The Effectiveness of the "Stepping On" Program for Reducing the Incidence of Falls in the Elderly: Measured by Four Stage Balance Test

Julia Nelson
University of North Dakota

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THE EFFECTIVENESS OF THE “STEPPING ON” PROGRAM FOR REDUCING THE INCIDENCE OF FALLS IN THE ELDERLY: MEASURED BY FOUR STAGE BALANCE TEST

By
Julia Nelson
University of North Dakota

A Scholarly Project
Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine
University of North Dakota
In partial fulfillment of the requirements
For the degree of
Doctor of Physical Therapy

Grand Forks, North Dakota
May
2016
This Scholarly Project, submitted by Julia Nelson 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 and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Chairperson, Physical Therapy)
The Effectiveness Of The “Stepping On” Program For Reducing The Incidence Of Falls In The Elderly: Measured By Four Stage Balance Test

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Date 10-30-15
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ABSTRACT

Introduction: The Stepping On program encompasses both a balance and strengthening exercise regimen that is targeted towards reducing falls in community-dwelling individuals over the age of 65, who have experienced a fall or are fearful of falling.

Purpose: The purpose of this study was to determine if the Four Stage Balance Test (FSBT) is an appropriate measure of fall risk in the Stepping On program and to determine if the Stepping On program is effective at reducing fall risk, measured by improved time performance.

Methods: Eight participants, all female, ages ranging from 80-94 years old (M=87.2), completed the FSBT at week one and week seven. The Four Stage Balance Test (FSBT) consists of maintaining the static position of four different stances: narrow base (feet together), semi-tandem, tandem, and single-leg stance (SLS). Each participant was to maintain each stance for 30 seconds without loss of balance.

Results/Conclusion: Five out of eight (62%) of the participants had increased times between pre- and post-test for the tandem stance. The mean improvement of the eight participants was 6.41 seconds. However, there was no statistically significant improvement in the tandem stance times. The FSBT is an appropriate test to be completed with the Stepping On program.
due to its similar testing stances with the Stepping On exercises. The Stepping On program showed positive benefits such as an increase in confidences for all participants. However, using the FSBT as a predictor of fall risk showed that the Stepping On program did not change ability to perform static balance over the seven-week program.
CHAPTER I

INTRODUCTION

Falls in the elderly population are common, dangerous, and costly. Each year one out of every three people aged 65 and older experience a fall.¹ These falls are the leading cause of fatal and nonfatal injuries, such as spine or pelvic fractures, among the elderly. In 2013 alone, 2.5 million nonfatal falls were treated in emergency departments in the United States with 734,000 of these falls requiring hospitalization. The cost of these falls in 2012 after adjusting for inflation was $30 billion.

Since falls are a major concern for senior citizens, several studies have been done to determine the effectiveness of fall prevention with the use of exercise. Rubenstein and colleagues² examined the effects of low- to moderate-intensity group exercise programs on strength, endurance, mobility, and fall rates in elderly men. Fifty-nine men were randomly assigned into a control group (general exercise group) or an exercise group (focused on strength and endurance exercises). The results showed that the exercise group marked significant improvement in measures of endurance and gait. The exercise group also had a 10% increase in distance walked in six minutes. When fall rates were adjusted for activity level, the exercise...
group had a lower 3-month fall rate than the control group (6 falls/1000 hours of activity verses 16.2 falls/1000 hours, p < .05).

Barnett and colleagues also researched the relationship between exercise and fall prevention. They studied the effects of participation in a weekly exercise group designed to improve balance and strength and to prevent falls in older people. The program consisted of a weekly one-hour clinical program (37 weeks total). The exercise program investigated by Barnett and colleagues included strength training, balance training, coordination activities, and aerobic capacity expansion. The research measured progress with functional measures such as: sit to stand, knee extension strength, simple reaction time (SRT), sway, walking speed and Short Form 36 (SF-36). The results showed a reduction in falls among participants with the rate of falls in the intervention group 40% lower than that of the control group.

Further narrowing the scope of the relationship between exercise and fall prevention, Clemson et al. investigated whether a program that included both an exercise element and an educational aspect would illustrate a significant reduction in falls. The study followed 300 participants who had experienced a fall or had a fear of falling. The program, entitled Stepping On, encompassed both a balance and strengthening exercise regimen that was aimed towards reducing falls in community-dwelling individuals over the age of 65. A key aspect of the program was improving balance and lower-limb
strength. The results of this study showed that the intervention group experienced a 31% reduction in falls versus the control group.

Various measures have been used to assess impairments in balance and reduction in fall risk. These measuring tools include but are not limited to: gait speed, Timed Up and Go (TUG), Sit-to-Stand (STS) Activities-specific Balance Confidence (ABC), endurance, Short Form 36 (SF-36) and the four Stage Balance Test (FSBT). The CDC suggests the use of the FSBT as one measuring tool to determine fall risk. The FSBT test assesses static balance by having the participant perform four progressively harder standing positions for 30 seconds. Limited research is available for the Four Stage Balance Test as a whole. This study will look at portions of the test separately: the single-leg stance (SLS), tandem standing, semi tandem stance, feet together stance, and the correlation between these stance tests’ times and fall risk amongst individuals in the Stepping On program. The purpose of this study is to determine if the FSBT is a predictor of fall risk in the elderly population and to conclude if the Stepping On program is effective at reducing fall risk.
CHAPTER II
METHODOLOGY

Volunteers that were participating in the Stepping On program were recruited to be a part of this research study. The Institutional Review Board (IRB) of North Dakota approval (IRB #201209-047) was approved by the University of North Dakota Physical Therapy Department to perform balance assessments and provide surveys for the Stepping On participants. Prior to taking part in the study each participant signed a consent form and was given a copy of the consent form. See Appendix A for a copy of the approved IRB and Appendix B for a copy of the consent form.

Subjects

The study included fourteen participants, all female, ages ranging from 80-94 years old (M=87.2). All participants lived alone in an assistive living community. They all met the inclusion criteria of ambulating independently for 300 feet. One participant left the study due to health concerns. Four participants dropped out of the class due to lack of interest in the program. One other participant did not attend the final session due to scheduling conflicts. Of the fourteen participants starting Stepping On, eight participants completed both the pre- and post- fall risk assessments. These
eight participants attended the Stepping On program at least five of the seven weeks, qualifying for course certificate. (Refer to Table 1)
Table 1. Demographics Information

<table>
<thead>
<tr>
<th>Subject #</th>
<th>Gender</th>
<th>Age</th>
<th>Type of Assistive Device Used</th>
<th># of Falls Last Year</th>
<th># of Fall Risk on UND Survey</th>
<th>Worry About Falling</th>
<th>Vision Issues/Type</th>
<th>Minimally Active &gt; 30 min/day</th>
<th>LE Sensation Deficits</th>
<th>Depressed</th>
<th>Med Hx</th>
</tr>
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<td>92</td>
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<td>0</td>
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<td>No/Yes</td>
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<td>Yes</td>
<td>No</td>
<td>Yes</td>
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<td>2</td>
<td>F</td>
<td>92</td>
<td>WW/WC</td>
<td>2</td>
<td>5/10</td>
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<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>89</td>
<td>Manual WC/FW</td>
<td>2</td>
<td>6/11</td>
<td>Yes</td>
<td>Yes; glasses, macular degeneration</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>87</td>
<td>FWW</td>
<td>0</td>
<td>4/11</td>
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<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>94</td>
<td>4WW for longer distances</td>
<td>0</td>
<td>1/11</td>
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<td>Yes; legally blind, bifocals</td>
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<td>Yes</td>
<td>No</td>
<td>No</td>
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<td>F</td>
<td>80</td>
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<td>0</td>
<td>3/11</td>
<td>No</td>
<td>Yes; deficits</td>
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<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>84</td>
<td>FWW</td>
<td>6-7</td>
<td>6/11</td>
<td>Yes</td>
<td>Yes; macular degeneration, glaucoma</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>8</td>
<td>F</td>
<td>85</td>
<td>SEC</td>
<td>0</td>
<td>6/11</td>
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<td>Yes; glasses</td>
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<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>80</td>
<td>None</td>
<td>2</td>
<td>8/11</td>
<td>Yes</td>
<td>Yes; glasses</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
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<td>F</td>
<td>87</td>
<td>FWW</td>
<td>0</td>
<td>3/11</td>
<td>No</td>
<td>Yes; macular degeneration</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td>11</td>
<td>F</td>
<td>84</td>
<td>FWW</td>
<td>2</td>
<td>6/11</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes-knee</td>
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<tr>
<td>12</td>
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<td>89</td>
<td>4WW</td>
<td>Yes</td>
<td>2/11</td>
<td>No/Yes</td>
<td>Yes; glasses</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>90</td>
<td>4WW</td>
<td>No</td>
<td>5/11</td>
<td>Yes</td>
<td>glaucoma</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>14</td>
<td>F</td>
<td>89</td>
<td>Power WC/4W</td>
<td>Yes</td>
<td>NT</td>
<td>Yes</td>
<td>glaucoma</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Notes: R knee pain, L ankle surgery, Dizzy, Bilat TKA, L knee pain, R hip pain, R rotator cuff tear, R TKA; OA; L knee
Instrumentation

The Four Stage Balance Test (FSBT) will be used in this study to assess the participant's static balance. The Center of Disease Control (CDC) created an older adult fall prevention program called Stopping Elderly Accidents, Deaths & Injuries (STEADI). The STEADI program identifies patients at low, moderate and high risk for a fall. STEADI recommended the use of the FSBT to determine participants balance and fall risk. The Four Stage Balance Test (FSBT) consists of maintaining the static position of four different stances: narrow base (feet together), semi-tandem, tandem, and single-leg stance. However, during this study, the tandem and single-leg stance were completed first, only digressing to the other tests if the participant was unable to complete the SLS for 30 seconds.

Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT-4) is a test of static balance that is similar to the FSBT. The FICSIT measures the ability to maintain balance in four positions: parallel, semi-tandem, tandem, and one legged stance. Rossiter-Fornoff et al, determined FICSIT test-retest reliability with a Pearson coefficient value of r=.66 and concluded that this balance scale appears to have acceptable reliability, validity, and discriminant ability. In this research, the residents of a nursing home had substantially more difficulty maintaining their balance than the community-dwelling individuals.
The narrow stance portion of the FSBT is similar to the first part of the Romberg test. The Romberg test is used for the clinical assessment of patients with disequilibrium or ataxia from sensory and motor disorders. The semi-tandem stance replicated with the new form of the Romberg test called the Sharpened Romberg test. If the patient is unable to complete the Romberg test the Sharpened Romberg will be performed. The implementation of the Sharpened Romberg is essentially the same as the Romberg. The patient has to place their feet next to each other with the sides of their feet touching and one foot placed slightly in front of the other. There is no consensus in the reliability (intra and inter) and validity for Romberg’s test in the literature as the test is more qualitative than quantitative.

Franchignoni et al. found good intra-test-retest reliability in healthy woman aged 55-71 years old: eyes open: 0.90-0.91, eyes closed: 0.74-0.75 during a single leg stance (SLS). The age group represented in Franchignoni’s study was significantly younger than the individuals that participated in Stepping On program with the mean age of 87.7. The high inter-rater reliability of Franchinoni’s research supports the use of the single-leg stance test as a clinical screening tool and/or outcome measure for rehabilitation. Inter-rater reliability for the best of three trials was determined to be excellent with an intra-class correlation coefficient of 0.994 (95% confidence interval 0.989–0.996) for eyes open and 0.998 (95% confidence interval 0.996–0.999) for eyes closed.
Maughan et al\textsuperscript{10} found that a measurable decline in single-leg balance may occur as early as the fifth decade of life, with a marked decline occurring between the ages of 70 and 80. The Single Leg Stance (SLS) Test showed significant age dependent decrease in the ability to stand on one limb with both the eyes open and eyes closed\textsuperscript{9}. (See Table 2)

Table 2. Age Related Female Normative Data for the Single Leg Stance\textsuperscript{9}

<table>
<thead>
<tr>
<th>Age</th>
<th>Eyes Open Mean (SE)</th>
<th>Eyes Closed Mean (SE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>80-99</td>
<td>7.4 (10.7) Sec</td>
<td>2.1 (1.1) Sec</td>
</tr>
</tbody>
</table>

Research by Springer et al\textsuperscript{9} showed that the difference in single-leg stance times were not gender specific but were related to age, with the eyes open condition always resulting in significantly longer SLS times than eyes closed. This relationship between age and balance was also confirmed by Bohannon’s\textsuperscript{11} meta-analysis of single limb stance times with eyes opened. This study helped establish typical performance values per respective age group for the eyes closed SLS Test and confirmed more in-depth normative values for the eyes open SLS Test compared to previous studies.

Physical activity or balance-training interventions have been shown to improve SLS times for frail elderly and community-dwelling older adults, with improvements ranging from 43\% to 123\% with the significant p value of .006.\textsuperscript{12} These results from Speers et al’s work showed balance training increased time for the tandem stance, which is the second measuring tool from the FSBT.
Delbaere et al\textsuperscript{13} discovered increased postural sway with the tandem stance test when the eyes were open. This test was selected as the best balance predictor for falls ($OR = 5.60; P = 0.010$). Also, significant age differences were found in the mean rate of successful performance for both tandem stand and tandem walk ($P<0.001$) between twelve young (mean age 23.3 years) and twelve old (mean age 72.0 years) healthy women.

Another researcher, Hile et al\textsuperscript{14} looked at the difference of balance scores between participants that needed initial support before starting the tandem stance test versus those who did not need initial support. When allowing initial support to stabilize in tests of tandem stance, hold times should be interpreted with caution. The comparisons between a group of community-dwelling older adults who could stabilize in tandem stance without support and those who could stabilize only with initial support suggest that the need for such support signals a meaningful distinction in balance-related mobility. Hile et al also looked at other aspects of this research program such as, TUG, gait speed, and ABCs.

Procedure

Limited research and normative data were found for the FSBT as a whole. In order to use the most accurate data to determine assessment scores for the tandem stance and SLS, normative values will be used. Along with the FSBT, the participants were also randomly assessed for overall balance with additional screens such as; Activities-specific Balance...
Confidence (ABC), Timed Up and Go (TUG) Cognitive Timed Up and Go (TUG), 30 second sit-to-stand and GAITRite to assess gait speed. (See appendix B for FSBT instructions).

Each stance in the FSBT was described to the participants and then demonstrated. Narrow base, was performed with feet side by side and ankles touching. In the semi-tandem stance, one foot was slightly in front of the other. During tandem stance, one foot was placed directly in front of the other so that the toes of one foot were touching the heel of the other foot with two feet together in a straight line. For the single-leg stance, individuals stood on one foot and could have the other foot at any position in space. (See Figure 1 for the diagram of the four different stances.)

The directions and guidelines were all from the Center of Disease Control. Instructions to the patient were as follows: “I’m going to show you two positions. Try to stand in each position for 30 seconds. You can hold your arms out or move your body to help keep your balance but do not move your feet. Hold this position until I tell you to stop. For each stage I will say, ‘ready, begin’ and after 30 seconds say, ‘stop.’” The participants were allowed to trial each foot to see which they felt more comfortable with. Participants were allowed to use the tester or a table to help them get into the position and to steady themselves. Time began when they were in position, had let go of the support, and verbalized that they were ready. Time was stopped if the participants needed to step out of the stance, used the tester or table for
support, or when they reached 30 seconds. (See Appendix B for FSBT full instructions)

Figure 1. Four stage balance test positions
CHAPTER III

RESULTS

The results from the Four Stage Balance Test are displayed in Table 3. Data prior to the Stepping On program (Week One) and following the program (Week Seven) are shown. If a participant was able to complete 30 seconds of a stance they did not complete easier stance options. Fall risk was determined by the age normative values of the SLS on Table 1.

Table 3: Results of the FTBT Week One (Pre) & Week Seven (Post)

<table>
<thead>
<tr>
<th>Subjects</th>
<th>Age</th>
<th>SLS (Sec.)</th>
<th>Tandem Stance (Sec.)</th>
<th>Semi-Tandem Stance (Sec.)</th>
<th>Narrow-Based Stance (Sec.)</th>
<th>Fall Risk</th>
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<tr>
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<td>Pre</td>
<td>Post</td>
<td>Pre</td>
<td>Post</td>
<td>Pre</td>
<td>Post</td>
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<td>9.5 12.7</td>
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<td>4.3 6.0</td>
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<td>11.5</td>
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<td>30</td>
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<td>2.2 2.1</td>
<td>4.8</td>
<td>30</td>
<td>15</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>94</td>
<td>1.5 1.3</td>
<td>15.2 30</td>
<td>30</td>
<td>30</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>80</td>
<td>6.6 2.6</td>
<td>30</td>
<td>30</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>11</td>
<td>84</td>
<td>0.3 5.6</td>
<td>7.4</td>
<td>7.2</td>
<td>30</td>
<td>30</td>
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<tr>
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<td>89</td>
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<tr>
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<td>5.3 2.1</td>
<td>10.1</td>
<td>17.8</td>
<td>30</td>
<td>30</td>
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</table>

*The symbol – in the graph means not applicable.

After gathering this data it was converted into a t-test to evaluate improvements based on changes from Week One to Week Seven. Most improvement was seen the in tandem stance. T-tests and Wilcoxon Signed
Rank Test were conducted on the tandem stance data. The results of the one sample t-test: mean of 6.42, standard deviation of 12.93, standard error of the mean of 4.57, 95% Confidence interval (CI) of (-4.39, 17.22) and P=0.203. Results of the Wilcoxon showed that the Wilcoxon Statistic was 21 with P=0.272.

The T-test and Wilcoxon data are in agreement. The tandem stance times have a p > 0.05. Which concludes, failure to reject null hypothesis, no statistically significant improvement. Mean 95% Confidence Interval (CI) contains the value 0, no statistical significance. No reason to reject normality, t-test is valid. Probability Plot of Improvements which shows the individual percent change from Week One compared to Week Seven are shown in Figure 2.

![Probability Plot of Improvement, sec](image)

Figure 2: Probability plot of improvements
Tandem stance was shown to have the most improvement out of the four stages of the test. Five out of eight (62%) of the participants had increased times between Week One and Week Seven. The mean improvement of the eight participants was 6.41 seconds. However, as previously stated above there was no statistically significant improvement in the tandem stance times. The tandem stance times are presented in Figure 3.

![Tandem Stance Times (Seconds)](image)

Figure 3: Tandem stance times

Other information was obtained from participants though numerous surveys, see Appendix A. These surveys were completed during the Week Seven session. The CDC determined a fall risk scale that puts persons at risk for a fall if they have four or more of the CDC’s risk factors. According to the CDC’s fall risk scale, all of the participants were at a fall risk due to indicating four of more risk factors. This information correlates with the data found with the FSBT and by using the participant’s SLS times, where as all but
Subject 1 were recorded as a fall risk. All subjects indicated that their confidence levels have improved after completing the Stepping On program. No falls were reported during the seven-week program. Pertinent data was collected from surveys and constructed into Table 4.
Table 4: Additional Information of Participants at Week Seven

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<th>Subject #</th>
<th>Age</th>
<th>Sessions Attended out of 7</th>
<th># of Fall Risks (CDC)</th>
<th>Improved Balance/Confidence</th>
<th>Falls during Stepping On Program</th>
<th>Present Level Of Activity</th>
<th>Faithful In Performing Stepping On Exercises</th>
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<td>5/12</td>
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CHAPTER IV
DISCUSSION

The purpose of this study is to determine if the FSBT is a predictor of fall risk in the elderly population and to conclude if the Stepping On program is effective at reducing fall risk. Participants showed the most improvements in the tandem stance phase of the FSBT. Participants 1, 4, 5 and 13 all had improved times, while Participant 6 stayed the same. Overall, five out of the eight participants showed an increase in their timed ability with the tandem stance over the seven weeks. This exercise was a part of the Stepping On program and the participants were to practice it on a daily basis. The tandem stance improvements are directly correlated with the participants in the Stepping On program that were consistently completing their exercise log, with exception of Participant 13 who reported not being consistent with her exercises.

Participants 3, 11 and 12 did not improve their tandem stance times. This may be due to their lack of compliance with the exercises based on self-reporting from both participant 11 and 12. Other factors that may have contributed to the lack of improvement for Participant 3 would be that her main mode of transportation was a manual wheelchair. This may have influenced her lack of balance due to not spending much time on her feet on a
daily basis. In the future, it is recommended that researchers complete a tandem walk on the GAITRite to determine improvements based on errors and gait speed. The tandem walk was also completed daily by the participants. Measuring the tandem walk before and after the Stepping On program would be beneficial to determine improvements in balance strategies.

The second purpose of this study was to determine if the Four Stage Balance Test (FSBT) is an effective balance tool to predict fall risk. There was no normative data of all four parts of the test to compare. However, the single leg portion of the FSBT was beneficial in determining fall risk. Seven out of eight participants that completed the pre and post testing were considered a fall risk due to their single leg stance times. All but three participants showed improvement in the tandem stance portion of the FSBT.

A recommendation for future study would be to focus on completing the middle stages, tandem stance and semi-tandem stance. The most challenging stage, SLS has shown to be difficult with the older population and not much improvement of times was shown in this study. The easiest stance, feet together stance was completed with relatively no challenge and every participant completed it. Only completing the middle stages would reduce time for testing. It would also be directly correlated with the Stepping On exercises and base improvements of times with compliance with the exercises.
It was previously determined that seven out of eight participants were at a fall risk based off of their SLS times. The normative data researched by Springer et al.,\textsuperscript{9} stated that individuals that are 80-99 years old had SLS times with eyes closed of 2.1 seconds. This brings up an interesting point due to all participants have some form of vision deficits. There are three sensory systems that provide input to brain to maintain balance; vision, proprioception and vestibular. When visual input is removed, instability due to lack of vision can be tested apart from other sensory impairments. When considering visual impairment, Participants 1, 3, 6, 11 and 13 would be considered within their age norms when compared with SLS with eyes closed times.

CONCLUSION

This study was completed to determine if the FSBT is an appropriate measure of fall risk in the Stepping On program and to determine if the Stepping On program is effective at reducing fall risk. The FSBT is an appropriate test to be completed with the Stepping On program, due to its similar testing stances with the Stepping On exercises. The Stepping On program showed positive benefits such as an increase in confidences for all participants. However, using the FSBT as a predictor of fall risk showed that the Stepping On program did not change ability to perform static balance over the seven-week program. Other factors should be considered such as vision deficits and compliance with the Stepping On exercises.
APPENDIX A:
March 13, 2015

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Meridee Danks, D.P.T. and Beverly Johnson, PT, DSc, GCS</th>
</tr>
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<tbody>
<tr>
<td>Project Title:</td>
<td>The Effectiveness of the &quot;Stepping On&quot; Program for Reducing the Incidence of Falls in the Elderly</td>
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<tr>
<td>IRB Project Number:</td>
<td>IRB-201209-047</td>
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<td>Project Review Level:</td>
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</tr>
<tr>
<td>Consent Form Approval Date:</td>
<td>03/12/2015</td>
</tr>
</tbody>
</table>

The Protocol Change Form and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the University of North Dakota Institutional Review Board.

Attached is your revised consent form that has been stamped with the UND IRB approval and expiration dates. Please maintain this original on file. You must use this original, stamped consent form to make copies for participant enrollment. No other consent form should be used. It must be signed by each participant prior to initiation of any research procedures. In addition, each participant must be given a copy of the consent form.

You have approval for this project through the above-listed expiration date. When this research is completed, please submit a termination form to the IRB. If the research will last longer than one year, an annual review and progress report must be submitted to the IRB prior to the submission deadline to ensure adequate time for IRB review.

The forms to assist you in filing your project termination, annual review and progress report, adverse event/unanticipated problem, protocol change, etc. may be accessed on the IRB website: http://und.edu/research/resources/human-subjects/

Sincerely,

Michelle L. Bowles, M.P.A., CIP
IRB Coordinator
MLB/jle
Enclosures
Cc: Chair, Physical Therapy
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. Handwritten forms are not accepted – responses must be typed on the form.

Principal Investigator: Meridee Danks and Beverly Johnson  
Telephone: 777-3861  
E-mail Address: meridee.danks@med.und.edu

Complete Mailing Address: 501 North Columbia Road, Stop 9037, Grand Forks, ND 58202-9037

School/College: UNDSMHS  
Department: Physical Therapy

Student Adviser (if applicable): _____________________________

Telephone:  
E-mail Address:  
Address or Box #:  
School/College:  
Department:  

Project Title: The Effectiveness of the "Stepping On" Program for Reducing the Incidence of Falls in the Elderly

Proposed Project Dates: Beginning Date: 9-12-2012  
Completion Date: ongoing (Including data analysis)

Funding agencies supporting this research: NA

Did the contract with the funding entity go through UND Grants and Contracts Administration?  □ YES or □ NO

Attach a copy of the contract. Do not include 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 any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?  

☑ YES or □ NO

Will any data be collected at or obtained from another organization outside the University of North Dakota?

☑ YES or □ NO

If yes to either of the previous two questions, list all organizations: Holy Family Church, Northwood Senior Center, Grand Forks Senior Center and Calvary Lutheran Church.

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement 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 organizational 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)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

<table>
<thead>
<tr>
<th>Board Name</th>
<th>Date Submitted</th>
<th>Status</th>
</tr>
</thead>
<tbody>
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(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

**Type of Project:** Check “Yes” or “No” for each of the following.

☐ YES or ☑ NO New Project
☐ YES or ☑ NO Continuation/Renewal
☐ YES or ☑ NO Dissertation/Thesis/Independent Study
☐ YES or ☑ NO Student Research Project
☐ YES or ☑ NO Protocol Change for previously approved project? If yes, submit a signed copy of this form with the changes bolded or highlighted.
☐ YES or ☑ NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.
☐ YES or ☑ NO Does your project include Genetic Research?

**Subject Classification:** This study will involve subjects who are in the following special populations: Check all that apply.

☐ Children (< 18 years) ☑ UND Students
☐ Prisoners ☑ Pregnant Women/Fetuses
☐ Cognitively impaired persons or persons unable to consent
☐ Other

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

**This study will involve:** Check all that apply.

☐ Deception (Attach Waiver or Alteration of Informed Consent Requirements)
☐ Radiation
☐ New Drugs (IND) IND # _______ Attach Approval
☐ Investigational Device Exemption (IDE) # _______ Attach Approval
☐ Non-approved Use of Drug(s)
☒ None of the above will be involved in this study

**I. Project Overview**

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

Falls are a major concern in the elderly population. Falls can lead to impairments, functional limitations and disabilities. The North Dakota Department of Health, Division of Injury Prevention and Control has initiated the Stepping On program in several communities across North Dakota. The Stepping On program is, an established multifaceted community-based program using small-group based learning, designed to improve fall self-efficacy, encourage behavioral change, and to reduce falls. Two-hour sessions are conducted weekly for 7 weeks with a follow-up home visit and a 3 month booster session. The aim of this study is to test whether the Stepping On program is effective in reducing falls in elderly people living at home.

Revised 04/02/12 2
II. Protocol Description

Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.

   a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, flyers, etc., that will be used to recruit subjects. Subjects will be recruited from participant in the Stepping On program by word of mouth at Holy Family Church, Northwood Senior Center, Grand Forks Senior Center and Calvary Lutheran Church. The Stepping On program is being set-up at these locations.

   b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the "Subject Classification" section above. Subjects need to be attendees of the Stepping On program which is designed for individuals who are 65 or older and living in his/her own home and able to walk independently outside their home.

   c) Describe your exclusionary criteria and provide a rationale for excluding subject categories. Exclusion criteria includes any cognitive problems associated with dementia and being homebound (unable to independently leave home).

   d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects. The goals recruit approx 12 subjects at each site (Holy Family, Northwood, Grand Forks Senior Centers and Calvary Lutheran Church) to participate in the research study. The Stepping On program recommends limiting the number of participants to no more than 15 for the 7-week program.

   e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method.

      Only 10-15 people will be attending the Stepping On program at each site so this will limit the number.

2. Description of Methodology.

   a) Describe the procedures used to obtain informed consent. Participants of the Stepping On program will be asked if they would like to be part of this study on the introduction day of the program. If they are interested they will be given an informed consent form to review. Questions will be addressed and if willing to participate signatures will be obtained. Each volunteer will be given a copy of the consent form.

   b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research. Holy Family Church in Grand Forks, ND, Northwood Senoir Center in Northwood, ND, Grand Forks Senior Center and Calvary Lutheran Church in Grand Forks, ND.

   c) Indicate who will carry out the research procedures. Meridee Danks and Bev Johnson, physical therapists from UND physical therapy department; UND-PT students will be assisting as needed.

   d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them. Assessments will occur at Weeks 1 and 7 and then at 3 month booster session and at 6 months post Stepping On program recheck. Assessment will include the following:

      1. Baseline Questionnaire and Fall Risk Survey - are filled out as part of the Stepping On program. Questionnaire is to gather demographic, mobility and falls information. Time to complete is ~10 minutes.

   Revised 04/02/12
Additional test performed (beyond Stepping On gathered information)

2. Activities-specific Balance Confidence (ABC) Scale - subject rates level of confidence in doing everyday activities with or without falling using a 0 – 100% scale (0 = no confidence to 100 = completely confident). Total score is sum of 16 individual activity scores, which is then averaged, the higher the score the less concerns the subject has about falling. Time to complete is less than 5 minutes.

3. Sit to Stand Test (STS) - the subject will be asked to go from a sit to stand for 30 seconds. The number of repetitions will be completed in 30 sec and the length of time to complete the first 5 sit to stands will be recorded. This is an objective measurement of strength and balance. Time to complete ~ 3 minutes.

4. Timed Up and Go Test (TUG) - the test requires that subjects stand up from a chair, walk 10 ft, turn around, and return. The time to complete the activity is recorded. A second trial will be performed with the subject performing a cognitive task (i.e. subtracting by 3s or spelling words) while walking. A safety belt will be used when performing the assessment. Time to complete is 1 minute. This is an objective measure of balance in an activity of daily function. GAITRite electronic walkway may be used if available to allow the researchers to gather greater data on subjects walking during the above 10 meter walk.

5. Four-Test Balance Scale (FTBS) - This is a balance test that progressively challenging. The test is stop if the person is unable to perform task for the required amount of time. Initially, the subject is asked to stand with feet together for 10 seconds with eyes open; if able to perform this activity the subject is then asked to stand in a semi-tandem position (feet touching but one foot slightly ahead of the other) for 10 sec; if able to do so, the subject then is asked to perform a tandem stand (heel to toe) for 10 sec; if able to do so, the subject will be progressed to one leg stand for up to 30 seconds. If subject is unable to stand for 30 sec, time of trial will be recorded. A safety belt will be used during this assessment. Time to complete is 3-5 minutes. This is an objective measure of balance and strength.

6. Fall and Activity Survey and Stepping On Participation Evaluation - each subject will be given a survey following the completion of Stepping On sessions at Week 7, at 3-month Booster session and at the 6 months recheck to record any falls that have occurred and to monitor follow through of assigned strength and balance exercises. Fall is defined as an event that results in a person unintentionally coming to rest on the ground, floor, or other lower level. (Buchner) If a subject is unable to attend the Booster session and/or at the 6-month recheck they will be contacted by phone or mail in regards to the survey.

e) Describe audio/visual procedures and proper disposal of tapes.

NA

f) Describe the qualifications of the individuals conducting all procedures used in the study.

Meridee Danks has been a practicing physical therapist for 28 years and has a specialty certification in Neurologic Physical Therapy. Bev Johnson has been a practicing physical therapist for 30+ years and has Doctoral of Science in Geriatrics. UND-PT students will be supervised & trained as needed.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).

NA
Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.

   a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.
   There is a minimal risk of loss of balance with the balance assessments (TUG/FTBS/etc). Each of these tests will be performed with a safety belt and spotter to prevent any falls. The subject will be instructed that they can quit the activity at any time if they do not feel safe performing it.
   b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.
   There will be a link to each subject in order to compare to survey information at recheck times. Once all the data (after 6-month recheck) is collected the link will be destroyed.
   c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.
      NA
   d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.
      NA

4. Subject Protection.
   a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).
      A safety belt and spotter will be used during each balance assessment. Subjects will be informed that they can stop any activity that they do not feel safe performing.
   b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.
      All data will be coded and identifying information removed once all data is gathered. Any reporting will be in aggregate form. The assessments will be performed in a private room. Follow-up survey's will be sent back to researcher with ID number only.
   c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
      Each subject will be provided with a copy of the consent form.
   d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will both be retained in separate locked locations for a minimum of three years following the completion of the study.
      Describe: 1) the storage location of the research data (separate from consent forms and subject personal data)
      2) who will have access to the data
      3) how the data will be destroyed
      4) the storage location of consent forms and personal data (separate from research data)
      5) how the consent forms will be destroyed
   1. The research data will be stored separately from the consent form and other personal data.
   2. Only the researchers will have access to the data.
   3. The data will be kept a minimum of 3 years and will be shredded once data analysis is completed.
   4. Consent forms/personal data and data will be stored in separate files in the locked office of the researcher.
   5. The consent forms will be kept a minimum of 3 years and then will be shredded.

Revised 04/02/12
e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.). Referrals will be made to family physician if subjects have concerns regarding their balance.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

Subject will be referred for medical treatment if required for any injury that may occur during assessment. The responsibility of cost related to any treatment will be the responsibility of the subject.

III. Benefits of the Study
Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

Subjects will be able to have their balance assessed at no cost. They will be able to see if there was any benefit of attending Stepping On program. General benefit to society to see how effective a preventative balance program can be.

IV. Consent Form
Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply stating 'see attached consent form' is not sufficient. The items listed below must be addressed on this form):

1. The person who will conduct the consent interview
2. The person who will provide consent or permission
3. Any waiting period between informing the prospective participant and obtaining consent
4. Steps taken to minimize the possibility of coercion or undue influence
5. The language to be used by those obtaining consent
6. The language understood by the prospective participant or the legally authorized representative
7. The information to be communicated to the prospective participant or the legally authorized representative

1. Meridee Danks and Bev Johnson will conduct the consent interview.
2. Researchers listed above will provide the consent forms.
3. No waiting period.
4. Prospective subjects will be told that research is voluntary and that if they do decide to participate that they are able to stop at any time without any penalty.
5. English
6. English
7. The consent form will indicate the assessments to be performed and the amount of time to perform them and who will be performing the assessments.

A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. Please note: All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. The consent form should be written at no higher than an 8th grade reading level, and it is recommended that it be written in the third person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

Necessary attachments:
- Signed Student Consent to Release of Educational Record Form (students only);
- Investigator Letter of Assurance of Compliance;
- Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- Surveys, interview questions, etc. (if applicable);
- Printed web screens (if survey is over the Internet); and
By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signature: [Signature]

(Principal Investigator) Date: [Date]

(Practice Investigator) Date:

Requirements for submitting proposals:
Additional information can be found on the IRB web site at: http://und.edu/research/research-economic-development/institutional-review-board/.

Original Proposals and all attachments should be submitted to: Institutional Review Board, 264 Centennial Drive Stop 7134, Grand Forks, ND 58202-7134, or brought to Room 106, Twamley Hall.

Prior to receiving IRB approval, researchers must complete the required IRB human subjects' education. Please go to: http://und.edu/research/research-economic-development/institutional-review-board/human-subject-education.cfm

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the IRB website regarding required copies and IRB review categories, or you may call the IRB office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form if the proposal is non-clinical; 5 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 5 copies of the company's protocol must be provided.
INFORMED CONSENT

TITLE: The Effectiveness of the "Stepping On" Program for Reducing the Incidence of Falls in the Elderly

PROJECT DIRECTOR: Meridee Danks and Beverly Johnson

PHONE #: 701-777-2831

DEPARTMENT: 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 that will look at the effectiveness of education and exercise in reducing falls. You have been identified as a possible subject as you are presently participating in the "Stepping On" program. The purpose of this research study is to test whether the Stepping On program is effective in reducing falls in older people living at home. Participants need to be 65 or older, live in on their own, and be able to walk independently in the community.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 10-12 people at each site will take part in this study being performed by University of North Dakota Department of Physical Therapy.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will last the same length of time you will be in the Stepping On program (7 weeks with a 3 & 6-month follow-up). The assessment times will be at the same days as when you will be attending your Stepping On program. Each visit will take about 20 minutes during the Day 1, Day 7, 3-month & 6-month recheck of the Stepping On program.
WHAT WILL HAPPEN DURING THIS STUDY?

Assessments will occur at Week 1 and 7 sessions and then at 3 month booster session and at 6 month recheck at the same site. Assessment will include the following:

1. **Baseline Questionnaire and Fall Risk Survey** - are filled out as part of the Stepping On program. Questionnaire is to gather demographic, mobility and fall information. You are free to skip any questions that you prefer not to answer. Time to complete is ~10 minutes.

Additional test performed (beyond Stepping On gathered information), include:

2. **Activities-specific Balance Confidence (ABC) Scale** - subject rates level of confidence in doing everyday activities with out falling using a 0 – 100% scale (0 = no confidence to 100 = completely confident). Total score is sum of 16 individual activity scores, which is than averaged, the higher the score the less concerns the subject has about falling. Time to complete is less than 5 minutes.

3. **Sit to Stand Test (STS)** - the subject will be asked to go from a sit to stand for 30 seconds. The number of repetitions will be completed in 30 sec and the length of time to complete the first 5 sit to stands will be recorded. This is an objective measurement of strength and balance. Time to complete is 3 minutes.

4. **Timed Up and Go Test (TUG)** - the test requires that subjects stand up from a chair, walk 10 ft, turn around, and return. The time to complete the activity is recorded. A second trial will be performed with the subject performing a cognitive task (i.e. subtracting by 3s or spelling words) while walking. A safety belt will be used when performing the assessment. Time to complete is 1 minute. This is an objective measure of balance in an activity of daily function. If available, the GAITRite electronic walkway may be used to allow the researchers to gather greater data on subjects walking parameters during the 10 meter walk.

5. **Four-Test Balance Scale** – This is a four part balance test, each part progressively challenges a person balance. The subject first will try to balance for 10 seconds with feet together, then with feet together but one slightly ahead of the other, progressing to one foot in front of the other (heel-toe) and lastly, the subject stands on one leg for up to 30 seconds with eyes open. If subject is unable to stand for the allotted time for any part the test will be stopped. A safety belt will be used during this assessment. Time to complete is 3-5 minutes. This is an objective measure of balance and strength.

6. **Fall and Activity Survey and Stepping On Participation Evaluation** - each subject will be given the 2 survey’s following the completion of Stepping On session at Week 7, 3-month Booster session and at the 6 months recheck to record any falls that have occurred and to monitor follow through of assigned strength and balance exercises. Fall is defined as an event that results in a person unintentionally coming to rest on the ground, floor, or
other lower level. (Buchner) If a subject is unable to attend the Booster session and/or at the 6-month recheck they will be contacted by phone or mail in regards to the survey.

WHAT ARE THE RISKS OF THE STUDY?

There may be some risk from being in this study, mainly with the potential to lose your balance. This risk will be minimized by use of safety precautions. For each physical balance assessment a safety belt and spotter will be used to prevent any falls. You can decide not to perform any assessment that you do not feel comfortable/safe performing.

WHAT ARE THE BENEFITS OF THIS STUDY?

You benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because it may help identify benefits of prevention education and exercise on falls in the elderly population. You may benefit by knowing your balance strengths and weakness that will be identified by the assessment scores.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY

You can decide to participant only in the Stepping On program and not in the research study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study. Nor will you be paid for being in this research study.

WHO IS FUNDING THE STUDY?

The University of North Dakota and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

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 and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of assigning you an identification number that will be used instead of your name on any data that is kept. Your signed consent form and your data will be stored separately in a locked room. Only the researchers will have access to any identifiable information. 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.

**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 or the Stepping On program.

**CONTACTS AND QUESTIONS?**

The researchers conducting this study are Meridee Danks and Beverly Johnson. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Meridee Danks or Beverly Johnson at 701-777-2831 during the day.

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: (Print) __________________________________________________

Signature of Subject ___________________________ Date __________

I have discussed the above points with the subject or, where appropriate, with the subject’s legally authorized representative.

Signature of Person Who Obtained Consent ___________________________ Date __________
Stepping On Workshop Participant Evaluation

Workshop Site: ___________________  Today's Date: ___________________

Please help us to make improvements to the design of the Stepping On program by completing this evaluation and returning it to one of the Leaders. Thank you.

1. What is your age? _____

2. What is your gender?
   - Male
   - Female

3. What is your race?
   - American Indian or Alaska Native
   - Asian or Asian-American
   - Black or African-American
   - Hawaiian Native or Pacific Islander
   - Hispanic
   - White or Caucasian
   - Other: _______________

4. What is your current marital status? (Check only one)
   - Married
   - Divorced
   - Widowed
   - Separated
   - Never married
   - Partnered (living with someone)

5. Have you fallen within the last year?
   - No
   - Yes
   - If yes, what was the cause of the fall? _____________________________

6. How many people live in your household (including yourself)? _____

7. What is your location of residence?
   - Rural/countryside
   - Small town
   - City/suburb of a city
Place an X in the box to indicate your response.

<table>
<thead>
<tr>
<th>Question</th>
<th>Nothing</th>
<th>Some</th>
<th>Alot</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Overall, how much did you learn from these sessions?</td>
<td></td>
<td></td>
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<tr>
<td>9. My understanding of how vision can influence the ability to get around safely.</td>
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<tr>
<td>Before Participation</td>
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<td></td>
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</tr>
<tr>
<td>Now, After Participation</td>
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<tr>
<td>10. My understanding of the importance of balance and strength exercises for preventing falls.</td>
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<tr>
<td>Before Participation</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Now, After Participation</td>
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<td></td>
<td></td>
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<tr>
<td>11. My knowledge of recognizing hazards in home environments.</td>
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<tr>
<td>Before Participation</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Now, After Participation</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>12. My understanding of the relation between safe footwear and fall prevention.</td>
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<tr>
<td>Before Participation</td>
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<tr>
<td>Now, After Participation</td>
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<tr>
<td>Before Participation</td>
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<td></td>
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</tr>
<tr>
<td>Now, After Participation</td>
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<tr>
<td>14. My understanding of the relation between medications and falls.</td>
<td></td>
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<tr>
<td>Before Participation</td>
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<td></td>
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<tr>
<td>Now, After Participation</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>15. My knowledge of the importance of good bone health and fall prevention.</td>
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<tr>
<td>Before Participation</td>
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<td></td>
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<tr>
<td>Now, After Participation</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
16. Which of your behaviors are you most likely to change?

17. List the three most important things you learned in this workshop.

   a. 
   
   b. 
   
   c. 

18. Which topic was least interesting?

19. Other comments concerning the workshop
## Fall Risk Survey

- **ID #**
- **Age:**
- **Gender:**
- **Date:**

<table>
<thead>
<tr>
<th>Fall Risk Factor</th>
<th>Factor Present</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any falls in the last year?</td>
<td>□ Yes □ No</td>
<td>If yes, how many?</td>
</tr>
<tr>
<td>Do you use an assistive device? (Cane, Walker, etc.)</td>
<td>□ Yes □ No</td>
<td>If yes, what kind?</td>
</tr>
<tr>
<td>Do you worry about falling when standing or walking?</td>
<td>□ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Do you spend <strong>less than 30 minutes</strong> per day <strong>5-7 days per week</strong> being physically active?</td>
<td>□ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Do you take <strong>more than 4 prescription medications</strong>?</td>
<td>□ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Has it been <strong>longer than 1 year</strong> since your last vision check?</td>
<td>□ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Do you have vision impairments? (glasses, macular degeneration, glaucoma, etc.)</td>
<td>□ Yes □ No</td>
<td>If yes, what kind?</td>
</tr>
<tr>
<td>Have you had any surgeries in the last year? (Hip, Knee, etc.)</td>
<td>□ Yes □ No</td>
<td>If yes, what kind?</td>
</tr>
<tr>
<td>Do you have any heart rate or rhythm issues?</td>
<td>□ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Do you have any sensation loss to your legs or feet?</td>
<td>□ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Are you depressed?</td>
<td>□ Yes □ No</td>
<td></td>
</tr>
<tr>
<td><strong>Yes TOTAL:</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The Activities-specific Balance Confidence (ABC) Scale*

Instructions to Participants:
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.

The 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 rating scale:

0% 10 20 30 40 50 60 70 80 90 100%
no confidence completely confident

"How confident are you that you will not lose your balance or become unsteady when you...
1. ...walk around the house? ____%
2. ...walk up or down stairs? ____%
3. ...bend over and pick up a slipper from the front of a closet floor ____%
4. ...reach for a small can off a shelf at eye level? ____%
5. ...stand on your tiptoes and reach for something above your head? ____%
6. ...stand on a chair and reach for something? ____%
7. ...sweep the floor? ____%
8. ...walk outside the house to a car parked in the driveway? ____%
9. ...get into or out of a car? ____%
10. ...walk across a parking lot to the mall? ____%
11. ...walk up or down a ramp? ____%
12. ...walk in a crowded mall where people rapidly walk past you? ____%
13. ...are bumped into by people as you walk through the mall? ____%
14. ...step onto or off an escalator while you are holding onto a railing? ____%
15. ...step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? ____%
16. ...walk outside on icy sidewalks? ____%

Stepping On Survey – Week 7

1. Do you feel your balance and confidence have improved while performing daily activities as a result of participating in the Stepping On Program?

   Balance  Yes   No
   Confidence  Yes   No

   If yes, what information helped you the most?

2. A fall is any event that led to an unplanned, unexpected contact with a supporting surface such as the floor. Have you fallen since starting the Stepping On Program?

   Yes   No

   If yes, how many falls since the program began: _____

   Describe the cause of fall(s) and any injuries that occurred:

3. How would you rate your present level of daily physical activity? (circle one)

   Inactive/Low  Moderate  High

   If your physical activity is limited, what do you think is the major reason?

4. Have you performed the Stepping On exercises faithfully?

   Yes   No

   If no, what has kept you from performing the exercises as per the recommended amount of times?
If **yes**, record on the chart below how often each week you perform the Stepping On exercises, the number of repetitions you do of each exercise, and the amount of weight you use with the strength exercises?

**Balance Exercises:**

<table>
<thead>
<tr>
<th></th>
<th># times/week</th>
<th># of repetitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sit-to-Stand</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sideways Walking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heel-toe standing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heel-toe walking</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Strength Exercises:**

<table>
<thead>
<tr>
<th></th>
<th># times/week</th>
<th># of reps &amp; weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side-hip-strengthening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knee-strengthening</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heel raises</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toe raises</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Do you have any difficulties performing the above exercises?
   Yes _____  No _____  If **yes**, describe what difficulties you are having?

6. Had you been actively exercising at home prior to the Stepping On program?
   Yes _____  No _____  If **yes**, what type of exercise did this include?
   How frequently do you perform these? ________

7. Do you participate in community exercise groups (other than Stepping On program)?
   Yes _____  No _____  If **yes**, what group and/or type of exercise?
   How often do you attend? ________
Stepping On Survey – 3 months after

1. Do you feel your balance and confidence have improved while performing daily activities as a result of participating in the Stepping On Program?
   
   Balance: Yes__ No__
   Confidence: Yes__ No__
   If yes, what strategies have helped you?

2. Do you feel that the Stepping On Program has helped you?
   
   Yes__ No__
   If yes, how has it helped you?

3. Have you had any falls since completing the Stepping On Program?
   
   Yes__ No__
   If yes, how many falls: ______
   What was the cause(s) of the fall(s)?

4. How often do you perform the Stepping On exercises usually? (Circle below)
   
   Strength: ≥3x/week  2x/week  1x/week  < than 1x/week  Not at all
   Balance: ≥3x/week  2x/week  1x/week  < than 1x/week  Not at all
   If you have not been doing the exercises regularly, what has kept you from doing so?

5. Have you joined or continued any community exercise groups since the Program?
   
   Yes__ No__
   If yes, what group?
APPENDIX B:
Four Stage Balance Test Directions

Equipment: Stopwatch, gait belt, table.

Set up: An open area is required which includes a table that participants may use to steady themselves. Demonstrate the stance positions, provide directions and begin the test.

General Instructions: “I am going to show you different standing foot positions. Try to stand in each position for 30 seconds. You can practice each position and decide which feet to use. You can hold on for support to steady yourself in each position but I will not start timing until you let go of the support. Hold this position until I tell you to stop.” Provide assistance to participants if needed to get into each position, but not to maintain each position. Demonstrate positions for each participant.

Single Leg Stance Directions. “Stand on one leg and do not let your other leg touch the ground or the leg you are standing on.”

Tandem Stance Directions. “Stand with one foot directly in front of the other, with the toe of one foot touching the heel of your other foot.”

Semi Tandem Stance Directions. “Place one foot just slightly ahead of the other while keeping your feet close together.

Narrow Base Stance Directions. “Stand with your feet side by side.”

Record: Start timing when the participant maintains the position. Stop timing if the participant reaches 30 seconds or is unable to maintain the position.
REFERENCES


7. Goebel JA. Practical management of the dizzy patient. Lippincott Williams & Wilkins: 8 (92) 2008; 384-93


