2016

Effectiveness of the 30 Second Chair Stand Test in Reducing the Fall Risk of Community Dwelling Older Adults Participating in the Stepping on Program

Corissa Kruse
University of North Dakota

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EFFECTIVENESS OF THE 30 SECOND CHAIR STAND TEST IN REDUCING THE FALL RISK OF COMMUNITY DWELLING OLDER ADULTS PARTICIPATING IN THE STEPPING ON PROGRAM

by

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Bachelor of Arts in Visual Arts, 2013
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A Scholarly Project Submitted to the Department of Physical Therapy Faculty in partial fulfillment of the requirements for the following degree, Doctor of Physical Therapy at the University of North Dakota

Grand Forks, North Dakota
May 2016
This Scholarly Project, submitted by Corissa Kruse 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.

[Signature]
Graduate Advisor

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Chairperson, Physical Therapy
PERMISSION

Title Effectiveness of the 30 Second Chair Stand Test in Reducing the Fall Risk of Community Dwelling Older Adults Participating in the Stepping On Program

Department Physical Therapy

Degree Doctor of Physical Therapy

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Date 9-30-2015
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ABSTRACT

Stepping On is a seven week fall prevention program that utilizes education and exercise. The purpose of this study is to see if the participants of Stepping On can show a decrease in fall risk through the use of the 30 Second Chair Stand Test (30sCST), a functional assessment tool used to assess fall risk. This study looked at a group of 14 females (M=87 y/o) at an assisted living facility, who met the program’s qualifications (community dwelling individuals and ≥65 y/o) and attended the Stepping On program. Only eight participants were tested using the 30sCST at Week 1 and Week 7 of the program in addition to four other fall risk assessments (Single Leg Stand/ Tandem Stance, Timed Up and Go, Cognitive Timed Up and Go, and the GAIT Rite).

This study specifically looks at the 30sCST and whether it is a good test to use with Stepping On participants, by comparing each individual’s score to normative data of their age group. Out of the eight participants assessed, only one showed an improved percent in change (100%), with a decrease in fall risk. Two of the eight participants were not at risk of falling when compared to the normative data for their age group. Factors that may have had an impact on the results of this study include; high mean age of group, visual and hearing deficits, lack of motivation, low compliance to exercise, musculoskeletal co-morbidities, use of assistive devices, slower rate of exercise progression within the program, and meeting one time per week as a group.
CHAPTER 1
INTRODUCTION

The Stepping On program is a seven week program that meets for two hours as a group, once a week. The program encompasses specific topics in regards to fall prevention strategies and education, as well as exercise, with the purpose of preventing falls, reducing individual’s fall risk, and to build self-confidence. The Stepping On program targets community-dwelling individuals over the age of 65, who live independently, and who have had a fall or are fearful of falling. Falls in older adults not only put them at risk for future falls, but it decreases self-confidence in their mobility and can alter their level of activity. It is important to be able to conclude initially at Week 1 of the Stepping On program, if the participants who enroll in the Stepping On program are at a risk of falling, and to know which functional screening tools are good predictors of a participant’s fall risk.

About one third of people over the age of 65 and almost half of people over the age of 80 will fall at least once this year.\(^1\) Lower extremity muscle weakness is a major contributor to falls\(^2,3\) and it can also be used as a predictor for fall risk. The sit to stand activity is used as a functional balance exercise in the Stepping On program (Refer to Appendix A for Stepping On’s exercise program) and also is used in this study as a screening tool to determine each participant’s fall risk. The 30 Second Chair Stand Test (30sCST) may be a more appropriate functional lower limb strength and endurance assessment instrument for older adults living in the community compared to the Five
Timcs Sit to Stand Test (FTSTS). The reason being is because the FTSTS measures functional lower limb strength, focusing on measuring speed and power, rather than just strength and endurance. More research using the 30sCST has been performed on active community-dwelling older adults, where as the FTSTS test has been performed mostly on older adults with lower physical functional abilities, such as those in nursing homes or assisted living facilities. Participants in the Stepping On program are community-dwelling and therefore are better assessed using the 30sCST. This test is more apt to compare their endurance and strength to functional activities they need to do independently at home and in the community. Since most of the individuals in the Stepping On program are higher functioning, the 30sCST avoids the ceiling effect that would occur with the FTSTS, had the participants within the program been in need of assistance, or lacked the strength and endurance to stand up from a chair on their own.

Studies have shown regular exercise can maintain or improve physical health and activity in older adults and it can also reduce the rate of falling by 17%. Since weakness and poor balance are contributing factors to falling, they are crucial predictors of fall risk during transitional movement. The Stepping On program incorporates sit to stand as a balance exercise; thus supporting the use of the 30sCST as an appropriate outcome measure.

The purpose of this study is to determine if Stepping On can show a decrease in fall risk amongst participants of the program as measured by the 30sCST. It also will look at identifying characteristics of Stepping On's participants that may impact their fall risk. The 30sCST examines poor balance and lower body weakness. This test is a functional task individuals do on a daily basis and it is important to determine if improvement occurs in these areas of deficit with performing Stepping On's exercise program.
CHAPTER 2

METHODOLOGY

Subjects

Participants for this study were recruited from a locally offered Stepping On program. Prior to the start of this study, a project proposal was submitted to the Institutional Review Board (IRB) of North Dakota. The IRB approved the University of North Dakota Physical Therapy Department’s conduction of this study (IRB-201209-047) to perform balance assessments and surveys amongst the individuals in the Stepping On program (See Appendix B for IRB). The study involved assessing 14 females in the Stepping On program at an assisted living facility. Prior to taking part in this study each participant signed and was given a copy of the approved consent form (Refer to Appendix C for Subject Consent Form). Each individual also completed a Demographic Questionnaire, a Week 1 Fall Risk Survey, and the Activities-specific Balance Confidence (ABC) Scale. A Week 7 Fall Risk Survey was completed at the end of the program, Week 7 (refer to Appendix D for Demographic Questionnaire, ABC form, and surveys). Table 1 displays the Week 1 characteristics of each participant. Five tests were performed on each participant in a random fashion to predict fall risk (30sCST, Single Leg Stand/ Tandem Stance, Timed Up and Go, Cognitive Timed Up and Go, and the GAIT Rite).
Table 1: Characteristics of Participants at Week 1 of Stepping On Program

<table>
<thead>
<tr>
<th>Subject #</th>
<th>Gender</th>
<th>Age</th>
<th>Type of Assistive Device</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>&gt;4 Meds</th>
<th>Minimally Active &gt;30 Min/day</th>
<th>Depressed</th>
<th>Med Hx</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>92</td>
<td>None</td>
<td>0</td>
<td>3/11</td>
<td>Yes, not specified</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>92</td>
<td>WW/WW</td>
<td>2</td>
<td>5/10</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>R knee pain</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>89</td>
<td>Manual WC/FW/W</td>
<td>2</td>
<td>6/11</td>
<td>Yes, glasses, macular degeneration</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>L ankle surgery, Dizzy</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>87</td>
<td>FWW</td>
<td>0</td>
<td>4/11</td>
<td>Yes, not specified</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Bilat TKA</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>
<td>Yes, legally blind, bifocals</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>80</td>
<td>None</td>
<td>0</td>
<td>3/11</td>
<td>Yes, deficits</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes-knee</td>
<td>No</td>
<td></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, macular degeneration, glaucoma</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>85</td>
<td>SEC</td>
<td>0</td>
<td>6/11</td>
<td>Yes, glasses</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>80</td>
<td>None</td>
<td>2</td>
<td>8/11</td>
<td>Yes, glasses</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>L knee pain</td>
</tr>
<tr>
<td>10</td>
<td>F</td>
<td>87</td>
<td>FWW</td>
<td>0</td>
<td>3/11</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>R hip pain</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>84</td>
<td>FWW</td>
<td>2</td>
<td>6/11</td>
<td>Yes, macular degeneration</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes-knee</td>
<td>No</td>
<td>R rotator cuff tear</td>
</tr>
<tr>
<td>12</td>
<td>F</td>
<td>89</td>
<td>4WW</td>
<td>Yes 70</td>
<td>2/11</td>
<td>Yes, glasses</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>90</td>
<td>4WW</td>
<td>0</td>
<td>5/11</td>
<td>Yes, glaucoma</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>R TKA, OA, L knee</td>
</tr>
<tr>
<td>14</td>
<td>F</td>
<td>89</td>
<td>Power WC/4W</td>
<td>Yes 70</td>
<td>NT</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

Though this group does not fall within the typical "community-dwelling individuals" requirement of the Stepping On program, it was still applicable for them to receive the fall prevention education, as they are required to live independently in the assisted living facility. The group consisted solely of females with differing levels of mobility and past medical histories. All could ambulate 200 ft independently; three required no assistive device, one ambulated with a cane, eight ambulated with wheeled walkers, and primary locomotion for two was by wheelchair for long distances (both were able to walk 200 ft with the use of a front wheeled walker). Assessment of the 30sCST was performed on two different occasions with each participant who gave consent. Initial data was collected at Week 1 and post-program data was collected at
Week 7. Of the 14 participants in the program, 13 were assessed at initial assessment and eight participants were assessed at Week 7. One participant was not at Week 1 session.

Instrumentation

As part of instrumentation class, a pilot study was performed prior to conduction of the study in this paper, with participant consent, to assess technique and administration of the 30sCST. It was found to have excellent inter-rater reliability ($r=.93$) in this pilot study, amongst two student physical therapists, who assessed a total of 14 females and 1 male ($n=15$), between the ages of 70 and 94, at a health expo in March of 2015. One participant was scored incorrectly amongst raters due to the participant’s inability to stand without the use of her arms and therefore should have automatically been scored a 0 by both raters, which did not occur. Table 2 displays the data collected.

Table 2: March 2015 Pilot Study 30sCST Inter-rater Reliability

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Sex</th>
<th>Rater 1 Sit to Stand Count</th>
<th>Rater 2 Sit to Stand Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>79</td>
<td>F</td>
<td>0</td>
<td>8 with Bilateral Arm Support</td>
</tr>
<tr>
<td>2</td>
<td>94</td>
<td>F</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>89</td>
<td>F</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>79</td>
<td>F</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>86</td>
<td>F</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>78</td>
<td>F</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>87</td>
<td>F</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>70</td>
<td>F</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>76</td>
<td>F</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>92</td>
<td>F</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>87</td>
<td>M</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>80</td>
<td>F</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>89</td>
<td>F</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>70</td>
<td>F</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>86</td>
<td>F</td>
<td>11</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1 illustrates the 30sCST from starting position to a full standing position. The 30sCST has high specificity and sensitivity values of 70% and 80% respectively in
the elderly population, and an excellent test-retest reliability value of .89.\textsuperscript{8} It also has excellent inter-rater reliability of .95 and intra-rater reliability of .93.\textsuperscript{8} According to a study performed by Alfonso-Rosa et al.,\textsuperscript{9} an improved score of 3.3 repetitions is considered a Minimal Detectable Change (MDC) score for the elderly participants studied.\textsuperscript{9} The 30sCST is quick and easy to administer and it does not require extra equipment other than an armless chair and a stopwatch.

Figure 1: Illustration of the 30sCST from starting position (image on left) to a full erect stance (Image on right).\textsuperscript{10}

Procedure

An armless chair and a seat height of 17 inches was used for the 30sCST to assess balance, functional strength and endurance of the lower limbs of individuals participating in the Stepping On program during Week 1 and 7, and was used at a 3-month follow-up subsequent to program completion. To administer the test, the chair was positioned against a wall for support. Each participant was given the same instructions and provided with one demonstration of a full sit to stand (which requires a full erect stance). The instructions given as per the CDC's instructions for the 30sCST, and are as follows:\textsuperscript{11}
“Sit in the middle of the chair with your back straight and feet flat on the floor. Place your hands across your chest and keep them there. I am going to time you for 30 seconds and I want you to do as many sit to stands as you can within those 30 seconds. You must come to a full standing and seated position. You may start when I say “Go.””

The participant starts the test on the word “Go,” in which the timing begins. At the end of 30 seconds, the individual is told to stop and if they are more than halfway up when rising from the chair at that time, it is counted as a stand and added to their total score. One single trial is recorded, and if the individual uses their hands for assistance, their score is zero. Since most of the participants in this study required the use of their hands to get up from the chair, a chair with arms that met the same 17” height requirement was used for testing.

Eleven of the 14 participants were observed to ambulate with an assistive device, before starting the 30sCST, each participant was asked if they were able to transfer out of a chair without the use of their arms. If they said “no,” then they were moved to another chair of the same height with arm rests, given the standardized instructions mentioned prior, and were told “you may use your arms if you need to.” If the participant used their arms during the 30sCST, they were automatically scored a zero, but their data was still collected and used to track their progress and to determine their level of improvement by partaking in the Stepping On program.

Data Analysis

Each individual score is compared to normative data for their age. Normative data for the 30sCST from the Centers for Disease Control and Prevention website and STEADI (Stop Elderly Accidents, Deaths, and Injuries) program is provided in Table 3.12
Individuals are identified as being at a risk for falling if they are below the normative data for their age and gender.

Table 3: Normative Data for the 30sCST^{12}

<table>
<thead>
<tr>
<th>Age</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>60-64</td>
<td>&lt;14</td>
<td>&lt;12</td>
</tr>
<tr>
<td>65-69</td>
<td>&lt;12</td>
<td>&lt;11</td>
</tr>
<tr>
<td>70-74</td>
<td>&lt;12</td>
<td>&lt;10</td>
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<tr>
<td>75-79</td>
<td>&lt;11</td>
<td>&lt;10</td>
</tr>
<tr>
<td>80-84</td>
<td>&lt;10</td>
<td>&lt;9</td>
</tr>
<tr>
<td>85-89</td>
<td>&lt;8</td>
<td>&lt;8</td>
</tr>
<tr>
<td>90-94</td>
<td>&lt;7</td>
<td>&lt;4</td>
</tr>
</tbody>
</table>
CHAPTER 3

RESULTS

Fourteen females attending the Stepping On program participated in this study. Eight of the 14 participants attended both Week 1 and Week 7 sessions. Table 3 presents the initial 30sCST data collected at Week 1 (which 13 of the 14 participants were assessed) and then reassessment data at Week 7 (which nine of the 14 were assessed, with 1 participant not tested at Week 1) of the program for each participant. It includes each individual’s 30sCST score without arm support and with arm support, as well as the national average score for their age group (listed as “Normative Data for Age” on table 1).

Out of all of the 14 participants, 12 were found to be at risk of falling at the initial start of the program (Week 1), when compared to normative data for their age. Participant 1 and Participant 8 were the only two who scored above the national average score for their age group, deeming them safe with functional transfers. There was one individual (Participant 6) who was one sit to stand repetition away from meeting the required normative repetitions for her age group. Ten of the 14 women assessed, required use of their hands to get up out of the chair, which already put them at risk for falling, and at a score of zero.

At Week 7, eight participants were reassessed to determine if fall risk was reduced from attending the course and completing their exercises. Table 5 displays the results for eight of the 14 participants who were reassessed with the 30sCST. Out of the
14 participants, one dropped out due to medical leave (consultations with neurologist) and three were uninterested in the program following first and second sessions. Five participants were not reassessed at Week 7 due to four of them dropping from the program and one being absent from Week 1's class session.

Table 4: Week 1 and Week 7 Results for the 30sCST of the Stepping On Participants

<table>
<thead>
<tr>
<th>Participant</th>
<th>Gender</th>
<th>Age</th>
<th>Normative Data for Age</th>
<th>Week 1 (Reps)</th>
<th>Week 7 (Reps)</th>
<th>Percent Change Without Arms (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Without Arms</td>
<td>With Arms</td>
<td>Without Arms</td>
</tr>
<tr>
<td>1</td>
<td>F</td>
<td>92</td>
<td>≥4</td>
<td>11</td>
<td>N/A</td>
<td>11</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>92</td>
<td>≥4</td>
<td>0</td>
<td>3</td>
<td>*</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>89</td>
<td>≥8</td>
<td>0</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>87</td>
<td>≥8</td>
<td>0</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>94</td>
<td>≥4</td>
<td>0</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>80</td>
<td>≥9</td>
<td>8</td>
<td>N/A</td>
<td>8</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>84</td>
<td>≥9</td>
<td>0</td>
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<tr>
<td>8</td>
<td>F</td>
<td>85</td>
<td>≥8</td>
<td>10</td>
<td>N/A</td>
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<tr>
<td>9</td>
<td>F</td>
<td>80</td>
<td>≥9</td>
<td>0</td>
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<tr>
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<td>F</td>
<td>87</td>
<td>≥8</td>
<td>0</td>
<td>11</td>
<td>*</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>84</td>
<td>≥9</td>
<td>0</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>12</td>
<td>F</td>
<td>89</td>
<td>≥8</td>
<td>0</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>90</td>
<td>≥4</td>
<td>0</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>14</td>
<td>F</td>
<td>89</td>
<td>≥8</td>
<td>*</td>
<td>*</td>
<td>0</td>
</tr>
</tbody>
</table>

N/A = not applicable for stage of test. * = Not Assessed. UD = Undetermined.

Seven out of the eight participants who were reassessed showed no percent of change between Week 1 and Week 7. Table 4 shows the results for pre- and post-assessment scores of the eight individuals for the 30sCST. Participant 5 was the only
participant to show improvement without arms. Participant 12 improved from three sit to stand repetitions to five sit to stand repetitions, however, she required the use of her hands. At initial assessment, she required the use of her arms during testing, and at Week 7 she was able to perform eight sit to stands without the use of her arms, showing a 100% change. The results of this study overall show there was no decrease in arm use for the 30sCST of the individuals from Week 1 to Week 7 of the Stepping On program. Two participants scored the same number of reps, four participants scored lower on the post-test compared to their pre-test score, and one participant scored two reps higher at post-testing, but required arm support. Only two of the 14 participants at Week 7 were not at risk of falling when compared to the normative data for their age group, which is the same as Week 1. No one reported having a fall during their participation in the program. Only one participant (Participant 5) met the MDC requirement of 3.3 repetitions for this test.
Table 5: Pre- and Post- 30sCST Assessment Scores of the 8 participants studied.

<table>
<thead>
<tr>
<th>Participant</th>
<th># Repetitions</th>
<th># Repetitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>5</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td>6</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>11</td>
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<td>4</td>
</tr>
<tr>
<td>12</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>13</td>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>

When compared to CDC’s fall risk assessment, eight of the 13 participants who filled out the UND Fall Risk survey at Week 1 were at a fall risk, meaning they responded “yes” to four or more of the 11 questions. Of those participants tested at Week 1, 11 of the 13 were at a risk of falling when compared to their 30sCST age normative data.

At Week 7 reassessment, seven of the eight participants subjectively reported they needed to push with their hands to stand up from a chair on the CDC survey. Objective Week 7 data from the 30sCST identifies five of the eight participants required the use of their hands to stand up from a chair. Participant 5 and Participant 1 reported they required hand support, however during the 30sCST they had performed it without the use
of their arms. Participant 3 indicated one of the most important things she has learned by participating in the program is how to stand up easier from a chair, which makes her feel more steady and confident.

Table 6 displays the Week 7 characteristics of each participant. Five out of the eight individuals who were assessed at Week 7 reported they had a fear of falling, but all eight stated their confidence had improved from participating in the program. Six participants reported they sometimes feel unsteady while walking, four stated they did not perform the exercises faithfully, and one said she had initially performed the exercises faithfully but hadn’t complied the entire time. Some of the participants’ reasons for not adhering to the exercise program include:

- “Have not been feeling well lately.”
- “Did not feel like exercising.”
- “Too busy.”
- “Neglect.”
- “Too many naps in a day.”
- “Not motivated.”
- “Fatigued.”
- “Tired.”
Table 6: Characteristics of Participants at Week 7 of Stepping On Program

<table>
<thead>
<tr>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>92</td>
<td>7</td>
<td>5/12</td>
<td>Yes</td>
<td>0</td>
<td>High</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>92</td>
<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>89</td>
<td>6</td>
<td>10/12</td>
<td>Yes “a little bit”</td>
<td>0</td>
<td>Moderate</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>87</td>
<td>7</td>
<td>6/12</td>
<td>Yes</td>
<td>0</td>
<td>Moderate</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>94</td>
<td>6</td>
<td>5/12</td>
<td>Yes</td>
<td>0</td>
<td>Moderate</td>
<td>Yes</td>
</tr>
<tr>
<td>6</td>
<td>80</td>
<td>6</td>
<td>2/12</td>
<td>Yes</td>
<td>0</td>
<td>Moderate</td>
<td>Yes</td>
</tr>
<tr>
<td>7</td>
<td>84</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>85</td>
<td>2</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td>1</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>10</td>
<td>87</td>
<td>6</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>11</td>
<td>84</td>
<td>6</td>
<td>10/12</td>
<td>Yes</td>
<td>0</td>
<td>Inactive/low</td>
<td>No</td>
</tr>
<tr>
<td>12</td>
<td>89</td>
<td>7</td>
<td>6/12</td>
<td>Yes</td>
<td>0</td>
<td>Moderate</td>
<td>No</td>
</tr>
<tr>
<td>13</td>
<td>90</td>
<td>7</td>
<td>5/12</td>
<td>Yes</td>
<td>0</td>
<td>High</td>
<td>No</td>
</tr>
<tr>
<td>10</td>
<td>87</td>
<td>6</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
CHAPTER 4
DISCUSSION

Besides the four participants who dropped out, everyone attended at least five or more sessions of the seven session program, showing 90% class attendance compliance. In order to receive a certificate of program completion, the Stepping On program requires its participants to attend five of the seven sessions. Out of all eight participants, only one participant showed an improved percent in change (100%) from Week 1 to Week 7 for the 30sCST.

There was a low weekly exercise completion rate for the group, which could be a limitation for the data collected at the end of the program. If the individual’s risk of falling is high, he/she may not want to perform the exercises because they do not feel confident or safe. Other factors limiting the outcome data of this study include; visual (macular degeneration, glaucoma, legally blind, wears bifocals) and hearing deficits, lack of motivation, high mean age of 87, assistive device use, minimally active lifestyles, and slower rate of progressing the exercises. This group required a lot of one on one attention, adaptations of the standard exercises of the program, and continuous review. They were very slow to progress with the exercises, with most of them not adding resistance or increasing repetitions without weight (0.5-1.0 lb) to the exercises until Week 4 of the program, which typically takes place at the Week 2 mark. All participants were at a two pounds or less resistance by Week 6, with only one participant achieving a five pounds maximal resistance by the end of the program. Looking at the high mean age and heavy
use of assistive devices, this group was truly at a risk of falls at the start of the program.

Participants were assessed with four other tests to predict their fall risk (Single Leg Stand/ Tandem Stance, Timed Up and Go, Cognitive Timed Up and Go, and the GAIT Rite) and the order of the testing may have also impacted their performance. If the 30sCST was their last test for fall risk assessment at either Week 1 or Week 7, fatigue may have impacted their scores. Since their exercise progression was delayed and exercise compliance was low, this may also suffice why no change was seen with pre and post assessment scores of the 30sCST. Further studies could look at whether more time is needed for individuals similar to those in this study to show improvement for both exercise and fall risk assessment. Another important notion to mention is, the Stepping On program uses the sit to stand as a balance exercise, but the component of balance was taken out when most of the participants required the use of their arms to get up from the chair. Though no change was seen in the 30sCST pre- and post-assessment scores, the participants' subjective reports of their level of confidence had improved from participating in the Stepping On program.

The Stepping On program has been proven effective through a study done by Clemson et al\textsuperscript{11} (mean age of 78) to reduce the risk of falls by 31% in the community-dwelling elderly who participated in the program. The 30sCST is an excellent assessment tool to determine the fall risk of participants within the program and allows the participants to compare their improvement from Week 1 to 7. Gillepsie et al\textsuperscript{13} conducted a study, exercise programs targeting two or more of the following components: strength, balance, flexibility, or endurance, to be an effective intervention for reducing the rate of falls and decreasing the risk of falling. Programs such as
Stepping On, where multi-faceted interventions and home based exercises are utilized, have proven to be an effective preventative intervention for reducing the risk of falls for our community-dwelling elders.

Further research needs to be performed on individuals in their late 80’s to 90’s, to determine if the Stepping On program reduces the amount of arm use for the 30sCST, and if individuals of that age group require more time for progression to reduce their arm use and risk of falls. Future studies can also look at older adult individuals with co-morbidities involving the hip and knee and also at what chair height is fall risk reduced with this population.

The FTSTS may have been a more appropriate screening assessment with this lower functioning group. Further research needs to be performed in order to determine whether the FTSTS or the 30sCST is the best screening tool for fall risk based on the patient’s age, deficits, level of function, and co-morbidities. More research also needs to be performed to determine what the overall best screening tool is for assessing fall risk, such as Single Leg Stand/ Tandem Stance, Timed Up and Go, Cognitive Timed Up and Go, and gait speed (GAIT Rite).
Balance Exercises
- Sideways Walking
- Sit-to-Stand
- Heel-Toe Standing
- Heel-Toe Walking

Strength Exercises
- Side Hip Strengthening
- Front Knee Strengthening
- Heel Raises
- Toe Raises

Exercises at a Glance
The Effectiveness of the "Stepping On" Program for Reducing the Incidence of Falls in the Elderly

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Meridee Danks, D.P.T. and Beverly Johnson, PT, DSc, GCS</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>IRB Project Number:</td>
<td>IRB-201209-047</td>
</tr>
<tr>
<td>Project Review Level:</td>
<td>Expedited 4, 7</td>
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<td>Date of IRB Approval:</td>
<td>03/12/2015</td>
</tr>
<tr>
<td>Expiration Date of This Approval:</td>
<td>06/24/2015</td>
</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@fe
Endosures
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 in 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 Ulvercy Johnson
Telephone: 775-3561  Email Address: meridee.danks@ned.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:  
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: ___________________ Completion Date: ___________________
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 where 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 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:

Letters from each organization must accompany this proposal. Each letter must indicate 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.

22
Revised 01/02/12
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 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>Date submitted</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Approved</td>
</tr>
<tr>
<td></td>
<td>Pending</td>
</tr>
</tbody>
</table>

(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

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

- Children (<18 years)
- Prisons
- Cognitively impaired persons or persons unable to consent
- Other

This study will involve: Check all that apply.

- Deception (Attach Waiver or Alteration of Informed Consent Requirements)
- Radiation
- New Drugs (IND, ND, NDA) # Attach Approval
- Investigational Device Exemption (IDE) # Attach Approval
- Non-approved Use of Drug(s)

5. 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.
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 participants 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 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.

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 first day of the program. If they are interested they will be given an informed consent 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 Senior 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.
Additional test performed (beyond Stepping On gathered information)

2. Activities-specific Balance Confidence (ABC) Scale - subject rates level of confidence in doing everyday activities 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 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 ~ 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 is then 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.

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

do) 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

a) Clearly describe the anticipated risks to the subjects 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 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, debriding, 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 participant's 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 those 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 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 destroyed 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.
Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.). Referrals will be made to family physicians if subjects have concerns regarding their balance.

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
Clear 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 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 IRBSC 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);

Revised 04/02/12
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]  Date: [date]

(Student Adviser) Date: [date]

Requirements for submitting proposals:
Additional information can be found on the IRB website at: [URL]

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: [URL]

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 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 – 5 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, 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.

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 weaknesses that will be identified by the assessment scores.

ALTERNATIVES TO PARTICIPATING IN THIS STUDY

You can decide to participate 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
In 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

[Page 33]
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 Pacific Islander
   ___ 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/Country
   ___ Small town
   ___ City/suburb of a city
Place an X in the box to indicate your response.

<table>
<thead>
<tr>
<th></th>
<th>Nothing</th>
<th>Some</th>
<th>A lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Overall, how much did you learn from those sessions?</td>
<td>[ ]</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

Please rate your level of knowledge on each of the following:

9. My understanding of how vision can influence the ability to get around safely.

<table>
<thead>
<tr>
<th>Before Participation</th>
<th>Now, After Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

10. My understanding of the importance of balance and strength exercises for preventing falls.

<table>
<thead>
<tr>
<th>Before Participation</th>
<th>Now, After Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

11. My knowledge of recognizing hazards at home environments.

<table>
<thead>
<tr>
<th>Before Participation</th>
<th>Now, After Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

12. My understanding of the relation between foot care and fall prevention.

<table>
<thead>
<tr>
<th>Before Participation</th>
<th>Now, After Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Before Participation</th>
<th>Now, After Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

14. My understanding of the relation between medications and falls.

<table>
<thead>
<tr>
<th>Before Participation</th>
<th>Now, After Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

15. My knowledge of the importance of good bone health and fall prevention.

<table>
<thead>
<tr>
<th>Before Participation</th>
<th>Now, After Participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>[ ]</td>
</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: □ Male  □ Female  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 less than 30 minutes per day 5-7 days per week being physically active?</td>
<td>□ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Do you take more than 4 prescription medications?</td>
<td>□ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Has it been longer than 1 year 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>
</tbody>
</table>

Yes TOTAL: 38
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>Exercise</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>Exercise</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? _________
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? __%

REFERENCES


