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Effectiveness of Cognitive Timed Up and Go Test in Assessing Fall Risk in the Older Adult

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EFFECTIVENESS OF COGNITIVE TIMED UP AND GO TEST IN ASSESSING FALL
RISK IN THE OLDER ADULT

by

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B.A. Music, Minor Biology, Minor Medical Health Sciences
Minnesota State University Moorhead

A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

University of North Dakota

In partial of the requirements


For the degree of

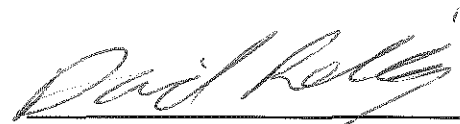
Doctor of Physical Therapy

Grand Forks, North Dakota

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This Scholarly Project, submitted by Cory Sailer 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.


(Graduate School Advisor)


(Chairperson, Physical Therapy)

PERMISSION PAGE

Title Effectiveness of Cognitive Timed Up and Go Test in Assessing Fall Risk in the Older Adult

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ABSTRACT

Introduction: Falls are a common and devastating injury for the older adult. Fall programs, such as the Stepping On program, are used to educate, strengthen, and sequentially reduce the number of falls its participant's endure. The Stepping On program is a multifactorial fall prevention program that addresses: balance and strength exercises, visual impairments, home modifications, pharmacologic effects, and even assistive devices. One aspect that has been found to be influential on fall risk is cognition, in particular executive functioning during ambulation.

Purpose: The purpose of this study was to screen participants of the Stepping On program for unknown cognitive issues and balance deficits that are adding to their fall risk. This will be determined by having the participants perform the TUG and the COG-TUG and assessing their results. Looking at the efficacy of performing the COG-TUG, 71% predictor of falls, this could be added to fall prevention programs to get a better understanding of the participants fall risk factors.

Methods: Of the 14 participants of the Stepping On Program, mean age 87.3, 13 were assessed during Week 1, 9 assessed during Week 7, and 8 of the 14 were present during both Week 1 and Week 7 of the program. The participants performance of both the TUG and the COG-TUG was assessed in order to determine if an increase in time spent to complete the TUG-COG by $\geq 10\%$ was present. An increase of ten percent identifies those who are at a higher risk of falls with the addition of a task, it has also been shown to an indicator of cognitive deficits. Individuals that required greater than 15 seconds to perform the COG-TUG are associated with an increased fall risk. Once this is determined it will be correlated with each individual's stated number of falls and their

overall number of fall risk factors provided on their initial/post surveys.

Results: During Week 1 of the program 46% of the participants, 6 of the 13, had an increased COG-TUG time by 10% or more. During the Week 7 assessment the percentage jumped up to 56%, 5 of the 9. These results compared to their balance confidence, ABC scores, and surveys (UND Fall Risk Survey, CDC Fall Risk Survey) indicate no significant correlation. There was a significant correlation, $p=.031$, between their reported number of falls and cognition deficits shown during the Week 1 performance of the COG-TUG and TUG. Only one individual that partook in both Week 1 and Week 7 assessments reduced the percent change between the COG-TUG and the TUG, this same individual was still above the 15 second COG-TUG fall risk threshold.

Conclusions: The performance of the COG-TUG to assess for fall risk has been found effective in numerous studies. The data collected during this Stepping On program did not find the COG-TUG to be an effective measure of fall risk. However, with further modifications to performing and scoring the COG-TUG better results may be had, providing increased clarity to the effect of cognition on a participant's fall risk. This Stepping On program participation pool had many limitations which influenced the effectiveness of determining the correlation between fall risk and cognitive deficits. It is clear that cognition plays a role in an individual's ability to ambulate and multitask.

CHAPTER I

INTRODUCTION

Stepping On is a fall prevention/education program intended for community dwelling older adults. These adults are usually 65 and older. Stepping On not only reduces falls but also increases confidence in the participants who complete the program. A study performed by Clemson et al¹ has found that participation in the Stepping on Program can lead to a 31% reduction in falls. A further description of the Stepping On program is provided in Appendix A. Falls are not only costly for the older adults but can lead to comorbidities and even death.

As the average life expectancy rises there are increasing numbers of cognitive problems in the elderly. The prevalence of dementia is 8% in adults over the age of 65 and rises to 35% when a person is older than 85. By 2050 there will be a projected 100 million people living with dementia.² The main clinical marker of dementia is cognitive decline.³ Major societal and economic costs are being accrued due to declined cognition and increasing numbers of individuals with dementia. Early detection of cognitive decline allows for interventions and treatments which may delay further progression of cognitive deterioration.⁴

Having an impairment in either gait or cognition contributes to an increased risk of falls. Gait and cognition are also closely related. Gait deficits increase an individual's risk of developing cognitive deficits and cognitive deficits increase the risk of gait deficits in older adults.² Reports indicate that motor function changes, such as gait abnormalities, precede the onset of cognition issues.⁴ Daily activities require the ability to

dual task, such as walking and talking with a friend. Dual tasking requires the utilization of cognitive resources.⁵ With the addition of cognitive demands during walking, the attention resources have to be shared between motor tasks as well as cognitive tasks.⁶ With advancing age and motor or cognitive impairments, division of attention resources is affected by an individual having to increase attention allocation to personal deficits.^{2,7} The neurocognitive abilities of executive functioning and attention related processes are the most significant in relating gait and predicted falls in the elderly population.⁸

Knowing this correlation between gait and cognition it is imperative that dual task tests be used to investigate this association in older adults. The implementation of the Timed Up and Go (TUG) test is used frequently to assess an individual's fall risk. The TUG however only tests with a single task condition, which does not show the influence of divided attention on gait control. The Cognitive TUG (TUG-COG) is an assessment for early detection of poor interplay between cognition and gait. Using the TUG-COG allows for early interventions to address deficits related to the relationship between cognition and gait.

Several methods have been used to add the cognitive aspect to an assessment of gait including but not limited to: counting backward from 50 by 2's, counting backwards from 50 by ones, counting backwards by 3's from a randomly selected number between 20-100, verbal fluency task-naming animals, and reciting alternating letters of the alphabet (a-c-e).^{3,6,7,9,10,11} MacAulay et al⁸ explored the difference between counting forward and backward on gait stride time and found that counting backward produced greater gait variance in elderly individuals with frontal lobe dysfunction.

Numerous research studies have been performed to assess the results of adding a cognitive aspect to a gait analysis. Theill et al⁷ found that gait velocity of cognitively impaired individuals was lower in both single and dual task walking conditions compared to cognitively healthy individuals. Vance et al⁹ study found that the addition of the

cognitive portion to the TUG enhanced the identification of fall risks in individuals with Parkinson's. A research study assessing community dwelling adults, ≥ 65 years old, and the ability of dual and triple task tests to predict future falls found that dual and triple task tests might be useful in predicting falls.¹² There were 8 dual task tests and 1 triple task test used (Table 1). The use of the TUG test in combination of a cognitive task reinforces the discriminatory ability to separate mild cognitive impairments, early stages of Alzheimer's disease, from cognitively healthy elders based on mean time of execution.³ Fischer et al¹¹ also indicated the TUG-COG scores were strongly associated with executive dysfunction and were significantly different between fallers grouped by number of falls.

Table 1: Tasks Performed in Muhaidat et al¹² Research Study

Dual Task	Triple Task
Straight walking and visuospatial clock task	Straight walking, visuospatial clock task, and carrying a cup
Walking with turns and naming animals	
Walking with turns and counting backwards in 3s	
Avoiding stationary obstacles and naming animals	
Avoiding a moving obstacle and carrying a cup	
Timed Up & Go (TUG) and carrying a cup	
Stair descent and naming animals	
Walking while talking complex	

Several studies have created normative data for different groups, yet there is discrepancy in created concrete normative values (Table 2). When correlating to individuals with Parkinson's disease they indicated that a cutoff of 14.7 seconds be used to perform the TUG-COG. Vance et al⁹ also stated that the TUG-COG is more likely to correctly classify participants with a low risk of falling (positive likelihood ratio 2.9, 14.7

seconds). Using this threshold it had higher estimates of sensitivity, .76, than of specificity, .73. Shumway-Cook¹³ found that when testing community dwelling elderly with a TUG-COG a 15 second cutoff value was able to classify fallers with an overall correct prediction rate of 87%. The research also indicated that a mean score for elderly without a fall history is 9.7 seconds for the TUG-COG. This is compared to 9.82 (2.39) indicated by a study performed by Hofheinz et al.¹⁴ The study also stated that the mean values for different age groups differ significantly from each other, no specific values were provided however. The TUG-COG has a positive predictive value of 71% for falls in older adults versus 42% for those undergoing TUG simple.¹⁰ The TUG-COG has a strong correlation with attention/executive function composite scores with an $r = -.39$. In the same study there was a significant difference between non-fallers + single fallers compared to multiple fallers, where the multiple fallers required an additional 3.72 seconds to complete the TUG-COG.¹¹ As per the MiniBESTest an increase of 10% or more to complete the TUG-COG compared to the TUG indicates an increased risk of falls due to cognition.¹⁵

Table 2: Normative Data for Cognitive TUG

Group	Cognitive TUG Times for Fall Risks (seconds)
Parkinson's Disease ⁹	≥14.7
Community-Dwelling ¹³ -no falls: (mean age=78 years, SD=6, range=65–85) -history of 2 or more falls in the previous 6 months: (mean age=86.2 years, SD=6, range=76–95)	≥15.0 Mean Score for Non-Fallers: 9.7
Community-Dwelling ¹⁴ healthy men/women aged 60 to 87 years living at home	Mean Score For Non-Fallers: 9.82 ±2.39
Mild to Moderate Cognitively Impaired ¹¹ 120 veterans: 76.4 ± 8.4 years (range 60–90) overwhelmingly male (98%)	16.73 ±8.09

As cognition plays a crucial role in one's ability to perform daily ambulatory tasks it was important to assess the Stepping On participants with this test. The TUG-COG allows for early detection of cognitive-gait abnormalities, thus allowing for early intervention. A study with a minimal sample size has shown that the combined intervention of treadmill training while performing dual tasks improves scores on tests of mobility, functional performance tasks, and cognition⁴. This indicates that dual task training can be implemented by therapists as part of a fall risk prevention program.⁴

The purpose of this study was to find out whether or not the participants of the Stepping On program have unknown cognitive issues that are adding to their fall risk. This is being assessed by having the participants perform both the TUG and the TUG-COG and seeing if there is an increase in time spent to complete the TUG-COG by $\geq 10\%$ or if it takes longer than 15 seconds to perform the TUG-COG.¹⁵ Once this is determined it will be correlated with each individual's stated number of falls and their overall number of fall risk factors provided on their initial/post surveys. The effectiveness of the Stepping On Program on reducing cognitive effects will also be assessed by comparing Week 1 and Week 7 results.

CHAPTER II

METHODS

Prior to performance of this research a UND Institutional Review Board, IRB, approval was obtained. The IRB and its approval is located in Appendix B.

Subjects

This session of Stepping On was performed at an assisted living facility. The participants were individuals that lived in the facility and little to no assistance in their day to day activities. All of the participants were women. Prior to participation of the research study all the participants signed a consent form, see Appendix C. During the totality of the program there were 14 participants; by Week 7, 3 participants dropped out due to medical complications or disinterest in the program. There were a total of 11 participants that attended 6 out of the 7 weeks. Thirteen participants were present for Week 1 while only 9 were present on Week 7. The age range of the participants is 80-94 years old, with a mean age of 87.3 years. The participants in our study were older than the average Stepping On age, according to research done between 3 states of 266 participants in the Stepping On program the average age was 78.7 years old.¹⁶ Eleven of the initial fourteen participants, 78.6%, also already used assistive devices for long distances or for all ambulation. Not only did many require assistive devices for ambulation, 78.6% also had vision deficits. These vision deficits included: the use of glasses, macular degeneration, bifocals, glaucoma, and one patient was even legally blind.

Instrumentation

Surveys Performed: Subjects were provided with a UND survey to assess fall risk in Week 1, and the CDC fall risk assessment survey Week 7. Both of these surveys ask

questions which are attributed to fall risk. The more yes's checked indicate an increased risk of a fall. Both are attached in the Appendix D section of this paper. The participants also filled out the Activities-Specific Balance Confidence (ABC) survey at Week 1 and Week 7 of the program. This is also attached in Appendix D. Table 3 and Table 4 are attached to provide further detail of the participants in this specific session of Stepping On.

Table 3: Demographics of Participants Week 1

Subject #	Gender	Age	Type of Assistive Device Used	# of Falls Last Year	# of Fall Risk on UND Survey	Worry About Falling	Vision Issues/Type	> 4 Meds	Minimally Active > 30 min/day	LE Sensation Deficits	Depressed	Med Hx
1	F	92	None	0	3/11	No/Yes	Yes; not specified	Yes	Yes	No	Yes	
2	F	92	WW/WC	2	5/10	Yes	No	Yes		Yes	No	R knee pain
3	F	89	Manual WC/FW W	2	6/11	Yes	Yes; glasses, macular degeneration	No	No	Yes	No	L ankle surgery; Dizzy
4	F	87	FWW	0	4/11	No	Yes; not specified	Yes	Yes	No	No	Bilat TKA
5	F	94	4WW for longer distances	0	1/11	No	Yes; legally blind, bifocals	No	Yes	No	No	
6	F	80	None	0	3/11	No	Yes; deficits	Yes	Yes	Yes-knee	No	
7	F	84	FWW	6-7	6/11	Yes	Yes; macular degeneration, glaucoma	Yes	No	No	No	
8	F	85	SEC	0	6/11	No	Yes; glasses	Yes	No	No	No	
9	F	80	None	2	8/11		Yes; glasses	Yes	No	Yes	Yes	L knee pain
10	F	87	FWW	0	3/11	No	No	Yes	No	No	No	R hip pain
11	F	84	FWW	2	6/11	Yes	Yes; macular degeneration	Yes	Yes	Yes-knee	No	R rotator cuff tear
12	F	89	4WW	Yes ?#	2/11	No/Yes	Yes; glasses	No	Yes	No	No	
13	F	90	4WW	0	5/11	No	Yes; glaucoma	No	No	Yes	No	R TKA; OAL knee
14	F	89	Power WC/4W	Yes ?#	NT	Yes						

Subject #	Age	Sessions Attended out of 7	# of Fall Risks (CDC)	Improved Balance/ Confidence	Falls during Stepping On Program	Present Level Of Activity	Faithful in Performing Stepping On Exercises
1	92	7	5/12	Yes	0	High	Yes
2	92	1	-	-	-	-	-
3	89	6	10/12	Yes "a little bit"	0	Moderate	Yes
4	87	7	6/12	Yes	0	Moderate	Yes
5	94	6	5/12	Yes	0	Moderate	Yes
6	80	6	2/12	Yes Balance/No for confidence	0	Moderate	Yes
7	84	2	-	-	-	-	-
8	85	2	-	-	-	-	-
9	80	1	-	-	-	-	-
10	87	6	-	-	-	-	-
11	84	6	10/12	Yes	0	Inactive/low	No
12	89	7	6/12	Yes	0	Moderate	No
13	90	7	5/12	Yes	0	High	No
14	89	5	11/12	Yes	0	Moderate	No

Table 4: Demographic Details after Week 7

Performing the TUG-COG: The standard TUG has the individual stand up from a standard arm chair and walk a distance of 3 meters or approximately 10 feet, turn around, walk back to the chair, and sit down. A stopwatch was used to time the trial. The subject is permitted to use any walking aid. No physical assistance is provided to the individual. Participants start with their back against the chair and arms on the armrests. The subjects are allowed to use the armrests to assist in getting out of the chair. They are instructed to start the test with the verbal cue of "go." Performers are informed to walk at their normal safe pace. A line of tape is placed on the floor represent the 3 meters/10 feet. The test is completed and stopwatch clocked as the individual makes contact with the chair to sit down. To incorporate the cognitive aspect of the TUG-COG the participants performed the TUG with the addition of naming as many fruits, animals, or colors as they could. The topic was chosen at random for each participant. The participant starts naming items in their chosen topic while they are sitting down prior to the verbal "go" cue.

Reliability of TUG-COG:

Hofheinz¹⁴ research showed there was an excellent test-retest reliability (.98) and intrarater reliability (.94). Shumway-Cook¹³ corroborated this as they also found an excellent interrater reliability (.99)

Procedures:

Data Collection: Each participant performed the TUG prior to the TUG-COG. This was done on both Week 1 and 7 of the program. There was no altering of data if patient did not start verbalizing items in chosen topic right away or repeated the same item. Notes were taken as to what assistive device was used as well as any physical abnormalities or comorbidities. During the first week data was collected from 13 participants, only 9 were present during the Week 7 assessment: 8 being reassessed and 1 being assessed for the first time. The participant also performed several other

assessments on Week 1 and Week 7; they each started at a randomly assigned assessment in order to increase the time efficiency in performing all the tests. The comprehensive list of assessments physically performed include: Semi-Tandem Stance, Tandem Stance, Single Leg Stance, 30 second Sit to Stands, TUG, COG-TUG, and GAITRite for gait analysis. Participants also completed the following written assessments: consent form (Week 1), UND Fall Risk Assessment (Week 1), CDC Fall Risk Assessment (Week 7), ABC survey (Both Week 1 & 7).

Data Analysis: Analysis of the results was performed using IBM SPSS program. Both Pearson and Spearman rho two-tailed correlations were performed in order to determine if a significant linear or monotonic relationship was present between data collected. Correlations were run for the following: Week 1 ABC score to percent change between Week 1 TUG and COG-TUG, Week 7 ABC score to percent change between Week 7 TUG and COG-TUG, number of falls recorded for last year and the percent change between Week 1 TUG and COG-TUG, number of fall risks per UND survey (Week 1 survey) and the percent change between Week 1 TUG and COG-TUG, number of fall risks per CDC survey (Week 7 survey) and the percent change between Week 7 TUG and COG-TUG, and percent change between Week 1 TUG and COG-TUG and the percent change between Week 7 TUG and COG-TUG.

CHAPTER III

RESULTS

When looking for evidence on the benefits of the Stepping On program and its correlation to the COG-TUG there were several relationships to assess. Normative data from other research was used to compare values collected, such as: fall risk time for COG-TUG, percent change between TUG and COG-TUG, and fall risk for the Activities-specific Balance Confidence (ABC) survey. Normative data indicates that anyone that takes longer than 15 seconds to complete the COG-TUG is at a fall risk¹³. Noting an increase of more than 10% in time to complete the TUG compared to that of the COG-TUG also has been found to increase an individual's risk of a fall. Data was assessed within Week 1 and Week 7 as well as between the two.

Week One

Figure 1 depicts the time each subject took to perform the TUG and the COG-TUG. The mean time to perform the TUG was 24.02 seconds while the mean time was 30.97 seconds to perform the COG-TUG. Using the normative data provided by Shumway-Cook,¹³ 10 of the 13 participants were in the fall risk category based on the TUG-COG times. Table 5 represents Figure 1 numerically. Of the three individuals that were below the 15 second fall risk marker for the COG-TUG only one, participant 6, produced a COG-TUG time that was an increase of more than 10% in time compared to their TUG time indicating they had cognitive deficits that may affect their fall risk. The subject pool only produced 2 subjects out of the 13 in which there was no cognitive deficits using the 10% guideline and had a COG-TUG time that was below 15 seconds. Of the 13 participants, 6 had an increase of 10% or more in performing the COG-TUG.

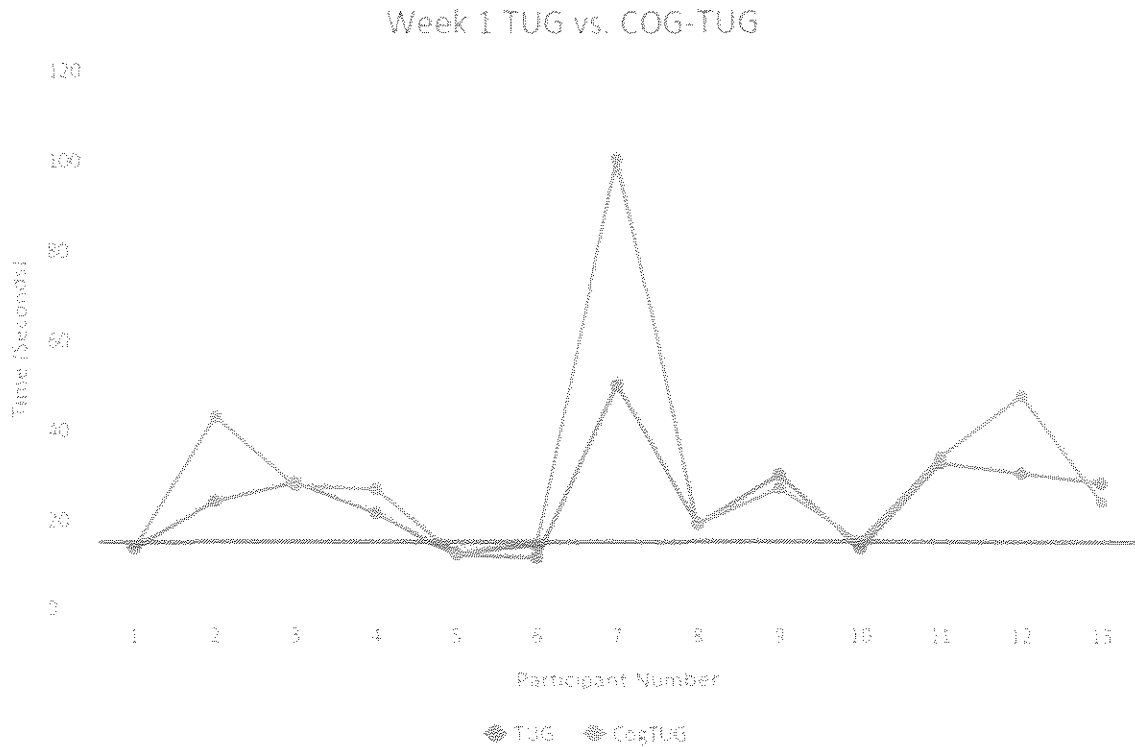


Figure 1: Week 1 TUG vs COG-TUG times
 ----- - 15 second line marker, any COG-TUG scores above are at a fall risk

Table 5: Week 1 Results TUG vs COG-TUG

Participant Number	TUG In Seconds	COG-TUG In Seconds	Difference In Seconds	Percent Difference %
1	13.52	13.39	-0.13	-0.96
2	23.87	*42.75	18.88	79.10
3	28	*27.4	-0.6	-2.14
4	21.2	*26.6	5.4	25.47
5	11.96	12.22	0.26	2.17
6	11.25	14.35	3.1	27.56
7	49.93	*100.25	50.32	100.78
8	18.77	*18.81	0.04	0.21
9	29.84	*26.72	-3.12	-10.46
10	13.32	*15.02	1.7	12.76
11	32.4	*33.76	1.36	4.20
12	30.13	*47.46	17.33	57.52
13	28.06	*23.82	-4.24	-15.11

*-Time to complete the COG-TUG is greater than 15 seconds, indicating fall risk category

Bolded #- Percent difference between the time to perform the TUG and the COG-TUG is greater than 10%, indicating fall risk category.

In order to assess if the presence of a cognitive impairment, shown by an increase in TUG to COG-TUG times by 10% or more, affected an individual's confidence the Week 1 ABC scores were compared to the percent change in time (Table 6). According to the ABC any score below a 65%, .65, indicates that you are at a fall risk. There is only one individual that had a score higher than a .65. There was no significant correlation (Pearson Correlation $p = .554$, Spearman's Rho $p = .901$) between the percent change in time to perform TUG to COG-TUG and the score provided on the ABC. Table 7 provides the number of falls a participant has had, their fall risks based on the UND survey, and the percent change between the COG-TUG and TUG times. There was no significant correlation between the UND fall risk number and the percent change between the TUG and COG-TUG in week 1 (Pearson Correlation $p = .813$, Spearman's Rho $p = .358$). Using the Pearson correlation there was a significant correlation, $p = .031$, between the number of falls the participant had in the previous year and the percent change between the TUG and COG-TUG during week 1. However this is not significant when using the Spearman's Rho correlation, $p = .574$.

Table 6: Week 1 ABC scores vs "COG Impairment"

Participant Number	ABC	Ranking Lowest Confidence to Highest	Percent Difference TUG vs. COG-TUG%
1	0.55	9	-0.96
2	0.35	5	79.10
3	0.11	1	-2.14
4	0.25	3	25.47
5	0.39	8	2.17
6	0.62	11	27.56
7	0.37	6	100.78
8	0.68	13	0.21
9	0.24	2	-10.46
10	0.63	12	12.76
11	0.37	7	4.20
12	0.32	4	57.52
13	0.61	10	-15.11

Table 7: Week 1 Comparing Falls/Fall Risks to “Cognitive Impairment”

Participant Number	Falls in last year per survey	UND Fall Risks Out of 11	Percent Difference TUG vs. COG-TUG%
1	0	3	-0.96
2	2	5	79.10
3	2	6	-2.14
4	0	4	25.47
5	0	1	2.17
6	0	3	27.56
7	6.5	6	100.78
8	0	6	0.21
9	2	8	-10.46
10	0	3	12.76
11	2	6	4.20
12	?	2	57.52
13	0	5	-15.11

Week Seven

Nine participants were available to be assessed during Week 7. Of the total a14 participants only 8 individuals were there for both the initial assessment and the end assessment. Their results for the TUG and COG-TUG are shown in Figure 2. The mean time to perform the TUG during Week 7 was 23.92 seconds while the mean time was 29.89 seconds to perform the COG-TUG. Table 8 is the numerical representation of Figure 2. There was only one individual during the Week 7 assessment that was below the increased fall risk. That individual also was able to perform the COG-TUG within less than a 10% change in time. Four of the nine subjects were able to complete the COG-TUG during Week 7 within the 10% or faster subcategory relative to the TUG. During Week 7 there was 1 participant who performed the COG-TUG faster, where as in Week 1 there were 4.

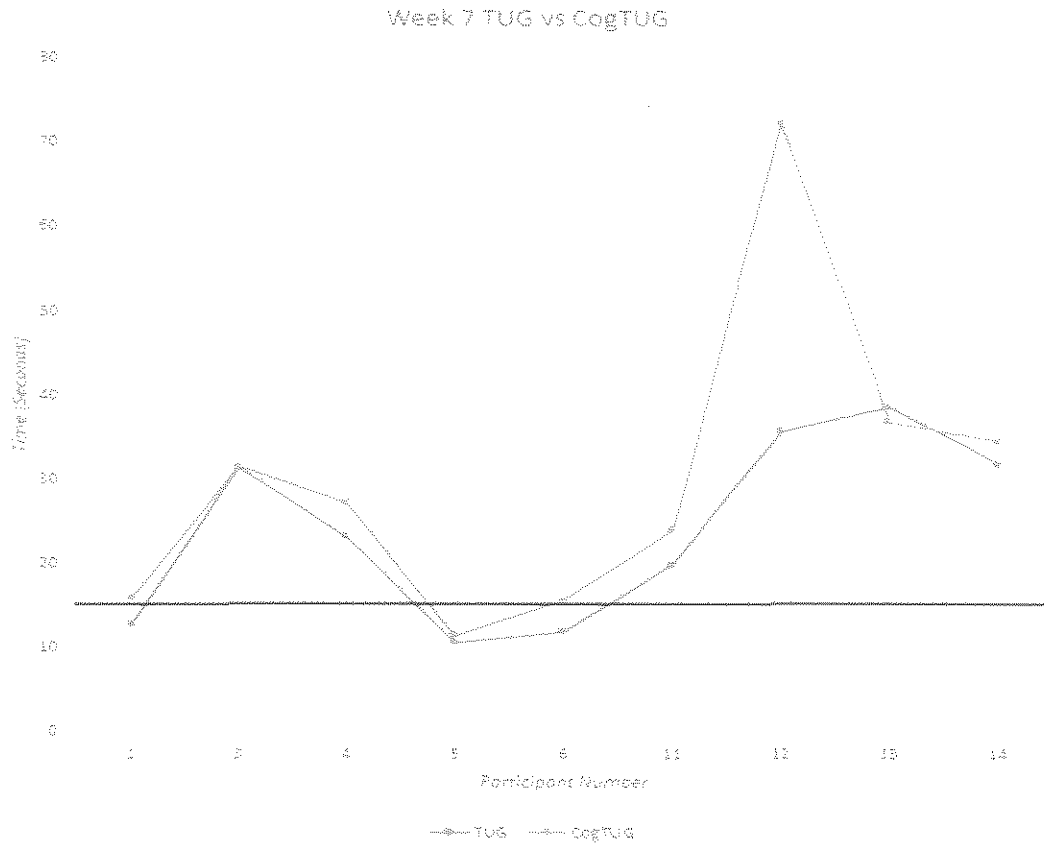


Figure 2: Week 7 TUG vs. COG-TUG Times
 ----- - 15 second line marker, any COG-TUG scores above are at a fall risk

Table 8: Week 7 Results TUG vs. COG-TUG

Participant Number	TUG In seconds	COG-TUG In Seconds	Difference In Seconds	Percent Difference %
1	12.69	*15.88	3.19	25.14
3	31.28	*31.45	0.17	0.54
4	23.09	*27.1	4.01	17.37
5	10.59	11.4	0.81	7.65
6	11.84	*15.71	3.87	32.69
11	19.88	*23.94	4.06	20.42
12	35.62	*72.34	36.72	103.09
13	38.53	*36.66	-1.87	-4.85
14	31.78	*34.53	2.75	8.65

*- Time to complete the COG-TUG is greater than 15 seconds, indicating fall risk category
Bold# - Percent difference between the time to perform the TUG and the COG-TUG is greater than 10%, indicating fall risk category.

Table 9 is used to compare the participant's confidence after completing the Stepping On program, Week 7 ABC survey, to the difference in TUG and COG-TUG times. This time two people scored above the fall risk of a .65 on the ABC survey. There was no significant correlation (Pearson Correlation $p = .869$, Spearman's Rho $p = 1.0$) between the percent change in time to perform TUG to COG-TUG and the score provided on the ABC.

Table 9: Week 7 ABC vs "COG Impairment"

Participant Number	ABC	Ranking Lowest Confidence to Highest	Percent Difference TUG vs. COG-TUG%
1	.35	4	25.14
3	.39	5	0.54
4	.29	2	17.37
5	.57	7	7.65
6	.78	9	32.69
11	.33	3	20.42
12	.49	6	103.09
13	.73	8	-4.85
14	.14	1	8.65

Table 10 is used to compare the results of taking the CDC Fall Risk survey and the percent change between the TUG and COG-TUG. If the individual has more than a 4 on the CDC Fall Risk survey they are at an increased risk of falls. Only one of the nine subjects scored less than a 4. There is no significant correlation between the score on the CDC Fall Risk survey and the individuals percent change between TUG and COG-TUG assessments (Pearson Correlation $p = .564$, Spearman's Rho $p = .628$).

Table 10: Week 7 CDC Risk vs “COG Impairment”

Participant Number	CDC Fall Risk	Percent Difference TUG vs. COG-TUG %
1	5	25.14
3	10	0.54
4	6	17.37
5	5	7.65
6	2	32.69
11	10	20.42
12	6	103.09
13	5	-4.85
14	11	8.65

A comparison of Week 1 and Week 7 provided in Table 11, which provides the perspective of how each participant completed the COG-TUG related to the TUG during Week 1 and compared to the Week 7 values. Of the 8 that were assessed both times, only Participant 5 was able to perform the COG-TUG faster, .82 seconds, in the Week 7 assessment. Even though there was an increase of .5 seconds between Week 1 and Week 7 of Participant 4’s times she had the only positive change related to cognition; a decreased percent difference between TUG and COG-TUG performed. This is indicated by the 8.1% overall change. There was a significant correlation between Week 1 and Week 7 percent changes (Pearson Correlation $p = .002$, Spearman’s Rho $p = .01$)

Table 11: Comparing Week 1 to Week 7 Percent Differences between TUG and COG-TUG

Subject Number	Week 1 COG Time In Seconds	Percent Difference from TUG %	Week 7 COG Time in Seconds	Percent Difference from TUG %	Percent Overall Change %
1	13.39	-0.96	15.88	25.14	26.10
3	27.4	-2.14	31.45	0.54	2.67
4	26.6	25.47	27.1	17.37	-8.10
5	12.22	2.17	11.4	7.65	5.47
6	14.35	27.56	15.71	32.69	5.13
11	33.76	4.20	23.94	20.42	16.23
12	47.46	57.52	72.34	103.09	45.57
13	23.82	-15.11	36.66	-4.85	10.26

Bold- indicates a decreased time to complete the COG-TUG on Week 7 compared to Week 1

CHAPTER IV

DISCUSSION/CONCLUSION

Summary of Results

The statistical analysis results provided further clarity to the impact of several of our limitations in this study. The correlation analysis between surveys and the appearance of a cognitive deficit, shown by a 10% or greater percentage difference between performance of the TUG and COG-TUG, indicated no significant relationship other than number of falls in the year prior to the Stepping On program (Pearson's Correlation $p = .031$). A better assessment may be to look at the raw data. Five out of 9, 56%, of the participants that were assessed on Week 7 would be classified as having a cognitive deficit. This was up from the 46%, 6/13, of the participants that were assessed Week 1. Due to the limitations of our research, found below, the data collected for this study didn't corroborate the results found by research performed by Ory et al.¹⁶ They found the Stepping On program to: decrease TUG test scores significantly ($p < 0.001$) for all 254 participants with pre-post data and confidence about keeping from falling was more than three times greater after completing *Stepping On*.¹⁶

Limitations

When assessing the outcomes of TUG and COG-TUG factoring in that there are several aspects that may influence the results obtained is crucial. In our study one of these factors is that the age range of the participants was 80-94, mean 87.3 years old. This is particularly important as many have comorbidities, see Table 3. Several of these comorbidities influence their day to day energy levels and ability to perform the assessments. Two subjective statements provided on Week 7 during assessments

included: "I'm having a poor vision day" and "I'm really tired today." During testing the participants performed the TUG prior to the COG-TUG, which could further exacerbate their fatigue symptoms thus skewing the data. Another one of these factors is the subject pool consisted of all female participants. It has been noted that men tend to have better results from the Stepping On program. The Stepping On program targets community dwelling older adults; the participants in this study may not an accurate representation of the programs targeted group. Participants in this study all lived in an assisted living facility with maximal independence and the ability to ambulate. However, eleven of the fourteen used some form of assistive device prior to this program. Two of the fourteen participants used wheelchairs as a primary mode of ambulation. The use of an assistive device or wheelchair indicates a higher risk of falls, as they already required the stability and balance assistance from these devices.

Many of the individuals used assistive devices while performing the assessments also. One situation in particular that may have affected the results was that a participant forgot her four wheeled-walker and performed the TUG and COG-TUG using her wheelchair as her assistive device. Better observational notes and subjective comments could have been taken Week 1 to ensure that the participants were using the same device in both assessments as well as provide increased clarity to how they felt that day.

Recommendations

There were several modifications that could be done in order to optimize the results when performing the TUG and COG-TUG. As a research group we chose to have the participants verbalize objects from several categories compared to the standard of counting backwards. This was done as a test group struggled significantly while trying to count backwards. Providing the individuals with a topic was easier to communicate via instructions as well as would fulfill the requirement of adding an executive function to the task. One modification that could be done moving forward is

making sure that the individual starts verbalizing objects while they are sitting down and then start the test. This enforces that they are continuously using allocation efforts to think of objects as they perform the whole test. Another modification would be to increase note taking on whether or not they repeated an item or stopped verbalizing items during the assessment. This could be overcome if a scoring system was implemented, such as the one used for the cognitive TUG when performing the Mini BESTest; the individual would score a 0 if they repeated any of the items or stopped talking. Participants score a 1 if it took more than 10% or more of the time to perform the TUG. A full score of a 2 would be provided if no deficiencies are present.

Conclusion

In conclusion there was a positive linear correlation, $+0.596$, with significance, $p=0.031$, between the number of falls in the year prior to participation of the Stepping On program and the percent change between TUG and COG-TUG. Yet, the rest of the results do not provide evidence to reinforce the validity of using the COG-TUG as an assessment for identifying fall risk in the older adult. However, the importance of cognition on one's fall risk is hard to dismiss. Fall prevention programs should implement not only the use of the TUG, as reported by Ory et al¹⁶, as an assessment but also the COG-TUG in order to identify if cognition is a factor in a participants fall risk. Cognition is vital, as our daily activities require the ability to ambulate and use executive functioning skills. With further modifications to performing and scoring the COG-TUG, creating a more standardized format, better results may be had. These results would provide increased clarity to the effect of cognition on a participants fall risk.

APPENDIX A



One in every three adults over age 65 falls every year. But falling is not normal for older adults and older adults can learn how to take steps to prevent falls. Stepping On is an exciting new fall prevention program for seniors age 65 plus. Stepping On is an interactive falls prevention program aimed at educating participants and building confidence in order to reduce or eliminate falls.

The Stepping On workshop meets for two hours each week for seven weeks focusing on how strength and balancing exercises, medication management, home safety, footwear, vision and mobility are important in preventing falls.

What will I learn?

- Simple and fun balance and strength training
- The role vision plays in keeping your balance.
- How medication can contribute to falls.
- Ways to stay safe when out and about in your community.
- What to look for in safe footwear.
- How to check your home for safety.

Wednesday 10:00 a.m. - Noon

Session 1	September 30, 2015
Session 2	October 7, 2015
Session 3	October 14, 2015
Session 4	October 21, 2015
Session 5	October 28, 2015
Session 6	November 4, 2015
Session 7	November 18, 2015

Bill Vasicek-Altru Health System
780-5939, bvasicek@altru.org

APPENDIX B



UND.edu

Institutional Review Board
Twamley Hall, Room 106
264 Centennial Drive Stop 7134
Grand Forks, ND 58202-7134
Phone: 701.777.4279
Fax: 701.777.6708

March 13, 2015

Principal Investigator:	Meridee Danks, D.P.T. and Beverly Johnson, PT, DSc, GCS
Project Title:	The Effectiveness of the "Stepping On" Program for Reducing the Incidence of Falls in the Elderly
IRB Project Number:	IRB-201209-047
Project Review Level:	Expedited 4, 7
Date of IRB Approval:	03/12/2015
Expiration Date of This Approval:	06/24/2015
Consent Form Approval Date:	03/12/2015

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.

YES or NO 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?

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.

_____ Date submitted: _____ Status: Approved Pending
_____ Date submitted: _____ Status: Approved Pending

(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 Dissertation/Thesis/Independent Study
 YES or NO Continuation/Renewal YES or NO Student Research Project
 YES or NO Is this a 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) Stem Cells
 Radiation Discarded Tissue
 New Drugs (IND) IND # _____ Attach Approval Fetal Tissue
 Investigational Device Exemption (IDE) # _____ Attach Approval Human Blood or Fluids
 Non-approved Use of Drug(s) Other _____
 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.

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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, fliers, 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.

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 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 ~ 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. Intially, 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 speciality 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.

3. Risk Identification.

- 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 test 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.

- 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

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Advertisements.

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.

Signatures:

(Principal Investigator)

Date:

(Student Adviser)

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.

APPENDIX C
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.

1

Date _____
Subject Initials: _____

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 ~ 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, 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 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

APPENDIX D

Fall Risk Survey

ID # _____ Age: _____ Gender: Male Female Date: _____

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

Fall Risk Checklist

Patient: _____ Date: _____ Time: _____ AM/PM

Fall Risk Factor Identified	Factor Present?	Notes
Falls History		
Any falls in past year?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Worries about falling or feels unsteady when standing or walking?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Medical Conditions		
Problems with heart rate and/or rhythm	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Cognitive impairment	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Incontinence	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Depression	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Foot problems	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Other medical conditions (Specify)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Medications		
Any psychoactive medications, medications with anticholinergic side effects, and/or sedating OTCs? (e.g., Benadryl, Tylenol PM)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Gait, Strength & Balance		
Timed Up and Go (TUG) Test ≥12 seconds	<input type="checkbox"/> Yes <input type="checkbox"/> No	
30-Second Chair Stand Test Below average score (See table on back)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4-Stage Balance Test Full tandem stance <10 seconds	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Vision		
Acuity <20/40 OR no eye exam in >1 year	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Postural Hypotension		
A decrease in systolic BP ≥20 mm Hg or a diastolic bp of ≥10 mm Hg or lightheadedness or dizziness from lying to standing?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Other Risk Factors (Specify)		
	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	



Centers for Disease
Control and Prevention
National Center for Injury
Prevention and Control

STEADI Stopping Elderly
Accidents, Deaths & Injuries

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