess gait velocity, average stride, cadence, coordination of movement, and balance. It has been found to be a reliable test of measure when assessing individuals with spinal cord injuries and stroke.\(^4\) Jones et al\(^9\) found the 30STS is a reasonable, reliable, and valid indicator of lower body strength in generally active, community-dwelling older adults.

The 10MWT is used to evaluate an individual's functional capacity while walking short distances. There is not sufficient evidence to show whether the application of different walking distances provides complementary information about ambulatory capacity in patients. A study conducted by Perron et al\(^{20}\) found that when working with total hip arthroplasty patients, the 10MWT was an acceptable measure of functional mobility.

A study by Wade et al\(^{21}\) found the 10MWT to be a reliable and safe test to assess gait velocity in patients at three months post stroke. They also found the 10MWT to be effective at detecting changes in gait. Salbach et al\(^{22}\) also found the 10MWT to be an effective measure of gait velocity and functional mobility in acute stroke patients. They found the 10MWT was responsive to gait velocity changes in patients. It was also found that gait velocity had a relationship in determining when a patient may be discharged from a hospital.

A study by Bohannon\(^{23}\) established normative data for gait velocity for individuals between the ages of 20-70 years. These data suggest that as people age, there is a general tendency for gait velocity to decline after the age of 60 years.
Activities-specific Balance Confidence Scale

The ABC Scale is a questionnaire that is comprised of 16 questions. It is designed to measure the impact, from a psychological standpoint, of balance impairment and falls. The questionnaire was developed by Hill\textsuperscript{24} to target older people and people at risk for falling. Given the fact this test is subjective, additional training is not required for a clinician to administer this test. The questionnaire takes five minutes for an individual to complete. The client is asked to rate his/her confidence in performing each of the listed activities on a scale from 0 (no confidence) to 100% (complete confidence) without losing balance or becoming unsteady. The client utilizes whole numbers.

Powell et al.,\textsuperscript{25} testing 60 community-dwelling seniors aged 65-95 years, found the ABC Scale both reliable and valid and suggested the scale was more sensitive in detecting loss of balance. The ABC Scale is a suitable measure to detect loss of balance confidence in highly functioning seniors.

A study conducted by Lajoie et al.,\textsuperscript{26} studying 125 subjects, divided the sample into a group of non-fallers (n = 80) and fallers (n = 45). This study found the ABC Scale yields significantly higher scores when comparing non-fallers to fallers. Both the ABC Scale and ABC-6 show high sensitivity in identifying patients with higher level gait disorders as well as moderate sensitivity in identifying Parkinson’s disease clients.\textsuperscript{27}

Purpose of Study

There were two primary purposes for this study. The first purpose is to determine intra-rater reliability through intra-class coefficients (ICC) in tests
utilizing interval and rational data. The tests in which an ICC was calculated included the FR, OLST, and the 30STS. The second purpose of this study is to establish normative age, sensitive age, and data ranges within all six of the balance tests. Normative data ranges are not available in literature for all the balance tests for all age groups (i.e., mCTSIB and the ABC Scale).

Clinical Significance

The results of this study are intended to determine appropriate physical functioning assessments to be used in a forthcoming pesticide study. High level exposure of pesticides yields both acute and long-term neurological effects. Groups of symptoms in several neurological arenas include cognition, autonomic motor function as well as vision.\textsuperscript{28} The future study will try to determine effects on balance and motor control due to pesticide exposure. This information will function clinically as well as within research. The information within this study will provide recommendations specific to testing, such as test order, the number of trials needed for accurate assessment, and time required. This study also provided additional normative data for a broader range of adults (ages 19-87).
CHAPTER II

METHODS

Prior to the start of this study, a project proposal was submitted to the University of North Dakota Institutional Review Board (Appendix A) for approval and for the use of human subjects for this study (IRB# 200705-347). This proposal included a consent form (Appendix B).

Participants

The inclusion criteria included subjects who were healthy, 18 years of age or older, without past medical history of orthopedic injuries, balance or coordination disorders, and had to be able to follow simple directions for the six different balance tests. Ninety-two men and women, aged 19 to 87 years old, were randomly recruited from a large rural region. Volunteers were recruited from the University of North Dakota and the local community. Subjects consisted of healthy ambulatory community-dwelling adults, age ranges from 19 to 87 years. Age cohorts were grouped as follows: 18-39 years (n = 30, mean age = 25.6), 40-59 years (n = 30, mean age = 49.0), and 60-87 years (n = 32, mean age = 72.5) (Table 1). Testing was carried out in the University of North Dakota Department of Physical Therapy and local fitness centers.
Table 1. Sample Size and Mean Age for Grouped Cohorts

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<tr>
<td>19-39 years</td>
<td>30</td>
<td>25.6</td>
</tr>
<tr>
<td>40-59 years</td>
<td>30</td>
<td>49.0</td>
</tr>
<tr>
<td>60-87 years</td>
<td>32</td>
<td>72.5</td>
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All eligible subjects (n = 92) were provided with a consent form describing the study. Subjects then gave written consent in order to participate, after receiving written information and verbal instructions concerning the study.

Instrumentation

The clinical balance measures used in this study included mCTSIB, OLST, FRT, 30STS, 10MWT, and the ABC Scale as described in Chapter I. Tests were performed using the protocols described by the original authors. These balance tests are simple to apply and have been found to be reliable and valid when measuring static and dynamic balance. Static and dynamic movement was measured to give a complete clinical representation of balance across the three age cohorts.

Modified Clinical Test for Sensory Integration and Balance

The mCTSIB is a test modified from the original CTSIB or “Foam and Dome” which eliminates the “dome” and adds subjective analysis of the patient’s static balance control. Inter-observer reliability has been found in literature between clinician and computerized posturography.
The mCTSIB is used among researchers as a measure of postural sway among four sensory conditions. The four static sensory conditions include eyes open-firm surface, eyes closed-firm surface, eyes open-unstable surface (foam), and eyes closed-unstable surface (foam). The classification scheme for identifying normal and abnormal postural control was based on patterns of normal versus abnormal sway in the four different conditions. Abnormal sway is defined as any loss of balance, any abnormal reach outside the base of support, excessive use of hip strategies, and any use of step strategies to regain control of balance. Equipment included a stopwatch and the NeuroCom Balance Master Foam.

**One-legged Stance Test**

The OLST is commonly used among clinical researchers to assess balance, coordination, and strength in static balance ability. The OLST has been found to be both a valid and reliable measure of static balance, coordination, and lower extremity strength.\(^{12,13}\) It is assessed by measuring single-leg stance time up to 30 seconds during three trials. Equipment used included a stopwatch.

**Functional Reach Test**

The FRT is used among clinical researchers to assess the predictability of falls, predominantly amongst individuals at risk.\(^4,5\) The FRT is found in literature to be both valid and reliable test of dynamic reach.\(^16,17\) The FRT is a dynamic balance test that measures how far an individual can reach past the center of gravity while maintaining a fixed base of support. Equipment included a camera tripod, 48-inch yardstick, and tape.
30-second Sit-to-Stand Test

The 30STS is commonly used among clinical researchers to assess lower extremity strength. The 30STS is found to be both valid and reliable as a measure of dynamic lower extremity strength. Individuals were asked to go from sit to stand as many times as they could in 30 seconds. Equipment included a stopwatch and a 43 cm chair.

10-meter Walk Test

The 10MWT is utilized among clinical researchers to assess functional mobility during gait. The 10MWT is found to be a reliable and valid measure of functional mobility. Individuals were asked to walk 13 meters at their normal comfortable pace. Time was measured when they started to walk and stopped when they passed the 10-meter mark. Equipment included a 15-meter walk space, tape, and stopwatch.

Activities-specific Balance Confidence Scale

The ABC Scale is utilized among researchers to measure the impact, from a psychological standpoint, of balance impairment and falls. It has been found in literature to be a valid and reliable test of measurement. Equipment used was a pencil and the ABC Scale questionnaire (Appendix C).

Procedure

After giving informed consent, subjects participated in a structured interview that included questions on health status, medications, mobility status, physical activity level, living status, and any history of orthopedic injury. If inclusion criterion was met, then clinical balance tests were conducted as part of
a balance battery. Testing procedure was always randomized and was established by drawing from six different cards to determine testing order. Ninety-two total subjects, 19 to 87 years of age, were tested. Ten subjects (n = 10) were retested two days later to assess intra-rater reliability through intra-class correlation (ICC) for the OLST, 30STS, FRT, and 10MWT.

All of the measurements were taken in the afternoons at approximately the same time of the day. The tests were administered in a room. Testing examinations were administered by a combination of three student physical therapists who were trained prior to examination. Subjects performed all static and dynamic tests without shoes and were given rests between tests. Safety was also ensured by utilizing a gait belt through all tests in conjunction with the use of a spotter. The tests were timed by a stopwatch and timing was stopped if testing protocol was violated for each test respectively. Standardized instruction forms were used for each test (Appendix D).

**Modified Clinical Test for Sensory Integration and Balance**

All participants were educated on the purpose of the mCSTIIB and how to perform the test using a standardized instruction form. The subjects were asked to perform a series of four conditions which included eyes open-firm surface, eyes closed-firm surface, eyes open-unstable surface (foam), and eyes closed-unstable surface (foam) (Figures 1a, 1b, 1c, 1d). Each individual condition was performed for a duration of 30 seconds. If the participant exhibited abnormal sway, the time was stopped and recorded for that trial in any of the four
Figure 1a. mCTSIB - Condition 1 - Floor.

Figure 1b. mCTSIB - Condition 2 - Floor.
Figure 1c. mCTSIB - Condition 2 - Foam.

Figure 1d. mCTSIB - Condition 2 - Foam.
conditions in which abnormality was observed. The time to administer this test was approximately five minutes in duration.

**One-legged Stance Test**

All participants were educated on the purpose of the OLST and how to perform the test using standardized instructions. Participants were required to stand on one leg, of the client’s choice, for 30 seconds with the arms folded across the chest (Figure 2). The client was timed in three different trials utilizing the original chosen leg. Instructions were also given to factors which would result in the time being stopped. These incidences included uncrossing the arms, touching the raised leg to the stance leg, regaining balance by lowering the raised leg to the ground, or exhibiting abnormal sway in order to re-establish single leg balance. The subject could take as long of a standing rest between trials as needed. The test took approximately four minutes to complete after averaging rest breaks between individuals. The average rest break between trials was 20 seconds in duration.

**Functional Reach Test**

All participants were educated on the purpose of the FRT and how to perform the test using standardized instructions. A level, 48-inch yardstick was secured to an adjustable camera tripod and adjusted to the level of the subject’s acromion. Individuals stood in a relaxed stance, raised their left arm until it was parallel with the yardstick (approximately 90 degrees of shoulder flexion). The subject placed the tip of the third metacarpal at the beginning of the yardstick and proceeded to reach as far forward as he/she could without taking a step or
losing balance (Figure 3). The position of the third metacarpal was recorded. No attempt is made to control the individual’s method of reach. The subject completed three trials, with the FRT calculated as the mean between the individual trials. Neither shoes nor socks were worn during the testing of the FRT. The complete Functional Reach Test was approximately five minutes in duration.

30-second Sit-to-Stand Test

All participants were educated on the purpose of the 30STS and how to perform the test using standardized instructions. After listening to the instructions, the participant were allowed to ask questions about the test. Participants began sitting in a chair 43 cm high without arm rests. Feet were flat
on the ground with arms crossed across the chest (Figure 4a). The researcher began the stopwatch when the participants began to rise from the chair and counted how many sit-to-stand repetitions the individual made in 30 seconds in a controlled fashion (Figure 4b). A sit was defined as touching an individual's rear to chair; a stand was defined as bringing knees to approximately 5-8 degrees of flexion. The subject completed three trials, with the 30STS calculated as the mean between the trials. Rest breaks were given to the subjects between trials; the length of the break was individually determined. The time to administer this test was approximately five minutes in duration.
Figure 4a. 30STS - Position 1.

Figure 4b. 30STS - Position 2.
10-meter Walk Test

All participants were educated on the purpose of the 10MWT and how to perform the test using standardized instructions. After listening to the instructions, the participants were allowed to ask questions about the test. The participants began at the starting line, waiting for the start signal from the examiner. The examiner would raise an arm to prepare the participants, and the time would begin when the arm was lowered. After the starting signal, the participants walked in a straight line two meters past the 10-meter mark line at normal walking pace (Figure 5). When the participant's foot crossed the end of the tape, the timer would be stopped. The performance time was kept by the researcher and was measured in seconds. Participants were asked to perform this test three times and an average was then recorded. The time to administer this test was approximately five minutes.

Activities-specific Balance Confidence Scale

All participants were educated on the purpose of the ABC Scale and how to perform the test using standardized instructions. Participants were allowed to sit at a table to complete this self-report balance questionnaire. The participant was informed he/she had as much time as necessary to fill out the questionnaire and questions could be asked at any time. The scale was scored by totaling the ratings (total range 0-1600) and dividing by 16 for the total ABC scores (See Appendix C). The test took approximately five minutes to complete respectively between individuals.
Inter-rater Reliability

Based on tester performance, an ICC was run for the FRT, 30STS, and 10MWT to determine the average measure intra-class correlation, comparing the mean score for the ten participants measured on two separate days. ICC was not run for the mCTSIB and OLST because the tests were run only for 30 seconds, not until participants lost their balance or fatigued, making it statistically impossible to run an ICC. An ICC score was not determined for the ABC Scale because previous research has established this test reliability. The results indicated clear and significant tester reliability within the FRT, 30STS, and the 10MWT (Table 2).
Table 2. ICC Significance Levels for FRT, 30STS, and 10MWT

<table>
<thead>
<tr>
<th>Test</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional Reach Test</td>
<td>0.977</td>
</tr>
<tr>
<td>30-second Sit-to-Stand Test</td>
<td>0.973</td>
</tr>
<tr>
<td>10-meter Walk Test</td>
<td>0.824</td>
</tr>
</tbody>
</table>

Data Analysis

Descriptive statistics provided means, standard deviation, and 95% confidence intervals (CIs) for each balance measure across all three age cohorts. The clinical balance test results were compared with existing available published norms.

All analyses were carried out with the SPSS (Version 15.0) statistical software package for windows. The statistical analyses conducted by SPSS software take into account the sampling design. A probability level of $p < 0.05$ was used to indicate statistically significant observations in all the analyses. A Kruskal-Wallis test and a repeated-measure ANOVA were used to analyze the differences between age groups and calculate the mean and standard deviation for age groups for the FRT, 30STS, 10MWT, and ABC Scale. Findings between the Kruskal-Wallis and repeated-measure ANOVA were similar. The repeated-measure ANOVA data are given. Statistical relationship between qualitative features for the mCTSIB and OLST were evaluated by cross tab analysis.
Recording of Results

Upon completion of this study, the results were analyzed and recorded. A copy was given to the University of North Dakota Library of the Health Sciences as well as the Department of Physical Therapy.
CHAPTER III

RESULTS

A Kruskal-Wallis test and a repeated-measure ANOVA were used to analyze the differences between age groups and calculate the mean and standard deviation for age groups for the Functional Reach Test (FRT), 30-second Sit-to-Stand Test (30STS), 10-meter Walk Test (10MWT), and Activities-specific Balance Confidence Scale (ABC Scale). Findings between the Kruskal-Wallis and repeated-measure ANOVA were similar. The repeated-measure ANOVA data are given. A cross tab analysis was used to evaluate the modified Clinical Test for Sensory Integration and Balance (mCTSIB) and the One-legged Stance Test (OLST). Findings are given among all three age cohorts (19-39 years, 40-59 years, and 60-87 years).

A cross tab analysis was used on the mCTSIB to assess the frequencies of stance time (0-9, 10-19, 20-29, and 30 seconds) in all age cohorts. The mCTSIB classification scheme for identifying normal and abnormal postural control was based on patterns of normal versus abnormal sway in the four different conditions (N = normal sway, A = abnormal sway). Abnormal was considered not meeting the 30-second time limit in the condition that was being tested. All participants were able to complete the 30-second time limit for eyes open-stable surface and eyes closed-stable surface conditions (Tables 3 and 4).
Table 3. Frequencies for mCTSIB Eyes Open-Stable Surface

<table>
<thead>
<tr>
<th>mCTSIB Eyes Open-Floor</th>
<th>n</th>
<th>≥ 30 seconds f</th>
</tr>
</thead>
<tbody>
<tr>
<td>19-39 years old</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>40-59 years old</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>60-87 years old</td>
<td>32</td>
<td>32</td>
</tr>
</tbody>
</table>

Table 4. Frequencies for mCTSIB Eyes Closed-Stable Surface

<table>
<thead>
<tr>
<th>mCTSIB Eyes Closed-Floor</th>
<th>n</th>
<th>≥ 30 seconds f</th>
</tr>
</thead>
<tbody>
<tr>
<td>19-39 years old</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>40-59 years old</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>60-87 years old</td>
<td>32</td>
<td>32</td>
</tr>
</tbody>
</table>

In condition three, eyes open-unstable surface, two subjects, in the oldest age group, exhibited abnormal postural sway and the time was stopped between 10-19.99 seconds (Table 5). The 19-39 year and the 40-59 year age cohorts completed the full 30 seconds and were considered within the normal limits of sway.

In condition four, eyes closed-unstable surface, there were two (n = 2) subjects who did not complete the full 30 seconds in the 41-59 year age group. The trial was subsequently stopped before ten seconds, thus illustrating the
Table 5. Frequencies for mCTSIB Eyes Open-Foam

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>19-39 years</td>
<td>30</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>40-59 years</td>
<td>30</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>60-87 years</td>
<td>32</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>30</td>
</tr>
</tbody>
</table>

inability to maintain a static stance in this condition. A total of 13 subjects (n = 13) exhibited abnormal postural sway in the 60-87 year age group. Ten participants (n = 10) completed the fourth trial with a duration of less than ten seconds, and three subjects (n = 3) completed the fourth trial with a duration of less than 20 seconds. This indicated that a total of 41% of participants in the 60-87-year-old group did not complete the full 30-second time limit and 7% of participants did not complete the full 30-second time limit in the 30-49 year age group. The 60-87 year age cohort tended to have significantly higher incidence of abnormal postural sway when compared to the 19-39 year and 40-59 year age groups. These findings illustrate the increasing difficulty of maintaining a static posture with increasing age between all age cohorts in this study.

A cross tab analysis was also utilized for the OLST data analysis. The analysis found that all participants in the 19-39 year age cohort (n = 30) were able to stand for 30 seconds. In contrast, 76% of the participants in the 40-59 year age cohort (n = 30) were able to stand for 30 seconds. For the 60-87 year
Table 6. Frequencies for mCTSIB Eyes Closed-Foam

<table>
<thead>
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<tbody>
<tr>
<td></td>
<td></td>
<td>f</td>
<td>f</td>
<td>f</td>
<td>f</td>
</tr>
<tr>
<td>19-39 years</td>
<td>30</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>40-59 years</td>
<td>30</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>28</td>
</tr>
<tr>
<td>60-87 years</td>
<td>32</td>
<td>10</td>
<td>3</td>
<td>0</td>
<td>19</td>
</tr>
</tbody>
</table>

Age cohorts (n = 32), 9.4% of the participants were able to stand for 30 seconds, while 90.6% of the participants were unable to stand greater than 19.99 seconds (Table 7). The 60-87 year age cohort has a tendency toward decreased single leg stance time when compared to the 19-39 year and 40-59 year age cohorts in this study.

Table 7. Frequencies for OLST Trial One

<table>
<thead>
<tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td>f</td>
<td>f</td>
<td>f</td>
<td>f</td>
</tr>
<tr>
<td>19-39 years</td>
<td>30</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>40-59 years</td>
<td>30</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>23</td>
</tr>
<tr>
<td>60-87 years</td>
<td>32</td>
<td>18</td>
<td>11</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>

For the FRT, 30STS, 10MWT, and the ABC Scale, the repeated-measure ANOVA found a significant difference between age groups. Using Bonferroni post hoc analysis, the younger two age cohorts (19-39 years, 40-59 years) performed at a higher functional status than the oldest age cohort (60-87 years).
for all the tests (Tables 8, 9, 10, and 11). There is no significant difference between the 19-39 years and 40-59 years age cohorts for any of the four tests.

Table 8. Repeated Measures ANOVA for the FRT-mean of 3 Trials

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>M</th>
<th>SD</th>
<th>F</th>
<th>df</th>
<th>p</th>
<th>eta^2</th>
<th>power</th>
</tr>
</thead>
<tbody>
<tr>
<td>19-39 years</td>
<td>30</td>
<td>16.71</td>
<td>1.91</td>
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<tr>
<td>40-59 years</td>
<td>30</td>
<td>15.52</td>
<td>6.63</td>
<td>13.63</td>
<td>2,89</td>
<td>&lt;0.001</td>
<td>0.234</td>
<td>0.998</td>
</tr>
<tr>
<td>60-87 years</td>
<td>32</td>
<td>11.36</td>
<td>2.74</td>
<td></td>
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<td></td>
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</table>

Table 9. Repeated Measures ANOVA for the 30STS-First Trial

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>M</th>
<th>SD</th>
<th>F</th>
<th>df</th>
<th>p</th>
<th>eta^2</th>
<th>power</th>
</tr>
</thead>
<tbody>
<tr>
<td>19-39 years</td>
<td>30</td>
<td>21.55</td>
<td>8.06</td>
<td></td>
<td></td>
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<td>40-59 years</td>
<td>30</td>
<td>18.53</td>
<td>5.52</td>
<td>20.75</td>
<td>2,88</td>
<td>&lt;0.001</td>
<td>0.320</td>
<td>1.000</td>
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<tr>
<td>60-87 years</td>
<td>32</td>
<td>11.68</td>
<td>4.51</td>
<td></td>
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<td></td>
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</tbody>
</table>

Table 10. Repeated Measure ANOVA for the 10MWT-Second Trial

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>M</th>
<th>SD</th>
<th>F</th>
<th>df</th>
<th>p</th>
<th>eta^2</th>
<th>power</th>
</tr>
</thead>
<tbody>
<tr>
<td>19-39 years</td>
<td>30</td>
<td>7.39</td>
<td>0.949</td>
<td></td>
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<tr>
<td>40-59 years</td>
<td>30</td>
<td>7.36</td>
<td>0.906</td>
<td>28.68</td>
<td>2,89</td>
<td>&lt;0.001</td>
<td>0.392</td>
<td>1.000</td>
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<tr>
<td>60-87 years</td>
<td>32</td>
<td>9.04</td>
<td>1.150</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Table 11. Repeated Measures ANOVA for the ABC Scale-Mean of 3 Trials

<table>
<thead>
<tr>
<th>ABC Scale</th>
<th>n</th>
<th>M</th>
<th>SD</th>
<th>F</th>
<th>df</th>
<th>p</th>
<th>eta²</th>
<th>power</th>
</tr>
</thead>
<tbody>
<tr>
<td>19-39 years</td>
<td>30</td>
<td>97.61</td>
<td>3.45</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-59 years</td>
<td>30</td>
<td>97.44</td>
<td>4.21</td>
<td>15.647</td>
<td>2, 89</td>
<td>&lt;0.001</td>
<td>0.260</td>
<td>.0999</td>
</tr>
<tr>
<td>60-87 years</td>
<td>32</td>
<td>86.96</td>
<td>13.64</td>
<td></td>
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</tbody>
</table>
CHAPTER IV

DISCUSSION

As stated previously, there were two purposes for this pilot study. The first purpose was to determine intra-rater reliability through intra-class coefficients (ICC) in tests utilizing interval and rational data. The tests in which an ICC was calculated included the FRT, OLST, and the 30STS. The intra-rater reliability proved to be fair to high (ICC = 0.824 to 0.976), with the highest reliability occurring with FRT and the OLST. The second purpose of this study was to establish normative age sensitive age and data ranges within all six of the balance tests. This study reported normative data across multiple adult age cohorts (19-39 years, 40-59 years, 60-87 years). This pilot study reports representative balance test results over a wide age spectrum. This study illustrates trends that with an increase in age, there are significant decreases in static and dynamic balance among healthy individuals between the ages of 19 year and 87 years.

Modified Clinical Test for Sensory Integration and Balance

The mCTSIB proved to yield a notable decrease in static balance ability in the oldest population between the 60 to 87 years with increasing difficulty within the four sensory conditions. The performances in the first two conditions did not show deviation in static posture between all age cohorts. In condition three,
where the eyes were kept open while standing on foam and retaining standing position, increasing age-related trends were clearly observable (Table 5). The mCTSIB illustrated the most significant static balance deficits in the 60 to 87 year age within condition four, where 13 subjects (n = 13) in the 60-87-year-old age group did not complete the full 30-second time limit (Table 6). In summary, this study has found a decrease in static balance ability in the oldest population between 60 to 87 years with an increase in difficulty within the four sensory conditions.

There are limitations with regard to the mCTSIB in clinical practice settings. Fatigue is a concern that arises when dealing with individuals with a lower functional capacity related to endurance issues. The mCTSIB takes approximately 30 seconds per condition to administer; therefore it might be considered too long a test for certain patient populations. Equipment concerns can also be addressed when administering the mCTSIB in clinical practice settings.

Although the mCTSIB is an excellent clinical test to measure abnormal static balance, there are three alternative tests that could be utilized in clinical practice. First, the mCTSIB on the NeuroCom Balance Master would give a more objective finding in relation to static postural balance. The limitation of this test would be the cost and equipment usage of the Balance Master. The second two tests include the Romberg and Sharpened Romberg tests which evaluate static postural sway among two conditions which include eyes open and eyes closed. These tests do not require equipment and do not require as long a
period of time to administer. The duration of this examination is approximately one minute as compared to the five-minute mCTSIB. This would address the limitations of fatigue and equipment issues. These would be more appropriate tests with individuals with a lower functional capacity.

One-legged Stance Test

Intra-rater reliability was not able to be tested with the OLST because it had a ceiling effect; data were collected only to 30 seconds. A significant difference was found when the younger two groups (19-39 years and 40-59 years) were compared against the oldest group (60-87 years). A possible limitation of this test is the concern in lower leg fatigue, specifically within the first 5 seconds of the test due to decreased balance ability and ankle strategies.\textsuperscript{20,23} There are two recommendations that are to be considered prior to administering the OLST. First, a trend illustrated a significant decline in stance time in the 60-87 year age group. When administering the OLST, it was found that only one trial is necessary to find a good estimate of a person's static balance. It is recommended that before the test is administered, participants be allowed to practice standing one time. Administering the test for one trial will decrease the time needed to manage the test by one minute. This does not include the rest time between trials. Also, when comparing the 60-87-year-old group to the other groups, the majority of this group was unable to stand for more than 20 seconds. This suggests that when using the OLST, it is not necessary to have these individuals stand for 30 seconds. Instead, having these
individuals stand for 20 seconds may be adequate when testing this age group's static balance.

**Functional Reach Test**

The FRT proved to yield a significant decrease in ability in the oldest population. Although the FRT had high intra-rater reliability and was easy to administer, there is concern in not documenting height and sex for this test, which will affect the reac scores as well as averages. Males are generally taller and have longer limbs contributing to a higher average reach among the participants within the age-related groupings, respectively.

This study focus was among different age cohorts. This led to a statistically significant drop in reach related to increase in age of the participant. Namely, the elderly have inferior lower limb support related to function, thereby causing a decrease in the distance from the center of gravity (COG) in which they could reach. Also, the elderly have an imbalance with equilibrium function which combined with lower limb instability causes decreases in the ability to transfer the weight forward while reaching with the hand. However, in the case of young adults with high physical functioning, the functional reach distance is considered to be related to other abilities, such as flexibility of the trunk, waist, and lower limb strength.

**30-second Sit-to-Stand Test**

The 30STS adequately discriminates between the age cohorts lower extremity strength and mobility levels. To find intra-rater reliability, the first ten participants were asked to perform the 30STS three times each day. For the
remaining participants, it was found that only one set was required to satisfactorily assess an individual's lower extremity strength.

It was found that there is no significant difference between the youngest group, 19-39-years-old, sit-to-stand repetitions (mean of 21.55) and the middle group, 40-59-years-old, sit-to-stand repetitions (mean of 18.53). The oldest group between the ages of 60-87 years had a significantly lower number of sit-to-stand repetitions (mean of 11.68). This suggests there is no reason to separate the young and middle-aged groups. Therefore, they are combined into a single group, 19-59-year-old. Jones et al\textsuperscript{19} and Macfarlane et al\textsuperscript{29} correlate with the number of sit-to-stand repetitions that are present in this study.

It is recommended that before performing the 30STS the participant be allowed to practice a few repetitions to become familiar with the test. With individuals who are capable of achieving only a low number of sit-to-stand repetitions, a different test such as the FRSST may be more appropriate to use to assess lower extremity strength.\textsuperscript{21} Using this test may decrease the risk of muscle fatigue when working with these individuals.

Limitations to the 30STS test include that participants were not allowed a practice trial before beginning the test. Participants may have improved their sit-to-stand repetitions if they had been allowed this. Individuals may not have given their best exertions on the 30STS. The majority of the participants in the 19-39 year age group were students from the University of North Dakota. Some of these participants may not have performed the test as well as they could. This may have altered the results for this test.
10-meter Walk Test

The 10MWT intra-rater reliability was established when participants were allowed a practice trial. If participants were not allowed trial runs, reliability was not established. Subsequently, after a practice run was implemented, intra-rater reliability was established for the 10MWT (ICC = 0.842). This shows that before administering this test, it is important to allow one practice trial to familiarize the participants with the testing procedure and protocols.

When comparing the younger two groups (19-39 years, 40-59 years) to the oldest group (60-87 years), a significant difference was observed. The 60-87 year age group had a significantly slower 10MWT (9.04 seconds) when compared to the other two groups (7.39 seconds, 7.36 seconds). These findings suggest that it is not necessary to separate the two younger groups from each other; that a combined normative data set group would be appropriate.

Limitations for the 10MWT include that, when assessing intra-rater reliability, only one measurement was used when comparing day one to day two times. Had there been a mean time used to determine the 10MWT, reliability may have been improved. A taped line was marked on the ground for participants to distinguish the finish point. Perron et al\textsuperscript{20} found that when participants were not able to see the end line, they had a more consistent walk time.

The Timed-Up-and-Go Test (TUG) or the Tinetti Balance Test are other options when assessing dynamic balance in individuals. Jette et al\textsuperscript{30} found TUG to be a reliable and valid tool for assessing functional mobility. Kristensen et al\textsuperscript{31}
found the TUG to be sensitive in predicting fall risk for people post hip fracture. A study by Montes et al\textsuperscript{32} found a correlation between TUG performance and fall risk in patients with ALS. As TUG performance decreased, fall risk would increase.

Activities-specific Balance Confidence Scale

Intra-rater reliability was not tested for the ABC Scale. Powell et al\textsuperscript{25} have previously established test-retest reliability for the ABC Scale. The ABC is a useful clinical tool for a range of client groups. However, administration of the scale does require the client to have reasonably intact cognition. In particular, the client must understand that what is being assessed is confidence in doing the activity, not ease with which the activity can be performed. When administering this test, assumptions about the cognition of the participant must be taken into account for an accurate test. Furthermore, cognition has been shown to decline with age indicating the importance of proper administration of this test to older population participants.

Limitations

There are several general limitations with this study. First, the study population did consist of a randomly selected sample, but the study sample was recruited for participation in a balance study of healthy individuals. This recruitment procedure could have favored enrollment of a healthier and more active group of participants, most notably from local fitness centers. In comparing data with reported normative ranges, the results were statistically higher for all tests. As previously stated, the participants were primarily recruited
from exercise classes, university level health-science students, and faculty members working within a medical school or exercise department. The majority of the participants had a significant exercise history. Subjective reports of exercise history were not collected at the onset of consent and testing. Given the daily exposure, interest, and dedication to general health, the sample population was likely healthier than the general public. This facilitated the concern that throughout testing, especially given this active, healthy population, was the participants improving upon prior performance. This was most notably evident in 10MWT and 30STS, respectively.

Randomized ordering was utilized. However, there is concern that physically fatiguing tests almost certainly affected results and performance for subsequent tests requiring substantial coordination and physical ability. Considering fatigue, the randomization, repetition, and time efficiency of testing may not have provided ample rest periods to ensure proper recovery.

Data were not collected concerning gender. The data collection focused on dividing data into three different age cohorts. This limitation added to the lack of standardized measures of physical fitness and functional performance between male and female genders. Due to the time constraint of this study, sufficient and equal amounts of gender representation were unwarranted. Due to the large imbalance between women and men in the study population which is common in general population age categories, the results and conclusions regarding the comparison to the age groups must be interpreted with care.
Recommendations

Recommendations for future studies include controlling the order of testing by providing a consistent, adequate time for full, proper recovery for the entire study sample. This will ensure that recovery time will be the same for each individual participant. Also, ordering tests so that breaks occur during written or less taxing activities could be a possible solution for confounding fatigue variables. Secondly, initial demographic collection should include a specific past medical history, gender, medications, and previous activity level and standardized measures of physical fitness and functional performance between male and female genders.

This study chose balance tests that have been reported in literature for use in people with neurological deficits (MS, Parkinson's, etc.). Clinicians also have the choice of other, closely related tests that prove reliable, valid, economical, and evidence-based. Those not included in this study include the Berg Balance Scale (BBS), the Multidirectional Functional Reach Test (MFRT), and the Clinical Test for Sensory Integration and Balance (CTSIB). These tests may be used for a substitute or in conjunction with the clinical tests that are outlined in this study.
CHAPTER V
CONCLUSION

The development of a study geared towards providing an understanding of the functional balance between different age cohorts can make clinicians more attentive to a greater number of associations between functional limitations and disabilities. Balance tests and measurements allow for a more precise functional diagnosis in rehabilitation and a better monitoring of the clinical picture development.

The six tests in this study are believed to be appropriate to use when a researcher is educated and familiar with the tests. The FRT, 30STS, and 10MWT have all been found to be reliable tests of measurement. Economically, all tests are cost effective, require a small amount of equipment, small amount of space to administer, and can be performed in different controlled environments. Performing the six balance tests as part of a balance battery takes approximately 30 minutes in their entirety with little risk of injury to an individual. The functional tests can be used independently or together. Each test has a particular, unique contribution to the total functional picture.

As individuals age, there is a functional decline in performance related to balance. Moreover, this indicates the need for further research to determine appropriate ages in which balance differences can be seen. Distinguishing
balance differences between younger and older adults aid in identifying new age-sensitive data ranges, normative data, and test reliability for individuals with balance deficits.
REPORT OF ACTION: PROTOCOL CHANGE
University of North Dakota Institutional Review Board

Date: 7/27/2007 Project Number: IRB-200706-347

Principal Investigator: Banks, Meridee; Jackson, Scott; Schrock, Ryan; Wilson, Mark

Department: Physical Therapy

Project Title: Establishing Intra-Reliability and Normative Data in Physical Functioning Assessments: A Pilot Study

The above referenced project was reviewed by a Designated Member for the University's Institutional Review Board on 7/27/07 and the following action was taken:

☑ Protocol Change approved. Expedited Review Category No. 4

Next scheduled review must be before: 5/20/08

☑ Copies of the attached consent form with the IRB approval stamp dated 5/21/07 must be used in obtaining consent for this study.


☐ This approval is valid until ______________________ as long as approved procedures are followed.

☐ No periodic review scheduled unless so stated in the Remarks Section.

☐ Copies of the attached consent form with the IRB approval stamp dated ______________________ must be used in obtaining consent for this study.

☐ Minor modifications required. The required corrections/additions must be submitted to RDC for review and approval. This study may NOT be started UNTIL final IRB approval has been received.

(See Remarks Section for further information.)

☐ Protocol Change approval deferred. This study may not be started until final IRB approval has been received.

(See Remarks Section for further information.)

☐ Protocol Change disapproved. This study may not be started until final IRB approval has been received.

REMARKS: Any unanticipated problem or adverse occurrence in the course of the research project must be reported within 5 days to the IRB Chairperson or RDC by submitting an Unanticipated Problem/Adverse Event Form.

Any changes to the Protocol or Consent Forms must receive IRB approval prior to being implemented (except where necessary to eliminate apparent immediate hazards to the subjects or others).

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature. All revisions MUST be highlighted.

☑ Education Requirements Completed. (Project cannot be started until IRB education requirements are met.)

cc: Chair, Physical Therapy

Signature of Designated IRB Member
UND's Institutional Review Board

Date

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact RDC to obtain the required documents.

(Revised 10/2006)
REPORT OF ACTION: EXEMPT/EXPEDITED REVIEW
University of North Dakota Institutional Review Board

Date: 5/8/2007 Project Number: IRB-200705-347

Principal Investigator: Danks, Meridee; Jackson, Scott; Schrock, Ryan; Wilson, Mark

Department: Physical Therapy

Project Title: Establishing Intra-Reliability and Normative Data in Physical Functioning Assessments: A Pilot Study

The above referenced project was reviewed by a designated member for the University's Institutional Review Board on May 21, 2007 and the following action was taken:

☑ Project approved. Expedited Review Category No. 447

Next scheduled review must be before: May 20, 2008

☑ Copies of the attached consent form with the IRB approval stamp dated May 21, 2007 must be used in obtaining consent for this study.

☐ This approval is valid until as long as approved procedures are followed. No periodic review scheduled unless so stated in the Remarks Section.

☐ Copies of the attached consent form with the IRB approval stamp dated must be used in obtaining consent for this study.

☐ Minor modifications required. The required corrections/additions must be submitted to RDC for review and approval. This study may NOT be started UNTIL final IRB approval has been received.

☐ Project approval deferred. This study may not be started until final IRB approval has been received.

(See Remarks Section for further information.)

☐ Disapproved claim of exemption. This project requires Expedited or Full Board review. The Human Subjects Review Form must be filled out and submitted to the IRB for review.

☐ Proposed project is not human subject research and does not require IRB review.

☐ Not Research ☐ Not Human Subject

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature. All revisions MUST be highlighted.

☑ Education Requirements Completed. (Project cannot be started until IRB education requirements are met.)

Douglas Peterson 5/21/07
Signature of Designated IRB Member
UND's Institutional Review Board

cc: Chair, Physical Therapy

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact RDC to obtain the required documents.

(Revised 10/2006)
University of North Dakota Human Subjects Review Form

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University’s policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the “IRB Checklist” for additional guidance.

Please provide the information requested below:

Principal Investigator: Meridee Danks, Scott Jackson, Ryan Schrock, Mark Wilson
Telephone: __________________________ E-mail Address: __________________________

Complete Mailing Address: __________________________ __________________________
School/College: __________________________ Department: __________________________

Student Adviser (if applicable): Meridee Danks
Telephone: 777-3861 E-mail Address: mgreen@medicine.nodak.edu
Address or Box #: 9037
School/College: Medicine Department: Physical Therapy

Project Title: Establishing intra-reliability and normative data in physical functioning assessments: A pilot study.

Proposed Project Dates: Beginning Date: 5/1/2007 Completion Date: 12/31/2007
(Including data analysis)

Funding agencies supporting this research: N/A

Did the contract with the funding entity go through UND Grants and Contracts Administration? ☐ YES or ☐ NO
Attach a copy of the contact. Do not include the any budgetary information. The IRB will not be able to review the study without a copy of the contract with the funding agency.

Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

☐ YES or ☐ NO

Will research subjects be recruited at another organization (e.g., hospitals, schools, YMCA) or will assistance with the data collection be obtained from another organization?

If yes, list all institutions: __________________________

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands their involvement in that study, and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on letterhead.

Does any external site where the research will be conducted have its own IRB? ☐ YES ☐ NO ☒ N/A

If yes, does the external site plan to rely on UND’s IRB for approval of this study? ☐ YES ☐ NO ☒ N/A
(If yes, contact the UND IRB at 701 777-4279 for additional requirements)
I. Project Overview
The purpose of this research is to launch a pilot study determining age-appropriate normative data in six functional balance tests through literature reviews and subject testing. We will also carry out small subgroup testing to test for intra-tester reliability and determine appropriate test order. This pilot study will function as a trial run for testing and procedures involved in a future pesticide study. Human subjects are necessary to establish appropriateness and normative data in these human functional performance tests.

II. Protocol Description
1. Subject Description
   a) Subjects will be recruited via word of mouth as well as recruitment flyers (see enclosure). Subjects will be recruited by the members of the research team. Each of the subjects will undergo orientation and performance of the tests for total of 60 minutes.
   b) Inclusion into the study will involve healthy subjects 18 and older, without a past medical history of orthopedic injuries, balance, or coordination disorders.
   c) Exclusion criteria will include any subject under the age of 18, as well as subjects with recent diagnoses and/or injuries that would affect balance, in order to ensure we test for age-appropriate normative data.
   d) We estimate up to 100 subjects will be tested. Our subgroup that will be used to ensure intra-tester reliability will be 10-30 subjects randomly drawn from the above group.
   e) This relatively high sample (n=100) will allow us to better represent different age populations for normative data.

2. Description of Methodology
   a) Informed consent will be gained by informed subject consent and rights form, to be completed prior to testing. The subjects will be given a copy of the consent form.
   b) Research will be carried out within the University of North Dakota Physical Therapy (UND-PT) Department. Adequate room is provided within the apartment to carry out all subject testing.
   c) The research will be carried out by a faculty principal investigator, and three Year 03 physical therapy students.
   d) The researchers will be utilizing the following tests in random order, as determined by drawing cards, with twenty-five minutes given for signing informed consent, transition between tests, answering questions, and set up time:
   e) All functional tests will be performed with a safety belt (gait belt).

Activities-specific Balance Confidence (ABC) Scales questionnaire:
Activities-specific Balance Confidence (ABC) Scales questionnaire is a 16-item self report questionnaire giving to patients to measure a patient’s confidence in performing various tasks without falling. The individual
doing the ABC uses a numerical rating scale (0-100 0 no confidence 100 complete confidence) to rate their balance confidence when performing certain task. The ABC score is calculated by adding the individual scores and dividing by the total items. The ABC questionnaire will take ten minutes to perform.

- **One-legged stance test:**
The one-legged stance test is used to discriminate between low and high fall risk individuals through a risk factor assessment. To perform the one-legged stance test the patient is asked to cross his/her arms and lifts their dominant leg as a clinician records how long the patient is able to maintain their balance. The best of 3 times are taken. Shoes should be off. Times do not need to exceed 30s. The one legged stance test will take five minutes to perform.

- **30 second chair stand test (30CST):**
The 30CST is used to assess the lower body strength of an individual. Participants will be asked to go from sit to stand to sit as many times as they can in 30s. Using a standard height approximately 43.2 cm without armrest. With arms crossed against their chest. The individual will be asked to repeat the test 3 times and the times will be averaged together. The 30CST will take five minutes to perform.

- **Ten-meter timed walk:**
The 10-meter timed walk test is used to quantify functional mobility of an individual. Individuals will be asked to walk a straight line 10m line barefoot. The start and stop lines will be marked with tape on the floor. The individual will be instructed to walk a his/her comfortable and preferred speed. The individual will start standing at the start tape. The timer will be at the finish line and raise their hand to prepare the individual to start walking. When the timer lowers their arm the individual will start walking. The stopwatch will start when the arm drops and stop when the individual walks through the finish line. The 10-meter timed walk will take five minutes to perform.

- **Functional Reach (FR):**
The FR (multidimensional test) is a performance based test to assess postural responses to voluntary movement responses to daily activity. It is a measure of the maximal distance one can reach forward beyond arm’s length while in a fixed standing position. The FR test will take five minutes to perform.
**-Modified Clinical Test for Sensory Interaction in Balance (mCTSIB)**

The mCTSIB test uses four sensory conditions to examine postural orientation under altered sensory conditions. It tests the ability to adapt how senses are used to maintain orientation. The mCTSIB will take five minutes to perform.

The four sensory conditions are:

1. Barefoot, standing in normal alignment with head in neutral on normal surface.
2. Barefoot, standing in normal alignment with head in neutral on normal surface with blindfold.
3. Barefoot, standing in normal alignment with head in neutral on foam surface.
4. Barefoot, standing in normal alignment with head in neutral on foam surface with blindfold.

All tests last 30 seconds in duration.

2.

f) N/A

g) The principal investigator within this study has 25 years of clinical physical therapy experience, and the student investigators are Year 03 physical therapy students. Each researcher is trained in the use of BalanceMaster technology, as well as the functional tests described above.

h) One subject will be randomly selected for a dinner for two.

3. Risk Identification

a) The nature of these functional tests is to assess balance and functional coordination. Inherent risk involves falling, injury during ambulation, or overexertion. However, these risks are minimal. Safety procedures will include pre-test guidance and trials, as well as utilizing gait belts, and stand by assistance.

b) There will initially be a link to subjects with their consent forms for research liability as well as educated consent. Confidentiality will be maintained from these consent forms will be kept under lock and key, separate from collected data, within the UND-PT department for three (3) years. Once testing is completed, there will be no need for identifiable information in determining results.

c) N/A

d) N/A

4. Subject Protection

a) Subjects will be briefed through informed consent, as well as verbally through pretest instructions. There are no foreseeable concerns in subjects having emotional reaction to the testing.
b) Consent forms will be kept under lock and key, separate from collected data, within the UND-PT department for three (3) years. Upon this time, the identifiable documents will be disposed of via department shredding.

c) The subjects will be provided with a copy of the consent form including all instructions, rights, and waiver material.

d) All records involved within this study will be maintained under lock and key within the UND-PT department for three (3) years. Following the three year period, said records will be disposed via department shredding.
   1) The research data will be held separately from identifiable data within the UND-PT department.
   2) Access will be granted to the data by the researchers stated above, department statistician, auditing teams, and the University of North Dakota Institutional Review Board.
   3) Data will be destroyed by departmental shredding.
   4) The storage of the consent forms and personal data, separate from the research data, will be kept under lock and key within the UND-PT department for three (3) years.
   5) The consent forms will be destroyed via departmental shredding upon storage for three (3) years.

e) Adverse reactions to testing of a non life threatening nature will be treated by researchers with medical training. Life-threatening emergencies will require emergency medical attention, contacted by the researchers. Non-life threatening injuries will be treated by a licensed physical therapist participating as a researcher. Emergencies will utilize medical emergency services. Subjects will be responsible for any payment required due to injury.

III. Benefits of the Study
The benefits expected of this study to the population include establishing needed normative data with the above listed functional balance and motor tests. This normative information will function as baseline data for functional motor tests, where patients in need of medical care and assessment will be compared against. Benefits afforded to the subject will be a free, professional quality assessment of their balance and motor coordination, as well consultation of the results. Lastly, this study will provide unidentifiable data for use in a future study.
INFORMED CONSENT

TITLE: Establishing intra-reliability and normative data in physical functioning assessments: A pilot study.

PROJECT DIRECTOR: Meridee Danks
PHONE #: 701-777-2831
DEPARTMENT: University of North Dakota-Physical Therapy

STATEMENT OF RESEARCH

A person who is to participate in the research must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Research projects include only subjects who choose to take part. Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to be in a research study about testing in six balance tests to develop normal data and reliability for a future research study because you are older than 18 and have no recent history of injury or disease that would decrease balance. The purpose of this research study is to determine normal data in six balance tests, as well as determining an order of performing all the tests to ensure that you are able to best perform each test. This information will then be used in a future study. Approximately 100 people will take part in this study at the University of North Dakota. You will need to visit the University of North Dakota Physical Therapy Department once. The visit will take about 60 minutes.

WHAT WILL HAPPEN DURING THIS STUDY?

Upon filling out this informed consent form, you will be tested with the following six tests:

-Activities-specific Balance Confidence (ABC) Scales questionnaire:
With this questionnaire you will answer 16 questions, on paper, in how you feel you are able to perform different tasks without falling.

-One-legged stance test:
You will begin this test by crossing your arms and lifting your dominant side leg. You will be timed up to 30 seconds. You will perform this test three times.

-30 second chair stand test (30CST):
You will begin this test with your arms crossed, sitting in a chair without armrests. You will then be asked to stand up and sit down as many times as possible for 30 seconds.
- **Ten-meter timed walk:**
  You will begin this test at a marked starting line. You will then be instructed to start, where you will walk straight forward at a comfortable speed to the finish line. You will be timed.

- **Functional Reach (FR):**
  The FR (multidimensional test) is a performance based test to assess postural responses to voluntary movement responses to daily activity. It is a measure of the maximal distance one can reach forward beyond arm’s length while in a fixed standing position. The FR test will take five minutes to perform.

- **Modified Clinical Test for Sensory Interaction in Balance (mCTSIB):**
  The mCTSIB test uses four sensory conditions to examine postural orientation under altered sensory conditions. It tests the ability to adapt how senses are used to maintain orientation. The mCTSIB will take five minutes to perform.

**WHAT ARE THE RISKS OF THE STUDY?**

There may be some risk from being in this study. The balance tests listed above may cause you to lose your balance, or become tired over time, which may cause injuries. These risks are both minimal and unforeseeable, as you will be provided with instruction and shown the tests before you will perform them. You will also be given standby assistance and use a safety belt when performing these tests. At any time, you may stop performing these tests. You are responsible for any medical care if injury occurs.

**WHAT ARE THE BENEFITS OF THIS STUDY?**

You will benefit from this study by receiving free testing of your balance, as well as discussing your results. In the future, the results from these tests will be used in health care settings as normal scores, which will help determine decrease in ability. This information will also be used to help plan a future study. You will not have any costs for being in this research study. By participating in the study, you will be eligible for a drawing for a dinner for two at a local restaurant.

**CONFIDENTIALITY**

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. Your study record may be reviewed by Government agencies, the UND Research Development and Compliance office, and the University of North Dakota Institutional Review Board. Any information that is obtained in this study and that can be identified with you will remain confidential. Confidentiality will be maintained by means of being held in a locked file that is held in the University of North Dakota Physical Therapy Department. The consent form will held separately under key an lock from the data collected.

If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified.

**University of North Dakota**
Institutional Review Board
Approved on **MAY 21 2007**
Expires on **MAY 20 2008**
IS THIS STUDY VOLUNTARY?

Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota.

CONTACTS AND QUESTIONS?

The researchers conducting this study are Meridee Danks, UND-PT Faculty member, Scott Jackson, Ryan Schrock, and Mark Wilson, UND-PT graduate students. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Meridee Danks, Scott Jackson, Ryan Schrock, and Mark Wilson at 701-777-2831.

If you have questions regarding your rights as a research subject, or if you have any concerns or complaints about the research, you may contact the University of North Dakota Institutional Review Board at (701) 777-4279. Please call this number if you cannot reach research staff, or you wish to talk with someone else.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subjects Name: ________________________

Signature of Subject

Date

University of North Dakota
Institutional Review Board
Approved on MAY 21 2007
Expires on MAY 20 2008
Subject #____

Activities-specific Balance Confidence (ABC) Scale

For each of the following activities, please indicate your level of self confidence by choosing a corresponding number from the following 0%-100% rating scale (0% = no confidence and 100% = complete confidence):

<table>
<thead>
<tr>
<th>0%</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
<th>70</th>
<th>80</th>
<th>90</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>no confidence</td>
<td>completely confident</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

How confident are you that you can maintain your balance and remain steady when you...

1. Walk around the house.  
2. Walk up and down stairs.  
3. Pick up a slipper from the floor.  
4. Reach at eye level.  
5. Reach while standing on your tiptoes.  
6. Stand on a chair to reach.  
7. Sweep the floor.  
8. Walk outside to nearby car.  
10. Walk across a parking lot.  
11. Walk up and down a ramp.  
12. Walk in a crowded mall.  
13. Walk in a crowd or get bumped.  
14. Ride an escalator holding the rail.  
15. Ride an escalator not holding the rail.  
16. Walk on icy sidewalks.
APPENDIX D
modified Clinical Test for Sensory Integration and Balance

- "There will be a series of four trials that consist of eyes open-firm surface, eyes closed firm surface, eyes open-unstable surface, and eyes closed-unstable surface for a duration of 30 seconds for each condition"
- "Stand with feet shoulder with apart, both on the stable surface and the unstable surface."
- "When you hear the word "GO", the test will begin."

One-Legged Stance Test

- "For this test, you will be asked to stand on one leg of your preference for thirty seconds.
- "During the test, you will keep your eyes open, looking straight forward, with your arms crossing your chest."
- "We will perform this test four times."
- "The clock will begin when you lift your leg."
- "If you have any questions, feel free to ask now."
Functional Reach Test

- “This test measures how far you are able to reach while keeping your balance without taking a step”
- “Please stand with the left middle finger against the beginning of the yardstick.”
- “Raise your arm so that it is parallel with the yardstick.”
- “Keeping your arm straight out in front of you, reach forward as far as you can without losing your balance or taking a step forward.
- “You will have one practice trial before the testing begins, and then you will be having three testing trials with an average taken of the three to determine your functional reach.”

30 Second Sit-to-Stand Test

- “The purpose of the 30STS is to assess your lower body strength.”
- “After I have giving you the directions for doing the 30STS, I will ask you to perform it for three trials.”
- “You will start out sitting in this chair with your arms crossed against your chest, and your feet shoulder width apart.”
- “I will start timing you as soon as you begin to rise from the chair, and try to go from sit-to-stand in a controlled manner as many times as you can.”
- “You can take rest during the 30 seconds if you need to.”
- “A sit is considered touching your rear to the chair, and complete stance is considered bringing your legs to approximately 5 degrees flexion.”
- “In-between the trials you will be allowed to rest to catch your breath.”
- “Do you have any questions?”
Ten-Meter Walk Test

- "I am going to ask that you walk 10-m barefoot 3 times at your normal comfortable pace."
- "You will begin at the starting line, and I will be measuring your time at the finish line."
- "I will raise my arm to prepare you to start walking."
- "When I lower my arm I will start the timer, I will stop the timer when you cross the finish line."
- "Do not stop at the finish line but continue to walk past the finish line. Do you have any questions?"

Activities-specific Confidence Scale

- "For each of the following, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale from 0% to 100%.”
- "If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity.”
- "If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as if you were using these supports.
- "If you have any questions about answering any of these items, please ask the administrator."
REFERENCES


