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EFFECTIVENESS OF THE TIMED UP AND GO (TUG) TEST IN ASSESSING FALL RISK IN COMMUNITY-DWELLING ELDERS PARTICIPATING IN THE STEPPING ON PROGRAM

By

Megan Shanahan University of North Dakota

A Scholarly Project

Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine

University of North Dakota

In partial fulfillment of the requirements

For the degree of

Doctor of Physical Therapy

Grand Forks, North Dakota

May

This Scholarly Project, submitted by Megan Shanahan 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

TitleEffectiveness of the Timed Up and Go (TUG) Test in Assessing
Fall Risk in Community-Dwelling Elders Participating in the
Stepping On Program

Department

Physical Therapy

Degree Doctor of Physical Therapy

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Signature_____

Date

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I would like to thank Meridee Danks, PT, DPT for all of her hard work and passion for the Stepping On program. Her guidance and expertise were beneficial to completing this research. I would also like to thank the Stepping On participants who made this study possible. Lastly, I would like to thank the Director of Stepping On, Bill Vasicek, for allowing University of North Dakota Physical Therapy students to actively be involved in the program.

ABSTRACT

Background: The Timed Up and Go (TUG) is intended to predict fall risk through assessment of balance, functional mobility, and gait in community-dwelling adults age 65 and older. The Stepping On program aims toward fall prevention through education, exercise, and shared experiences among participants. Previous evidence has displayed positive, significant results for Stepping On and the TUG, indicating use of the assessment to track participants' progress in the program.

Objective: The purpose of this study was: 1) to determine if the Stepping On program decreases fall risk in community-dwelling elderly individuals as measured by the TUG test, 2) to distinguish if the TUG is an effective screening tool in assessing fall risk in program participants, and 3) to describe characteristics of Stepping On participants. **Methods:** Two females and one male participant with an average age of 87.6 years (81-93) were recruited from a local Stepping On program, and agreed to participate in additional functional screening. The CDC Fall Risk Checklist and Stepping On Baseline Questionnaire were administered on Week 1. The TUG was administered on Week 1 and Weeks 7 of the program. Subjects performed a two trials of the TUG, one of which was done at a comfortable pace, and other at a quick pace.

Results: Two of three participants completed the 7 week Stepping On program as well as the initial and final TUG assessment. The following results were obtained when the TUG was performed at Week 7 in comparison to Week 1: Subject 1 progressed at comfortable pace by 1.05 seconds ($15.34 \rightarrow 14.29$ seconds; 6.85% improvement) but demonstrated a

slower score at quick pace by 1.13 seconds ($12.09 \rightarrow 13.22$ seconds; 9.35% decline), and Subject 2 demonstrated a slower score at comfortable pace by 2.18 seconds ($11.88 \rightarrow 14.06$; 18.35% decline) as well as a slower score at quick pace by 1.21 seconds ($10.07 \rightarrow 11.28$ seconds; 12.02% decline). These results classified Subject 1 as being 'moderate risk' for falls at both comfortable and quick pace, and Subject 2 as being 'high-risk' at comfortable pace and 'low-risk' at quick pace. On the Week 7 Stepping On Survey, both subjects indicated they had not experienced any falls since the start of the program.

Conclusion: The TUG displayed validity in appropriately classifying those experiencing recent falls at a fall risk. The TUG displayed validity in appropriately classifying those experiencing recent falls at a fall risk. Ongoing data collection will be performed with 3-month recheck to analyze if categorized fall-risk based off of TUG performance times are directly related to reported falls (if any). With continuation of the Stepping On program, as well as a focus on increased age when testing, comes opportunity to further assess the effectiveness of the TUG as a screening tool for assessing fall risk in the community-dwelling elderly population.

CHAPTER I

INTRODUCTION

Each year, 2.5 million older adults are treated in emergency departments for injuries following a fall.¹ Fall-related injuries not only have a significant effect on medical costs, but also greatly impact an individual's overall well-being. Previously experiencing a fall or being fearful that one might fall can result in restriction of mobility and activity, feelings of helplessness, loss of confidence, depression, and institutionalization.² To assist in preventing these things in the elderly population, community programs that focus on improving strength, balance, safety, and overall awareness of fall risk are available.

Stepping On is a fall prevention program that targets community-dwelling elders age 65 years or older who have fallen in the past year or have a fear of falling.³ Once a week, participants meet for a two hour session for a total of seven consecutive weeks. Through a multifactorial approach, Stepping On implements educational tips from various "experts" for increased home and community safety, emphasizing the importance of vision assessments and medication reviews, and providing exercises to improve balance and strength.⁴

Physical Therapists maintain a key role during Weeks 2 and 6 at which time exercises to improve balance and strength are provided, and recently learned safe mobility techniques are practiced. A total of four strength and four balance exercises based off of the Otego Home Exercise Program are practiced.⁵ Balance exercises include

sit-to-stands, sideways walking, tandem standing, and tandem walking. Strength exercises include standing hip abduction, sitting knee extension, heel raises, and toe raises. Ankle weights are utilized as tolerated for resistance during hip abduction and knee extension strengthening exercises. All exercises are reviewed and progressed as necessary throughout the program. Weekly activity logs are recorded individually to assess compliance and assist in progressions. Refer to Appendix A for a list of all exercises and a copy of the weekly activity log.

The Stepping On program, established in Australia by Clemson et al³ in 2004, was designed to utilize a variety of learning strategies to raise fall-risk awareness. Such strategies included being more informed about factors that contribute to risk, targeting behaviors that have the most effect on reducing risk, reinforcing application of those behaviors to the home and community setting, and using specific techniques such as storytelling, mastery experiences and the group process as a learning environment. These learned strategies, along with self-report falls schedules and follow-up reassessments within a time frame of 14 months from baseline, contributed to a 31% reduction in falls within the intervention group.²

Prior to participation in the strategies for the 7-weeks of the Stepping On program, Clemson et al³ recorded baseline measures of all subjects through completion of questionnaires, surveys, and functional assessments of mobility and balance. One of the assessments used to evaluate balance and functional mobility in relation to fall risk was the "Get Up and Go" (GUG). Within the noted 31% reduction in falls, the GUG held a better average score of 1.92 ± 0.99 within the Stepping On group in comparison to an average score of 2.11 ± 1.11 within the control group. A 1 to 5 scale was utilized for

scoring a subject's balance based on the test administrator's perception (1=normal, 2=slightly normal, 3=mildly abnormal, 4=moderately abnormal, 5=severely abnormal).

As positive effects were displayed in the first study, the Stepping On program has been spread internationally as a falls prevention program, and has been utilized in the U.S. within 19 different states.⁷ A recent study by Ory et al,⁴ examined 2 years of evaluation data collected from older adults in 3 different states (Oregon, Colorado, and New York) who participated in the Stepping On program. Unlike the first study which used the GUG for functional assessment, the study utilized the Timed Up and Go (TUG), in which scoring is based off time in seconds to complete the test at a typical or normal pace. Significant improvements in scores (p<0.001) were demonstrated as a whole (n=254), as well as within those classified as 'high-risk' (n=123). Average participant age was 78.7 (SD \pm 8) years, with most being female (83.4%). Those participants who completed the TUG in less than 12 seconds were classified as low fall risk, and those who took 12 or more seconds were classified as high risk. Following completion of the Stepping On program, overall TUG scores improved from 13.5 to 11.4 seconds as a whole, and from 17.6 to 14.4 seconds in those classified as high-risk. This concludes that as a whole, after completion of Stepping On, baseline TUG scores initially classified as 'high risk' improved to being classified as 'low-risk' in relation to the study's 12 second cut-off. Fall-related confidence had also significantly improved from approximately 70% to 90% in feeling confident that falls could be avoided. The improved confidence supported that reduction of fear in addition to an increase in functional mobility was a key factor in creating an effective fall prevention program.

The Center for Disease Control and Prevention (CDC) created the STEADI (Stopping Elderly Accidents, Deaths, & Injuries) Tool Kit to functionally assess older adults who are at risk of falling or who may have fallen in the past year. The tool kit provides basic information about falls, case studies, conversation starters, and standardized gait and balance assessment tests in addition to educational handouts about fall prevention. Included in the standardized assessments are the Timed Up and Go (TUG), 30-Second Chair Stand Test (30s CST), 4-Stage Balance Test (FSBT), and orthostatic blood pressure measurement.⁶

Overall, the TUG remains a popular fall risk assessment as it is easy and quick to perform, and does not require specialist equipment.¹ Components of the TUG involve intrinsic and extrinsic factors, both of which the risk of falling are dependent on. Functional mobility and balance are assessed as the participant rises from a seated position in a chair, walks 3 meters, turns around, walks back to the chair, and returns to sitting. Cognitive function is also assessable as the motor performance of transferring and turning may require intact cognitive function for optimal performance.⁸ Also of significance is the participant's ability to change walking speeds such as when turning around at the marked distance. The ability to increase or decrease walking speed above or below a "comfortable" pace suggests a potential to adapt to varying environments and task demands, essential in assessing overall fall risk.⁹

A study by Giladi et al,¹¹ found that older adults (mean age 78.4 years) who walked more slowly and with shorter strides had increased unsteadiness, excessive fear of falling, lower muscle strength, and worse static and dynamic balance and gait performance (p<0.0001) when compared to "healthy" controls (mean age 78.2 years).

This proves the importance of maintaining a functionally fast but safe mobility pace as age increases. Functioning at a faster pace is also important as a subject's ability to increase walking speed above a "comfortable" pace suggest a potential to adapt to varying environments and task demands, both of which the risk of falls are dependent on.⁹ A lot of falls in the elderly population occur in rushed situations as the effects of aging tend to naturally slow people down. Examples of such situations include rushing across a busy street, hurrying to the bathroom at night, or quickly getting to the telephone as it is ringing. In support of maintaining a functionally fast speed, it is now common for the TUG to be administered at a faster pace in addition to at a comfortable and safe pace.^{12,13}

The purpose of this study was: 1) to determine if the Stepping On program decreases fall risk in community-dwelling elderly individuals as measured by the TUG test, 2) to distinguish if the TUG is an effective screening tool in assessing fall risk in program participants in reference to CDC fall risk, history of falls and a 12 second cut-off score, and 3) to describe characteristics of Stepping On participants.

CHAPTER II

METHODOLOGY

This research was approved by the University of North Dakota Institutional Review Board (IRB #201209-047). See Appendix B for IRB and consent forms. Subjects were recruited from a local Stepping On program (n=3). Those who volunteered for the study signed and were given a consent form before completing surveys and questionnaires, and participating in the following functional assessments: Timed Up and Go (TUG), 30second Chair Stand Test, Four-Test Balance Scale, and Activities-specific Balance Confidence (ABC) Scale.

Subjects

All 3 subjects were caucasian (1 male: 2 female) with ages ranging from 81-93 years old (mean=87.6). Subject demographics and characteristics can be located in Table 1. Inclusion criteria for *Stepping On* was satisfied as each individual was older than 65 years of age, had a fear of falling or had experienced a fall in the past year, walked and lived independently, was cognitively intact, and spoke English.³

Instrumentation

The TUG is a popular functional assessment as it assesses components of mobility, balance, gait, and fall risk in older adults. It is commonly used as preparation and performance requires minimal equipment and time. Necessary equipment includes a standard chair (46 cm) with armrests, masking tape, a stopwatch, and a gait belt for patient safety. Equipment for the participants includes a normal pair of walking shoes.

An assistive device can be used during assessment by participants if the device is used regularly with baseline mobility. In setting up the TUG, a visible line of masking tape is placed on the floor 10 feet in front of the chair.

	Subject #1	Subject #2	Subject #3
Age	89	93	81
Gender	Female	Male	Female
Fall History	Yes, x 2	Yes, x 1	Yes, x 5-6
Past Medical History	None	Mild stroke with L sided weakness 20 years prior	Knee pain from past car accident, balance/walking difficulties
Vision Impairments	Yes	Yes – glasses	Yes – glasses, L macular degeneration
Self Rated Activity Level (Inactive/Min/Mod/Highly active)	Minimally Active	Minimally Active	Minimally Active

Table 1. Subject Demographics and Characteristics

The TUG is intended to predict fall risk through assessment of balance, functional mobility, and gait in community-dwelling adults age 65 and older.¹⁴ Scoring is based off the time it takes in seconds for an individual to perform the TUG. Table 2 indicates normative mean data for time it takes community-dwelling older adults to complete the TUG.¹⁵

Age	Time (s)	р
60-69	8.1	.953
70-79	9.2	.995
80-99	11.3	.318

Table 2. Normative Mean Data for TUG Performance (95% CI)

While assessing risk of falls in community dwelling older adults, a study by Barry et al¹⁶ found that the TUG should not be used in isolation to identify an individual's risk. This study found the TUG to be more useful in ruling in rather than ruling out falls in individuals classified as high risk (>13.5 seconds), with a higher pooled specificity (0.74, 95% CI 0.52-0.88) than sensitivity (0.31, 95% CI 0.13-0.57). Overall, the study concluded that the TUG score was not a significant predictor of falls (p=0.05).

In support of these findings, as well as the CDC STEADI Tool Kit, balance and fall risk functional assessments for this study were performed within four different stations.⁷ Each station consisted of one of the four functional assessments. All four assessments focused on functional mobility, balance, fall risk, and fall-related confidence. Performance of all four functional assessments was practiced during an instrumentation course prior to this study.

In addition to functional assessments, participants completed the following surveys: Week 1 Stepping On Baseline Questionnaire, Week 1 CDC Fall Risk Checklist, and Week 7 Stepping On Survey. The Week 1 Stepping On Baseline Questionnaire had participants note any vision impairments, surgeries, major past health issues, and walking or balance difficulties. The amount/type of exercise and level of physical activity was also noted at this time. The Week 1 CDC Fall Risk Checklist gave a series of "yes" or "no" statements that required participants to circle the answer that best related to their individual circumstances. Points were assigned to each statement with "yes" being 1 or 2 points, and "no" being 0 points. The number of points for each "yes" answer was totaled. A score of 4 or more points indicates an individual may be at risk for falling. The Week 7 Stepping On Survey allowed participants to note if their balance, confidence, and

physical activity level had improved following completion of the program. Participants at this time also documented if they had any falls since the start of the program. See Appendix C for copies of questionnaires and surveys.

Procedure

As per CDC STEADI Tool Kit, when performing the TUG, participants were instructed to begin by sitting in the chair with their back completely against the back rest.⁷ Upon hearing the word "Go," they were instructed to stand up, walk 3 meters to a line taped on the floor, fully cross the line, turn around, walk back to the chair, and end by again sitting in the chair with their back completely against the back rest. Participants were told that time would start with the word "Go," and end when they returned to sitting with their backs against the back rest of the chair. See Figure 1.

Following instruction and demonstration of the test, each participant completed the test a total of three times. The first time, participants were allowed a practice trial to ensure understanding of instructions and test performance. The second time, participants were instructed to walk at their "normal pace." The third time, participants were instructed to walk "as quickly but safely as possible." Only the second and third walk times were recorded. For added safety, gait belts were used in all tests, and a spotter was present a comfortable distance behind the participant when walking.



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Data Analysis

Subject data was collected during Week 1 and Week 7 of the Stepping On program through surveys and functional assessments. Following completion of the program, 3 month follow-up data will be collected to assess if a long term exercise program had an effect on the subjects previously determined fall risk. In data analysis for TUG results, two separate cut-off scores of 12 seconds and 13.5 seconds were considered. Subjects taking greater than 13.5 seconds to complete the TUG were classified as being at 'high-risk' of falls.^{8,13,14} Subjects taking less than 12 seconds to complete the TUG were classified as 'low-risk'.⁴ Subjects taking between 12-13.5 seconds were classified as being at 'moderate-risk' of falls. Outcomes were compared from Week 1 to Week 7 based on a percent change.

CHAPTER III

RESULTS

All 3 subjects completed the TUG during Week 1. In comparison to normative age values for each subject, the following results were obtained at Week 1: Subject 1 demonstrated a slower time at both comfortable and quick pace, Subject 2 demonstrated a slower time at comfortable pace and a faster time at quick pace, and Subject 3 demonstrated a slower time at comfortable pace and an average time at quick pace. In reference to the two cut-off scores, subjects were classified for fall risk at Week 1 as follows: Subject 1 'high-risk' (>13.5 seconds) at normal pace but 'moderate-risk' (between 12-13.5 seconds) at faster pace, Subject 2 'low-risk' (<12 seconds) at both normal and faster paces, and Subject 3 'moderate-risk' at normal pace but 'low-risk' at faster pace. Specific completion times of the TUG are indicated in Table 3 for all subjects. Following Week 1, Subject 3 left the study due to previous health concerns. Subjects 1 and 2 participated throughout the entire Stepping On program, and completed the fall risk assessment during Week 7.

		Comfortable Pace (s)		Normal Pace % Change	Quick Pace (s)		Quick Pace % Change	
Subject	Normative Age Value (s)	Week 1	Week 7	Week 1→7	Week 1	Week 7	Week 1 → 7	
1	11.3	15.34	14.29	-6.85%	12.09	13.22	+9.35%	
2	11.3	11.88	14.06	+18.35%	10.07	11.28	+12.02%	
3	11.3	13.06	NA	NA	11.31	NA	NA	

Table 3. TU(Times for A	Il Subjects ((n=3)	ĺ
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Subject 1 and 2 being at risk of falls as demonstrated through performance of the TUG correlates with scores obtained from the CDC Fall Risk Survey. Both Subjects had areas of concern upon completion of the survey. Subject 1 indicated she/he had fallen twice in the past year, had trouble stepping up on to a curb, often had to rush to the toilet, and took medicine to sleep or improve mood. Subject 2 indicated she/he had fallen once in the past year, often had to rush to the toilet, had some lost feeling in her/his feet, took 6 types of medications, and took medicine to sleep or improve mood. Both Subject 1 and 2 scored a total of 5/12 points on the survey, indicative that they were both at risk for falling.

The following results were obtained when the TUG was performed at Week 7 in comparison to Week 1: Subject 1 progressed at comfortable pace by 1.05 seconds $(15.34 \rightarrow 14.29 \text{ seconds}; 6.85\% \text{ improvement})$ but demonstrated a slower score at quick pace by 1.13 seconds $(12.09 \rightarrow 13.22 \text{ seconds}; 9.35\% \text{ decline})$, and Subject 2 demonstrated a slower score at comfortable pace by 2.18 seconds $(11.88 \rightarrow 14.06; 18.35\% \text{ decline})$ as well as a slower score at quick pace by 1.21 seconds $(10.07 \rightarrow 11.28 \text{ seconds}; 12.02\% \text{ decline})$.

In summary, although Subject 1 progressed at comfortable pace, she/he continued to perform at times slower than mean normative data for her/his age. This classified Subject 1 as 'moderate risk' for falls at both comfortable and quick pace during Week 7. Subject 2 performed at a worsened time at both comfortable and quick pace during Week 7. She/he demonstrated a time well above mean normative data for her/his age at comfortable pace. Although worsened time was demonstrated at quick pace for this subject, she/he remained below the average time for her/his age. Times taken to

complete the TUG at Week 7 classified Subject 2 as 'high-risk' for falls at comfortable pace and 'low-risk' for falls at quick pace.

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CHAPTER IV

DISCUSSION

The first purpose of the study was to determine if the Stepping On program decreased fall risk in community-dwelling elderly individuals as measured by the TUG. At the end of the Stepping On Program, only one of the two subjects displayed a faster time when performed at normal pace. A possible factor contributing to why Subject 2 displayed a slower time during Week 7 at this pace was her/his report of history of mild stroke that caused left sided weakness about 20 years ago. This past medical history made balance exercises difficult to perform. In comparison, Subject 1 had more easily performed and progressed balance exercises. These results coincide with the Week 7 Stepping On Survey in which Subject 2 had documented his/her balance had stayed the same, and Subject 1 had documented that his/her balance had improved following the program.

In comparison, both Subject 1 and Subject 2 displayed slower times when the TUG was performed at quick pace. Possibilities of why slower times were displayed at this pace during Week 7 included unchanged fall-related confidence levels, increased knowledge of safe strategies, and overall higher mean age as mentioned previously. When asked on the Week 7 Stepping On Survey if their confidence had improved, both Subject 1 and 2 indicated it had stayed the same. As both subjects had also noted increased knowledge of safe strategies, it was believed that slower times were a result of being more cautious and aware of their mobility when the TUG was performed at quick pace.

The second purpose of the study was to determine if the TUG was an effective screening tool in assessing fall risk. When comparing TUG scores to the Subjects' self-reported recent falls as an indicator of fall-risk, the TUG displayed poor validity in categorizing the participants in the proper category as no recent falls had been reported at Week 7. As previously noted, a systematic review by Barry et al¹⁶ found through higher specificity than sensitivity that the TUG was more useful in ruling in falls rather than ruling out. Although no recent falls had been reported at Week 7, according to TUG results, both subjects had remained at moderate-high risk for falling. The primary factors considered are from unmodifiable factors of high age (89-93 years), visual impairments that required glasses to be worn, and multiple medications used.

Once data collection was completed, physical factors were considered that may have altered the subjects' scores. Testing was performed in a station-to-station rotating format between the TUG, 30s CST, FSBT, ABC Scale, and written surveys and questionnaires in no particular order. A small subject size provided a continuous paced flow for tests to be performed, but could have created opportunities for physical fatigue as little rest time was given between stations.

Variation in testing parameters of the TUG could also have affected scores. The use of a cone rather than a taped line for a floor marker 3 m away from the chair is a variation that could have affected results.⁹ If a larger and more visible marker had been used, possible error that may have occurred from visual deficits could have been avoided. Lastly, the use of arm rests versus no arm rests on the chair could have affected our results. Participants are typically allowed to utilize the arm rests upon standing, but some studies that administered the TUG had specifically instructed participants to not use the

arm rests.^{8,15,17} The use of arm rests did not directly affect subjects in this study as both subjects did not need to use them upon standing. Some error could have occurred though with the type of chair used. Typically, the same chair is used during each test administration. A standard chair with armrests was used during Week 1, but had broken after that, requiring the use of a different chair at Week 7 which had no arm rests. Although both subjects did not utilize the arm rests, the different style of chair could have produced some error in ease of standing.

Limitations

The major limitation of this study was the small sample size. Only having 2 participants affected the legitimacy of the results when testing the effectiveness of both the Stepping On program and TUG in assessing fall risk. Subject characteristics may have also limited the results. This study demonstrated a significantly higher mean age (87.6 years) in comparison to previous Stepping On studies who's subjects mean ages remained around 75±4 years.^{4,8} Although our study had a higher age range for the program, our high mean age was more fitting when comparing results of the Otago Exercise Program,⁵ as this programs subjects were aged 80 years or older. Overall Similar characteristics of this study's subjects compared to previous studies included all subjects were at risk individuals living at home, had good health, functioned independently, and had a recent history of falls or fear of falling.^{2,4,5,8,9}

Another limitation of the study could have been the number of trials subjects were allowed. Typically, as followed in this study, participants are given 1 practice trial that is not included in the score before 1 official test time is recorded.^{14,16,17} In comparison, other studies have utilized 1 practice trial followed by 2 official trials of which the

average time is recorded.^{8,9} Performing the test twice after the practice trial could have eliminated any error potentially caused by distraction or confusion in test performance. Taking an average of 2 trials could have resulted in better TUG performance times at a quick pace, as subjects most likely do not utilize this pace very often day-to-day, and may have needed more time to adjust.

One more limitation of the study could be the seven weeks not allowing ample time for significant improvements to be displayed. Subjects in this study performed the Stepping On home exercise program for approximately 2 hours per week, which totaled 14 hours after Week 7. In a systematic review and meta-analysis, Sherrington¹⁸ found that to reduce risk of falls, an exercise program should devote at least 50 hours to exercises and activities to improve balance. In relation to our findings, improved balance and decreased fall-risk may have been more likely with a longer duration between pre and post testing.

Conclusion

The TUG displayed validity in appropriately classifying those experiencing recent falls at a fall risk. Ongoing data collection will be performed with 3-month recheck to analyze if categorized fall-risk based off of TUG performance times are directly related to reported falls (if any). With continuation of the Stepping On program, as well as a focus on increased age when testing, comes opportunity to further assess the effectiveness of the TUG as a screening tool for assessing fall risk in the communitydwelling elderly population.

APPENDIX A

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Exercise L	og			
Name				
Week (plea	se circle the w	/eek number -	- circle one)	
	1 2 3	4 5 (6 7	
🗹 Check —	if I did my ex	ercises this w	eek	
Balance Exe	ercises (daily)	:		
🗌 Monday	🗌 Tuesday	🗆 Wednesda	ay 🗌 Thursday	
🗌 Friday	🗌 Saturday	🗌 Sunday		
Strength Ex have one da	e rcises (3 tim ay of rest betv	es a week — b veen strength	e sure you exercises):	
🗌 Monday	🗆 Tuesday	🗆 Wednesda	ay 🗆 Thursday	
🗌 Friday	🗆 Saturday	🗆 Sunday		

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ND REDUCING FALLS

APPENDIX B

Research Project R	eview and Progre	ess Report	
DATE: 2/26/2016 DEPARTMENT: F	hysical Therapy		
PRINCIPAL INVESTIGATOR: Danks, Meridee; Johr	ison, Beverly		Computer
PROJECT TITLE: The Effectiveness of the "Stepping C	n" Program for Reducing	the Incidence of Falls in th	ne Elderly
PROPOSAL NUMBER: IRB-201209-047			
F MEDICAL COMPONENT, PLEASE GIVE PHYSICIA	N'S NAME:		
IRB USE ONLY FULL BOARD REVIEW REQUIRED, EVEN THOU CONTINUED APPROVAL, "EXPEDITED" CATEG NEXT REVIEW REQUIRED BEFORE: CONTINUED APPROVAL, BASED ON FULL BOA NEXT REVIEW REQUIRED BEFORE: SUSPEND APPROVAL, PENDING INVESTIGATION APPROVAL TERMINATED COMMENTS OF REVIEWER:	DGH ORIGINAL APPRC ORY <u>4, 7</u> RD REVIEW	VAL WAS EXPEDITED	
Signature of Chair/Vice Chair or Desig cc: Chair, Physical Therapy Approval Da	inee: Band te: 4.0	K 5.16	
Signature of Chair/Vice Chair or Designator cc: Chair, Physical Therapy Approval Da . Is project complete? Yes \Box No \Box . Is project ongoing? Yes Δ No \Box If No, explain below and indicate if continued approval . How many subjects have been enrolled in the research \Box \Box . How many subjects have been enrolled in the research \Box . How many subjects have been enrolled in the research \Box . How many subjects have been enrolled in the research . If Δ . Since the date of last approval, and since the initial approval . Is the research permanently closed to the enrollment	nee: <u>Payww</u> te: <u>4.c</u> al and continuing review oh project? of new subjects?	j · j (g is desired. Yes □ No ⊠	
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INFORMED CONSENT

TITLE:

PROJECT DIRECTOR: PHONE # DEPARTMENT: The Effectiveness of the "Stepping On" Program for Reducing the Incidence of Falls in the Elderly

Meridee Danks and Beverly Johnson

701-777-2831

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.

Approval Date:	MAY	11.	2015-*/	
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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. <u>Baseline Questionnaire and Fall Risk Survey</u> - 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. <u>Activities-specific Balance Confidence (ABC) Scale</u> - 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. <u>Sit to Stand Test (STS)</u> - 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 \sim 3 minutes.

4. <u>Timed Up and Go Test (TUG)</u> - 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. <u>Four-Test Balance Scale</u> – 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 alotted 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. <u>Fall and Activity Survey and Stepping On Participation Evaluation</u> - each subject will be given the 2 survey's following the completion of Stepping On session at Week 7, at 3month 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

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Date_____ Subject Initials: 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 <u>safety belt and spotter will be used to prevent any falls</u>. 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 <u>no</u> 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

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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

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Date_____ Subject Initials:

APPENDIX C

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Stepping On Baseline Questionnaire – Week 1

Yes or No Do you have any vision impairments? (glasses, macular degeneration, glaucoma, etc.)

*If yes, what kind?

Yes or No Have you had any surgeries in the last year? (hip, knee, etc.) *<u>If yes</u>, what kind?

Yes or No Have you had any major health issues in the past year? *<u>If yes</u>, briefly describe.

Yes or No Do you have difficulty with walking or balance?

Yes or No Do you exercise regularly (3x/week or more)?

*If ves, what type of exercise & how often do you perform it?

*How would you rate your <u>level of physical activity</u> on a typical day? (circle one) Inactive Minimally Active Moderately Active Highly Active Date _____

Name		

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 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
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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 <u>no</u>, what has kept you from performing the exercises as per the recommended amount of times?

If <u>ves</u>, 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:

	# times/week	# of repetitions
Sit-to-Stand		
Sideways Walking		
Heel-toe standing		
Heel-toe walking		

Strength Exercises:

	# times/week	# of reps & weight
Side-hip-strengthening		
Knee-strengthening		
Heel raises		
Toe raises		

5. Do you have any difficulties performing the above exercises?

Yes _____ No _____ If <u>yes</u>, describe what difficulties you are having?

6. Had you been actively exercising at home prior to the Stepping On program?

Yes ____ No ____ If <u>yes</u>, 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?

Date _____

ID # _____

Stepping On Survey – 3 months after

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

Balance Yes____ No____

Confidence Yes No If <u>yes</u>, what strategies have helped you?

2. Do you feel that the Stepping On Program has helped you?

Yes___ No____ If <u>yes</u>, how has it helped you?

3. Have you had any falls since completing the Stepping On Program?

Yes	No	If <u>ves</u> , how many falls:
		What was the cause(s) of the fall(s)?

4. How often do you perform the Stepping On exercises usually? (Circle below)

Strength: ≥3x/week 2x/week 1x/week < than 1x/week Not at all

Balance: ≥3x/week 2x/week 1x/week < than 1x/week Not at all

If you have <u>not</u> been doing the exercises regularly, what has kept you from doing so?

Have you joined or continued any community exercise groups since the Program?
 Yes No If <u>yes</u>, what group?

Stepping On – Week 1 Fall Risk Checklist (CDC)

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Name	Age Date
Please Circle "Yes	" or "No" for each statement below. () indicates # of points .
Yes (2) or No (0)	I have fallen in the past year. If yes, how many times?
Yes (2) or No (0)	I use or have been advised to use a cane or walker to get around safely. * <u>If yes</u> , what assistive device do you use most`often?
Yes (1) or No (0)	Sometimes I feel unsteady when I am walking.
Yes (1) or No (0)	I steady myself by holding onto furniture when walking at home.
Yes (1) or No (0)	l am worried about falling.
Yes (1) or No (0)	I need to push with my hands to stand up from a chair.
Yes (1) or No (0)	I have some trouble stepping up onto a curb.
Yes (1) or No (0)	I often have to rush to the toilet.
Yes (1) or No (0)	I have lost some feeling in my feet.
Yes (1) or No (0)	I take medicine that sometimes makes me feel light-headed or more tired than usual. *How many prescription medicines do you take per day?
Yes (1) or No (0)	I take medicine to help me sleep or improve my mood.
Yes (1) or No (0)	I often feel sad or depressed.
TOTAL	Add up the number of points for each "yes" answer. If you

scored 4 points or more, you may be at <u>risk for falling</u>.

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