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Evaluation of Program Satisfaction, Quality of Life, Strength, and Fall Risk of Community-Dwelling Older Adults Participating in a Community Exercise Program: Part 2

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EVALUATION OF PROGRAM SATISFACTION, QUALITY OF LIFE,
STRENGTH, AND FALL RISK OF COMMUNITY-DWELLING OLDER ADULTS
PARTICIPATING IN A COMMUNITY EXERCISE PROGRAM: PART 2

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A Scholarly Project Submitted to the Graduate Faculty of the
Department of Physical Therapy
School of Medicine and Health Sciences
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In partial fulfillment of the requirements for the degree of
Doctor of Physical Therapy

Grand Forks, North Dakota
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This Scholarly Project, submitted by Marissa Adolphson, Roy Nelson, and Jenna Wyffels 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 Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.



(Graduate School Advisor)



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PERMISSION

Title EVALUATION OF PROGRAM SATISFACTION, QUALITY OF LIFE, STRENGTH, AND FALL RISK OF COMMUNITY-DWELLING OLDER ADULTS PARTICIPATING IN A COMMUNITY EXERCISE PROGRAM: PART 2

Department Physical Therapy

Degree Doctor of Physical Therapy

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TABLE OF CONTENTS

LIST OF FIGURES	v
LIST OF TABLES.....	vi
ACKNOWLEDGEMENTS.....	vii
ABSTRACT	viii
CHAPTERS	
I. INTRODUCTION.....	1
II. METHODS.....	5
III. RESULTS.....	16
IV. DISCUSSION.....	30
APPENDIX	
A. OUTLINE OF EXERCISE PROGRAM	37
B. CONSENT FORM.....	39
C. IRB	44
D. BONE BUILDERS DATA SHEET	49
E. QUALITY OF LIFE QUESTIONNAIRE	52
F. FES-I.....	55
G. CDC STANDARD INSTRUCTIONS.....	57
REFERENCES.....	63

LIST OF FIGURES

Figure 1. Flowchart of participant recruitment.....	7
Figure 2. Quality of life/satisfaction questionnaire level of improvement results in 65-69 age group.....	20
Figure 3. Quality of life/satisfaction questionnaire level of improvement results in 70-79 age group.....	20
Figure 4. Quality of life/satisfaction questionnaire level of improvement results in 80-89 age group.....	21

LIST OF TABLES

Table 1. Categories of fall risk based on FES-I score.....	9
Table 2. Normative Data for Females.....	9
Table 3. Demographic characteristics of study participants and scores summary.....	16
Table 4. Score Summary of Assessments.....	17
Table 5. Quality of life/satisfaction survey results.....	17
Table 6. Average FES-I scores for age groups.....	22
Table 7. Average 30 Second Sit-To-Stand scores compared to age norms for women.....	23
Table 8. Average grip strength compared to age norms for women.....	23
Table 9. Average Gait Speed compared to age norms.....	24
Table 10. Average TUG compared to age norms.....	25
Table 11. 4 Stage Balance Test Averages.....	26
Table 12. 4 Stage Balance Test Averages by Age Group.....	27
Table 13. Age range averages comparing each year.....	29
Table 14. Repeat Subject Data.....	29

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ABSTRACT

Background and Purpose:

Bone Builders is an exercise program that incorporates both lower and upper extremities and is specifically designed for the older adult population. It was originally created for those that wanted to reduce their risk of osteoporosis, but currently there is no evidence that demonstrates these effects. However, exercises that are completed in the class are those that target causes of fall risk such as strengthening of hip abductors and balance activities. Participants have also reported that benefits of the class include improved balance, increased energy and mobility, and social support. Our study consisted of testing the fall risk of participants in this program, which were all women aged 65 years and older. This was compared to previous studies done, to determine whether this community exercise program decreases fall risk over time.

Methods:

Twenty-six participants, with ages ranging from 68-86 that are currently attending the Bone Builder's program volunteered to participate in our study. Tests included were the 30 second sit-to-stand, grip strength, gait speed, TUG, and 4 stage balance tests. They also completed the Functional Efficacy Scale-International and a quality of life questionnaire, which measured subjective views of fall concern and overall satisfaction of attending the program.

Results:

The majority of participants were within the normative data ranges on all tests. Some assessments showed scores lower than the norms, particularly the 30 second sit-to-stand test. The majority of repeat subject's scores improved or stayed the same, but some did worsen in the assessments, particularly for grip strength and gait speed. Overall, the age group ranging from 70-79 had the most scores above the normative data, and also scored higher on every assessment than the other age groups, except for the TUG.

Conclusion:

Bone builders has been shown to have a positive effect on participation in exercise, as well as improving the fall risk and safety of the participants. The program has a social aspect that allows for accountability among participants. On average, scores were above the normative data for each age group, which is indicative of a decreased fall risk and higher level of mobility.

CHAPTER I

INTRODUCTION

Background

Bone Builders is a free, alternative exercise program for individuals who want to reduce the risk of osteoporosis. Bone builders was originally developed from the Strong Living Program at Tufts University and is coordinated by ServeYES!, formerly known as RSVP, in the state of North Dakota. Volunteers lead Bone Builders participants in weight bearing exercises designed to address specific areas of the body affected by osteoporosis. Participants of these classes note improved balance and poise, increased energy and mobility, and decreased blood pressure.¹

Bone Builders targets those who suffer from osteoporosis but truly anyone over the age of 55 can participate in North Dakota's program. The community-based exercise program is offered at the Grand Forks Senior Center for community-dwelling older adults, and is offered Tuesday, Thursday and Friday. A sign-in sheet is present at each session in order to keep record of attendance. Participants are encouraged to attend twice a week while having at least one day of rest in between sessions. Bone Builders includes balance exercises, exercises using body weight, and exercises utilizing hand and ankle weights for the upper

and lower extremities (**APPENDIX A**). The participants count out each exercise along with the instructor to monitor speed and to promote good breathing technique.

Osteoporosis is considered one of the most common diseases in the adult population and is defined as an illness of the skeleton, characterized by an increased risk of bone fractures and reduced mechanical bone resistance.² Bone mineral density (BMD) and the quality of the bone tissue present are the two factors that have an effect on mechanical resistance.³ The combination of suffering from osteoporosis and having frequent falls can lead to osteoporotic fractures. Osteoporotic fractures are defined as fractures that are disproportionate to the forces that caused it and occur from a fall from one's own height.⁴ The most common fractures occur in the vertebrae while hip fractures are also quite common. Osteoporotic fractures are associated with significant mortality, morbidity, and low quality of life and they have become a relevant issue with health care and health insurance.⁵ Reducing fall risk is the best way to prevent osteoporotic fractures from occurring. With the increasing age of the population, it is important as a society to promote the prevention of osteoporosis.

Postmenopausal women are at the highest risk for developing osteoporosis. Decreasing levels of estrogen can affect the trabecular bone and can lead to the possibility of vertebral and wrist fractures if a fall occurs. Changes in bone cellularity occur with aging in men and women and as falls also increase with age osteoporosis can be positively correlated with falls.⁶ Of those that are ages 65 and older, approximately 30-50% of them will fall once or more a year.⁷

Falls are the most common cause of injury as they account for 87% of all fractures and more than 50% of brain injuries in the older adult.^{8,9} The age range of 65 and older is estimated to increase from 13% (2010) to 20% of the U.S. population by the year 2030. This means that there is likely to be an increased incidence of falls with an increase in the aging population and education on fall prevention is crucial for the future elderly population.¹⁰ Reduction of muscle strength as well as muscle imbalances also occur and can become more extreme with aging. These muscle imbalances can also lead to falls which shows that the elderly population, not only those with osteoporosis, can benefit from exercise programs in order to reduce the risk of falling.

Those with osteoporosis can benefit from group exercise programs such as Bone Builders by increasing muscle function, postural stability, and bone mass by different types of loading. Evidence shows that low loading activities like walking can have an effect on mineral bone density. Other activities that could produce a greater response would be high impact exercise or high intensity resistance training that would produce a higher loading on the skeletal structure.^{11,12} This has been proven in a study conducted by Allison et al where a 12 month high impact exercise program was effective in improving femoral neck BMD in older men.¹³ Bone Builders promotes lower extremity exercises while weight bearing on a single leg which would increase the loading response down each leg and provide for a variation of loading which could potentially assist in increasing BMD. Group exercise programs such as Bone Builders also provide a social active atmosphere so that the participants can be active with their peers as

well as receive proper instruction from the group leader instead of having to rely on their own knowledge to perform the exercise alone at home. Although there is a lack of evidence based literature to support the “bone building” efficacy of this program, there is evidence that weight bearing exercise and weight training are beneficial in treatment of osteoporosis.

The purpose of this study was to address how the Bone Builders program can benefit the older population and reduce their risk of falls. Our analysis consisted of a quality of life assessment, the Falls Efficacy Scale-International, and five functional assessments. This allowed us to evaluate whether the repeat participants have maintained or improved their fall risk and to assess how the new participants’ scores compared to the norms for their age group.

CHAPTER II

METHODS

This research is a continuation of the 2013 and 2014 study conducted by the University of North Dakota Physical Therapy students and the Bone Builder's program in Grand Forks, ND.

Setting

This study took place in the Spring of 2016 at the Grand Forks Senior Center. The tests were completed by second year, graduate level physical therapy students from the University of North Dakota. Two exercise groups were assessed, a Tuesday group (that meets 3:30-4:30 pm) and a Friday group (that meets 9-10 am). Prior to testing, the researchers had practiced each assessment on peers and community volunteers, and passed a learning module for the Institutional Review Board. The researchers also participated in multiple program sessions prior to testing, to have a better understanding of how the exercises were completed. Emphasis for the Bone Builders exercises consist of slow counting, continued breathing, and challenges such as added hand/ankle weights if desired. Bone Builders also takes into account functional activities that can promote balance, such as tandem walking (both forward and backward), single leg stance, and toe/heel raisers.

A faculty advisor who is also a licensed physical therapist and a certified geriatric specialist supervised the students. This advisor has contributed to

previous Bone Builder studies, and has had an amplitude of experience in assessing and testing the older adult population.

Subjects

Twenty-six participants from two different Bone Builder classes at the Senior Center volunteered to partake in this study. Inclusion criteria followed previous studies and include the following: 65 years or older, community dwelling, participation in a community exercise program for two weeks or longer, ability to walk unaided by another individual for 200-400 meters with or without an assistive device without resting, and ability to follow and understand directions. Exclusion criteria were as followed: medically unstable and uncontrolled health status (cardiopulmonary, infection, inflammation, or terminal illness) and being homebound (unable to independently leave home). Out of the twenty six volunteers that were assessed, twenty-two of the participants met the inclusion criteria. Those excluded included four participants that did not meet the minimum age requirement (at least 65 years old). (Fig. 1) All participants gave written informed consent prior to participation. They were allowed to bring the consent form home to read before the actual testing day in order to provide enough time for the participants to understand each part of the study. **(Appendix B)** They were also offered a copy of the informed consent form. The study was approved by the University of North Dakota Institutional Review Board. **(Appendix C)** There was no compensation given to those participants that volunteered for the study. Following the testing day, the students returned to

distribute copies of the scores of the assessment to each specific participant.

These were provided at no cost to the participants. **(Appendix D)**

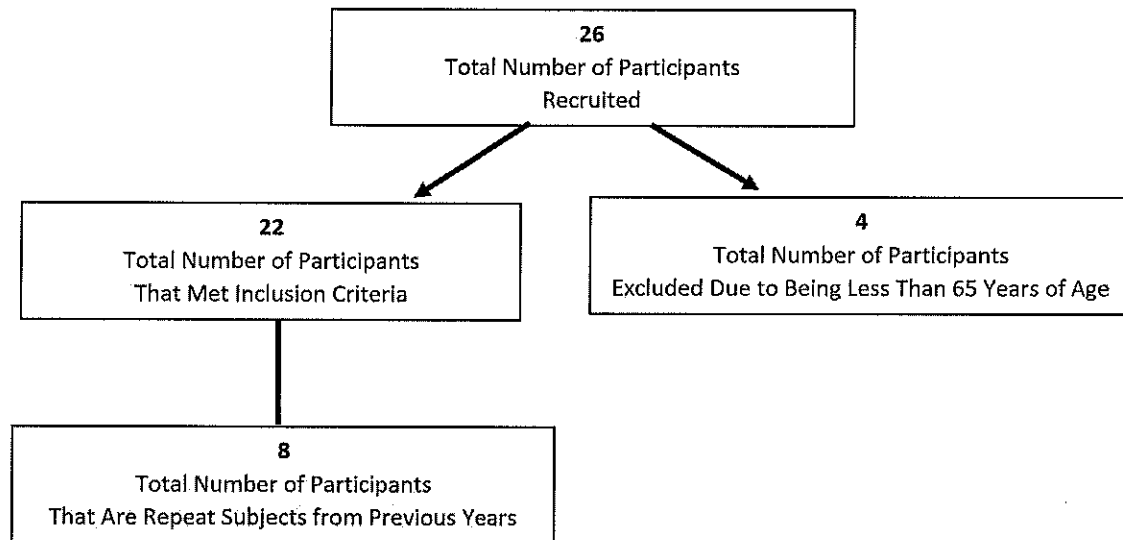


Figure 1. Flowchart of participant recruitment.

Quality of life/satisfaction questionnaire

On testing day, participants were instructed to fill out a questionnaire regarding their perception on quality of life and overall satisfaction with the program. **(Appendix E)** The previous questionnaire was modified to collect additional data. It consisted of basic demographic information such as age and gender, number of falls in the last year and number of current medications. Background information included length of involvement in the program, whether weights were used, and how many pounds. The participants were also asked questions relating to their perception on certain aspects of their lives such as sleep, balance, energy level, flexibility, state of mind, and strength. These ratings

were based on the program, and if they felt the program has benefited them. The survey also asked participants their perception of how the program has affected them, and if they prefer exercising in a group setting. Our faculty advisor provided help with filling out the survey, the context of the questions, and read questions for those that were visually impaired. If needed, the researcher transcribed answers from verbal dictation if the participant had difficulty writing.

Falls Efficacy Scale-International (FES-I)

Fear of falling is present in 21-85% of community-dwelling elders, according to Scheffer, et al.¹⁴ The rate of reported fear of falling has been found to be higher in community dwelling females over age 65 than in community dwelling males in the same age range.¹⁵ The Falls Efficacy Scale – International (FES-I) is a short questionnaire that assesses fear of falling based on 16 activities. The individual rates their perceived risk on falling on a four-point Likert scale (1 = not at all concerned, 4 = very concerned). The individual's score is added up with the greater number meaning a greater perceived risk of falling. Based on the individual's score, they can be placed in low, moderate, or high concern categories as established by Delbaere K et al.¹⁶ The FES-I has been found to have internal consistency reliability (Cronbach's alpha 0.94) and high relative reliability (intra-class correlation 0.88).¹⁷

Table 1. Categories of fall risk based on FES-I score¹⁶

Level of Concern about Falling	FES-I Score
Low	16-19
Moderate	20-27
High	28-64

Normative Data for Each Assessment

Table 2 includes all the normative data for females over sixty years of age.

This table can be referenced for each assessment that we discuss in the methods section.

Table 2. Normative Data for Females

Age Groupings		30SecSTS ¹⁹	Grip DH ²⁵	Gait Speed ³³	TUG ^{32*}	4 Stage Tandem ^{40**}
60-64 65-69	Mean	15 stands 14 stands	43 lbs.	1.0 m/sec	8.1 sec	≥10 sec
70-74 75-79	Mean	13 stands 12 stands	37.4 lbs.	0.9 m/sec	9.2 sec	≥10 sec
80-84 85-89 90-94	Mean	11 stands 10 stands 8 stands	36.5 lbs. 30.3 lbs.	0.8 m/sec	11.3 sec	≥10 sec

* TUG: ≥12 seconds to complete the TUG are at a high risk for falling

** Increased risk of falls if unable to hold tandem stance ≥10 seconds

30 Second Sit-To-Stand

The 30-second sit-to-stand test was done to measure lower extremity strength and endurance. One study using EMG determined that the top three highest muscle activation for the 30 second sit to stand test was found in the Vastus Medialis, Rectus Femoris and Tibialis Anterior muscles.²⁰ The test-retest reliability of this method was high, $r = 0.89$ (95% confidence interval 0.79-0.93). The test-retest reliability when using only female participants was found to be

$r=0.92$ (95% confidence interval 0.87-0.95). This was important to analyze, as all of our participants were female. It has also been shown that sitting and standing reflects upon a person's mobility, which in turn has an impact on their quality of life and overall function- particularly those with dementia in nursing homes.²¹ This indicates that this test is an excellent way of not only measuring lower extremity strength and endurance, but also gives us an idea of a person's functional capabilities.

The Centers for Disease Control and Prevention standard for instructions and test set-ups was used. Chair height was 17 inches with the chair against a wall to provide stability. Participants were instructed to sit in the middle of the chair, keep their feet flat on the floor, and cross their arms over their chest. All participants were able to cross their arms for this exam. Participants were instructed to perform as many stands as they could in 30 seconds. Prior to timing, each participant completed one stand, and was instructed to stand all the way up and sit all the way down. The participant was then told "Go" and was timed for 30 seconds, and then told to "Stop". A clicker was used to keep track of the number of stands, and the participant was wearing a gait belt with a volunteer nearby for safety. The recorder watched the timer and was responsible for using the clicker to count the number of stands. At the end, the participant must have been over halfway standing to count the last stand.

The normative data is listed in Table 2. This normative data is also included on our data sheet so that we could inform the participants of their score

right away when testing. We compared each person's total number of stands with the 50th percentile from Rikli and Jones.¹⁹

Grip Strength

A JAMAR Dynamometer was used to assess upper extremity grip strength. This has been found to be a valid and useful tool for determining functionality for this population.²² The test-retest reliability of grip strength measurements for community-dwelling elders is excellent (interclass correlation coefficients of 0.954 and 0.912).²³ For this procedure, the subject sat upright in a chair with their feet flat on the floor. The subject's shoulder was adducted and in neutral rotation. The elbow was bent at a 90 degree angle with the wrist in a neutral position. The subject was instructed to squeeze the dynamometer as hard as they could for 3-5 seconds. A measurement of each hand was taken. The stronger of the two hands was considered dominant and was repeated for a total of three measurements. The subject had a 1-2 minute break between trials. The American Society of Hand Therapists recommends using an average of three tests to determine the person's grip strength.²⁴ The average of the three trials was calculated to determine the subject's average, which was compared against the norms established by Luna-Heredia, Marin-Pena and Ruiz-Galiana (2005).²⁵

Gait Speed

Gait speed, or walking speed, was measured for each patient using the GAITRite system. Gait speed is known as the functional vital sign and can be used to guide clinical decision making.²⁶ Clinical evidence supports the use of walking speed tests to assess and monitor a variety of age ranges to properly determine if any pathology is present and if there is a need for intervention.²⁶ One tool that can be used to assess gait speed is the GAITRite which is a portable gait analysis walkway system that provides temporospatial measures of gait.²⁷ This system not only measures gait speed, but it also measures cadence, step length and width, foot placement (in-toeing), and various other measures that are useful in assessing gait.²⁷ The GAITRite has strong concurrent validity and test retest reliability in addition to being a portable, simple clinical tool for the objective assessment. Using intraclass correlation Bilney et al²⁸ concluded that the GAITRite had excellent validity for slow and fast gait speed (ICC 2,1=0.99) and good test retest reliability with preferred gait speed (ICC 3,1=0.93), in addition to being a portable, simple clinical tool for the objective assessment. Our study utilized the gait speed measurement given by the GAITRite in order to retrieve a precise measurement as there could be error if gait speed were measured using tape lines on a floor and a stopwatch.

This study incorporated measuring gait speed using the GAITRite system mat and computer program. Each participant was given two trials to complete their normal walking speed on the mat. A tape line was placed on the floor three feet before the start of the GAITRite mat to allow for participants to accelerate to

their normal gait speed and another tape mark was placed three feet after the end of the mat, letting the participant know to start decelerating and come to a stop. The participants were offered a gait belt if they felt it was necessary for their safety. Each participant was given instruction on how to walk on the mat, complete the test and what cues they would be given. After they were positioned behind the starting line, the participant was instructed to “start walking” and come to a stop after the last tape line. The GAITRite program was then reset in order to allow their walking speed to be measured a second time. A research assistant walked posterolaterally to the participant in order to provide assistance if any was needed but also to avoid unintentional pacing. If an error happened with the GAITRite system the participant was asked to perform the assessment again in order to obtain a correct reading without any error. The fastest of the two test speeds was used in this study’s data collection.

Timed Up and Go (TUG) Test

A commonly used screening tool that clinicians use to help identify patients at risk for falling is the Timed Up and Go test.²⁹ The Timed Up and Go test measures functional mobility, looking at a sit to stand transfer, gait, turning ability, and a stand to sit transfer. The TUG has been found to be both sensitive (87%) and specific (87%) when measuring community dwelling elderly adults prone to falls.³⁰ A chair with armrests was positioned against a wall and participants were instructed to get up, walk 10 feet indicated by a line on the floor, turn around, walk back to the chair, and sit down. The subjects wore their

regular shoes and could use an assistive device, but were not provided with any manual assistance from the researchers. According to the Center for Disease Control and Prevention (CDC), an older adult has an increased risk of falls if it takes 12 or more seconds to complete the TUG, from the time they are seated in the chair to the time they are seated with their back against the back of the chair after walking.³¹ Bohannon found the normative values as shown in Table 2.³²

4 Stage Balance Test

The CDC standards were used for the 4 stage balance test to assess the balance of each individual. The CDC states that an inability to hold tandem stance for more than ten seconds puts the participant at an increased risk for falls.³⁹

The test started with the participant standing and wearing a gait belt, with a volunteer standing next to them for safety. The instructions were to have the participant hold four different positions for 10-20 seconds each. They were told they could move their arms or body, but could not touch the wall or step out of position (or the timer would stop). The recorder demonstrated each position, and used the timer. The first position was to have the participant stand with their feet as close together as they could, and were timed for 10 seconds. The next position was to have the participant place one foot so that it was touching the big toe of the other foot, and timed for 10 seconds. The next position was tandem stance, with one foot directly in front of the other, and timed for 20 seconds. We timed this position longer as we wanted to be consistent with the previous Bone

Builders study. The last test (if the participant could do all other listed positions), was to have them stand on one leg (either leg), for 10 seconds. Between each position the participant was instructed to "march" out of place to regain their balance and reset their foot position. The recorder checked which foot was placed forward and recorded it on the data sheet, along with which foot they stood on for the single leg stance. If the participant had difficulty getting into the position, they were instructed to use the recorder's arm to get into the position, and the timer was started once the participant let go of the recorder's arm in a stable position. If unable to perform any of the positions, testing was stopped and assessment of tandem stance was not completed.

CHAPTER III

RESULTS

Demographics and Mean Values

Demographic characteristics were collected for all participants and included age, sex, length of time participating in the program, if weights are used for arms/legs and how many pounds, number of medications currently taking, and number of falls in the last year. These characteristics are outlined in Table 3. Overall mean scores for each assessment are outlined in Table 4.

Table 3. Demographic characteristics of study participants and scores summary

Characteristic	Mean Value	Range
Age (years) (N=22)	76.54	68-86
Gender		
Female (N=22)	22	
Male (N=0)	0	
Pounds used for arms (N=20)*	2.20	1-4
Pounds used for legs (N=20)*	3.33	2-5
Number of medications currently taking (N=16)*	3.25	1-12
Number of falls in the last year (N=5)*	1.20	1-2

* Missing Data

Table 4. Score Summary of Assessments

Assessments	Mean Value	Range
FES-I (N=22)	20.91	18-27
30-Second Sit-to-Stand Test (N=22)	11.45	9-16
Grip Strength (dominant hand) (N=)	43.71	17.7-66.0
Gait Speed (m/sec) (N=22)	1.21	0.92-1.86
TUG (N=)	9.59	6.65-11.97
4 Stage Balance Test (N=22)*		
- Narrow Based Stance (N=22)	10	All participants completed 10 sec
- Semi-Tandem Stance (N=22)	10	All participants completed 10 sec
- Tandem Stance (N=22)	18.6	5-20
- Single Leg Stance (N=15)	8.27	2-10

* This assessment is further outlined later in the results section

Quality of life/satisfaction questionnaire

Table 5 summarizes the results from the Quality of Life/Satisfaction Questionnaire, and Figure 2 breaks the results into each age group. There was one participant in the 65-69 group, fifteen in the 70-79 group, and six in the 80-89 group.

Table 5. Quality of life/satisfaction survey results

Participation Changes	No Change	Slight Improvement	Significant Improvement
Ability to Sleep At Night	15	5	2
Balance	4	15	3
Energy Level	6	13	3
Flexibility	1	16	5
State of Mind	4	12	6
Strength	2	16	4
Totals in each category:	32	77	23

Overall, most people found "slight improvement" in different aspects of their lives due to Bone Builders, and the least amount of people showed

"significant improvement". In the "no change" category, the majority of people found that their ability to sleep at night had not been effected. In the "slight improvement" category, both flexibility and strength had the largest number of responses. In the "significant improvement" category, the largest group of people found that their state of mind is what improved the most due to participation in the program.

In the 65-69 age group, the only participant that qualified for that age group found "slight improvement" for each aspect.

In the 70-79 age group, the majority found "slight improvement" for each aspect except for the ability to sleep at night. This aspect showed mostly "no change" for this age group. The largest "slight improvement" was shown for balance, flexibility, and strength. The largest "significant improvement" was shown for flexibility, state of mind, and strength. Each aspect contained answers including all three categories (no change, slight improvement, and significant improvement).

In the 80-89 age group, the majority found "slight improvement" for each aspect except for the ability to sleep at night. This aspect also showed mostly "no change" for this age group. The largest "slight improvement" was shown for flexibility and strength. The largest "significant improvement" was shown for state of mind. Each aspect contained answers including all three categories (no change, slight improvement, and significant improvement) except for flexibility and state of mind which only included slight or significant improvement.

As mentioned in previous studies, three common themes continue to play an important role when analyzing reasons why the subjects participate in the Bone Builders program. These themes are socialization/fellowship, motivation, and health benefits. The following are quotes regarding the program:

“It’s easier for me to reach the top shelf and lift things overhead. More strength in arms and shoulders. Better balance.” (Age 76)

“It’s a great program. I’m lucky to be in it.” (Age 86)

“It has improved my balance and attitude.” (Age 79)

Quotes regarding exercising in a group:

“More fun - more incentive to do them with others. I have met so many nice ladies that I otherwise would not have.” (Age 77)

“It keeps me coming and participating - I find all kinds of other things to do if left on my own.” (Age 73)

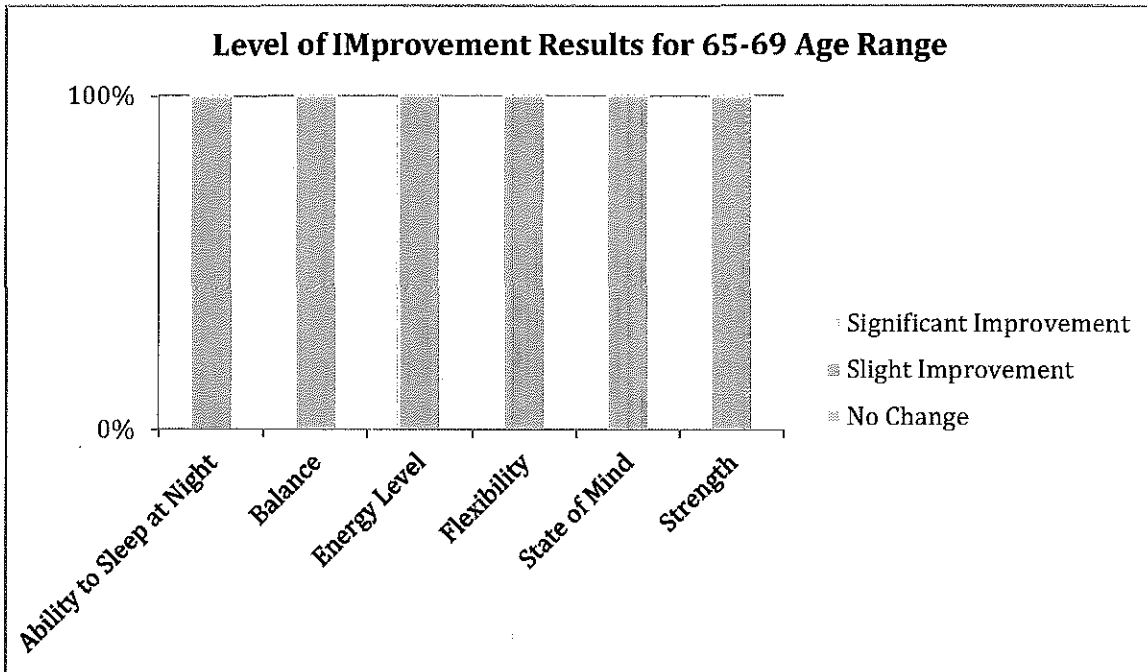


Figure 2. Quality of life/satisfaction questionnaire level of improvement results in 65-69 age group

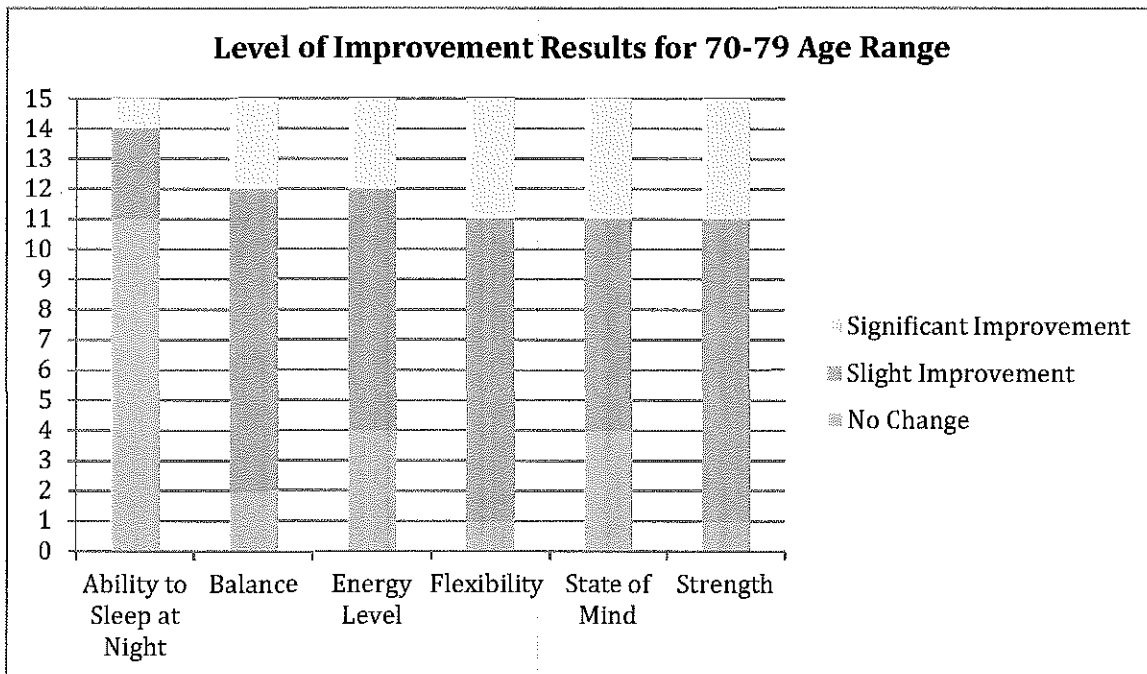


Figure 3. Quality of life/satisfaction questionnaire level of improvement results in 70-79 age group

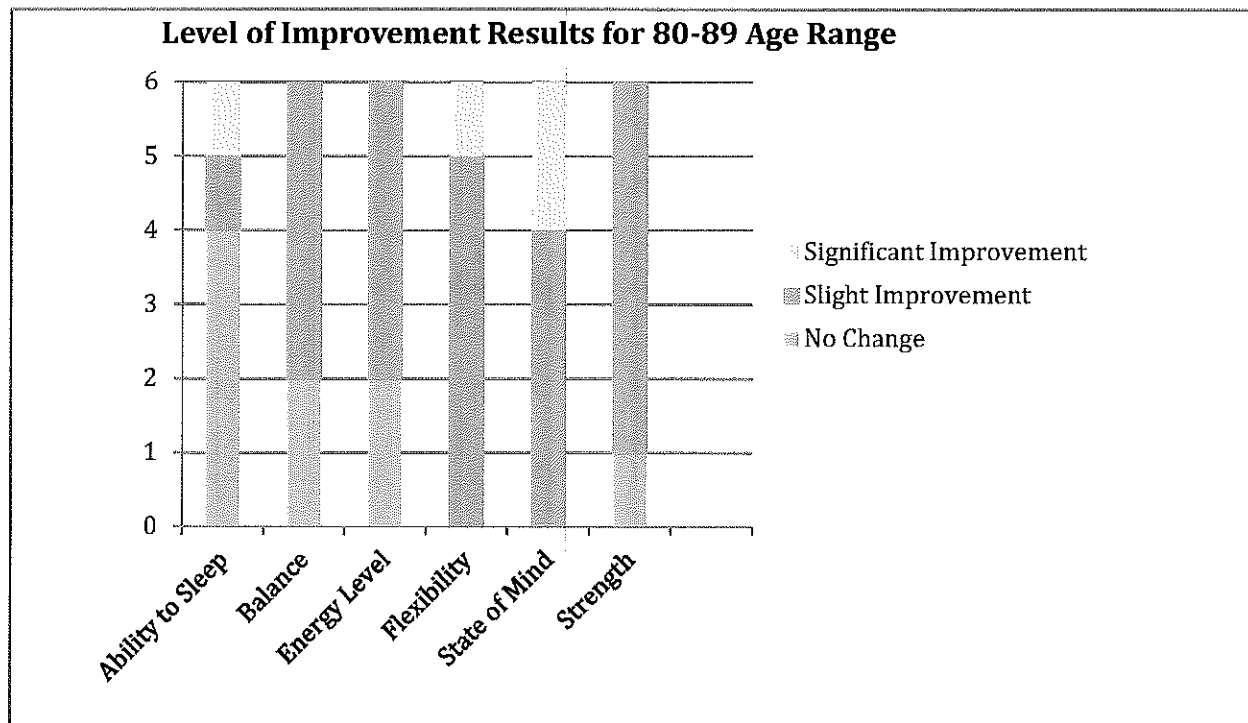


Figure 4. Quality of life/satisfaction questionnaire level of improvement results for 80-89 age range

Falls Efficacy Scale-International (FES-I)

The average FES-I score ranged from 18 to 27 and averaged 20.91 out of 64 for all study participants. The participant in the 65-69 year old age category scored a 19 out of 64, putting her in the low concern for falls category. The participants in the 70-79 year old age category averaged a score of 20.87 out of 64. The 80-89 year old age category averaged 21.33 out of 64. This trend indicates that as age increases, so does the participant's concern of falls.

Table 6. Average FES-I scores for age groups

Age Range	n	Score Range	Age Group Average Score	Level of Concern about Falling¹⁶
65-69	1	19	19	Low Concern
70-79	15	18-27	20.87	Moderate Concern
80-89	6	18-25	21.33	Moderate Concern

30 Second Sit-To-Stand

The overall average stands completed between all participants was 11.3. The table below further summarizes the results, with each age group listed. All twenty-two participants were able to complete this test. The highest average scores were in the 70-79 age group, although this could easily be skewed due to only having one participant in the 65-69 age group. These results were much different than expected, with lower number of stands than found in previous years (see Comparison to Previous Studies on page 29). This will be analyzed further in our discussion section, but the belief is that due to the CDC standard wording of this test, participants became confused with "On Go, rise to a full standing position and then sit back down again. Repeat this for 30 seconds." They did not stand as quickly or as many times as possible, which would be better wording to use in the future. The only age group that was at the 50th percentile were the 70-79 age group.

Table 7. Average 30 Second Sit-To-Stand scores compared to age norms for women

Age Range	n	Score Range (# of stands)	Age Group Average Score	Age Norms
65-69	1	12	12	14
70-79	15	9-16	12.07	13 (70-74)
				12 (75-79)
80-89	6	9-12	9.83	11 (80-84)
				10 (>85)

Grip Strength

The overall dominant grip strength average was 43.71 pounds. Table 8 summarizes the results for each age group. There were 21 participants in this test. One participant in the 80-89 year old category could not complete the grip strength measurement due to advanced rheumatoid arthritis and was not counted in the average scores. The 70-79 and 80-89 year old age groups both tested several pounds higher than the average age norms. The participant in the 65-69 group tested lower than the norms for her age.

Table 8. Average grip strength compared to age norms for women

Age Range	n	Range (lbs.)	Age Group Average (lbs.)	Age Norms (lbs)²⁵
65-69	1	40	40	43.0
70-79	15	17.7 – 66.0	44.39	37.4
80-89	5	26.7 – 57.7	42.42	36.5 (80-85)
				30.3 (>85)

Gait Speed

The overall average normal gait speed was 1.215 m/s. Table 9 summarizes the results based on the age ranges of the participants. The age groups 70-79 (1.30 m/s) and 80-89 (1.04 m/s) both had average normal gait speeds above the average norm for their age group. There was only one participant in the age group of 65-69 and she scored slightly below (0.945 m/s) her age group's average norm of 1.0 m/s. None of the participants in the age groups 70-79 and 80-89 scored below the age norm gait speed. There were no participants that used any type of ambulation device during gait speed testing.

The lone participant in the 65-69 age group is considered to have a higher fall risk because she scored below the gait speed norm for her age group.

Table 9. Average Gait Speed compared to age norms

Age Range	n	Score Range (m/s)	Age Group Average (m/s)	Age Norms³³ (m/s)
65-69	1	.945	.945	1.0
70-79	15	0.92-1.86	1.30	0.9
80-89	6	0.92-1.19	1.04	0.8

Timed Up and Go (TUG) Test

Overall TUG scores for all participants walking at a normal, safe pace was 9.59 seconds. Table 10 summarizes the results for each age group. The participant in the 65-69 age group tested lower than her age norms. The participants in the 70-79 and 80-89 age groups tested faster than the norms for their respective age categories. No participants used an assistive device during

the timed up and go test. No participants took longer than 12 seconds to complete the TUG, which would have put them at high risk for falling.

Table 10. Average TUG compared to age norms

Age Range	n	Range (sec.)	Age Group Average (sec.)	Age Norms ³² (sec.)
65-69	1	10.47	10.47	8.1
70-79	15	6.65 – 11.41	9.09	9.2
80-89	6	10.15 – 11.97	10.69	11.3

4 Stage Balance Test

Table 11 summarizes the overall averages, and Table 12 summarizes it based on age groups. Each stage was done for ten seconds, except for the Tandem Stance which was done for 20 seconds. However, if a participant could hold the tandem stance for greater than 10 seconds, they had a decreased risk of falling. In summarizing the averages, each participant was able to complete both the Narrow Based Stance stage, and the Semi-Tandem Stance stage. One person needed support to get into the Semi-Tandem Stance. For Tandem Stance, every participant tried to complete it, but six needed support into the position. Only 18 could do the complete 20 seconds, 3 could complete 10-20 seconds, and 1 could not reach the full 10 seconds. For Single Leg Stance, only 15 participants that attempted to complete it scored above zero seconds. Two participants needed support into the position. Nine of the fifteen participants could complete the full 10 seconds, while the remaining six could only complete 0-10 seconds.

For the 65-69 age group, the one participant was able to complete all stages. In the 70-79 age group, all fifteen participants could complete the Narrow

Based and Semi-Tandem stance. Fourteen could complete the Tandem Stance, and eight could complete the Single Leg Stance. In the 80-89 age group, all six participants could complete the Narrow Based and Semi-Tandem stance. Three could complete the Tandem Stance, and zero completed the Single Leg Stance.

Table 11. 4 Stage Balance Test Averages

4 Stage Balance Test (N=22)	Mean Value	Range
Narrow Based Stance (10 sec total) (N=22)	10	All participants completed 10 sec without support
Semi-Tandem Stance (10 sec total) (N=22)	10	All participants completed 10 sec
-Those that needed support to position (N=1)		
Tandem Stance (20 sec total) (N=22) *	18.6	Not all participants completed full 20 sec.
-Those that needed support to position (N=6)		
-Those that could complete full 20 sec (N=18)	20	
-Those that could complete 10-20 sec (N=3)	14.7	
-Those that completed 0-10 sec (N=1)	5	
Single Leg Stance (10 sec total) (N=15)	8.27	Not all participants completed full 10 sec.
-Those that needed support to position (N=2)		
-Those that could complete the full 10 sec (N=9)	10	
-Those that could complete 0-10 sec (N=6)	5.67	

(CDC norm source)

* Increased risk of falls if unable to hold tandem stance ≥ 10 seconds

Table 12. 4 Stage Balance Test Averages by Age Group

Age Range	N	Stage	Able to Complete Stage	Unable to Complete Stage	Unable to Complete Stage Range (sec)	Unable to Complete Stage Average (sec)
65-69	1	Narrow Based Stance	1	-	-	-
		Semi-Tandem Stance	1	-	-	-
		Tandem Stance*	1	-	-	-
		Single Leg Stance	1	-	-	-
70-79	15	Narrow Based Stance	15	-	-	-
		Semi-Tandem Stance	15	-	-	-
		Tandem Stance*	14	1	11.0	11.0 sec
		Single Leg Stance	8	7	0.0-9.0	6.0 sec
80-89	6	Narrow Based Stance	6	-	-	-
		Semi-Tandem Stance	6	-	-	-
		Tandem Stance*	3	3	5.0-18.0	12.67 sec
		Single Leg Stance	0	6	0.0-8.0	5.0 sec

(CDC norm source)* Increased risk of falls if unable to hold tandem stance ≥ 10 seconds*Comparisons to Previous Studies*

Table 13 shows a side by side comparison of the data collected in the 2013, 2014, and 2016 studies for each age group. The overall averages showed a decline each year in the 30 second sit to stand for the 65-69 and 80-89 year old age groups. The 70-79 year old age group showed a decline from 2013 to 2014, but improved from 2014 to 2016, though still under the score in 2013. Average grip strength also showed that the 65-69 and 80-89 year old age groups declined, while the 70-79 year old age group improved from 2013 to 2014 but then declined from 2014 to 2016. Average gait speed for the 65-69 year old age group has declined each year. It has done the opposite in the 70-79 year old age

range and improved each year. The 80-89 year old age group declined from 2013 to 2014, and maintained from 2014 to 2016. Average TUG time has gone up each year in the 65-69 year old age range, gone down each year in the 70-79 year old age range, and went up from 2013 to 2014 and then down from 2014 to 2016 in the 80-89 year old age range.

Table 14 presents the data collected for each of the repeat subjects, those subjects that have participated in the study at least two of the three years. Eight participants were considered repeat subjects. This allows for us to see if those who have been participating in Bone Builders have been improving, maintaining, or declining in their ability to perform the tests we have given them. Of the 8 repeat participants, 4 improved in their FES scores, 4 improved in their gait speed, 5 improved their TUG times, and 2 improved their grip strength (only 7 of the 8 repeats were able to perform the grip strength test). Also for the 30 second sit to stand test, 4 out of the 8 repeats maintained their same number, 2 improved their number of stands, and the remaining 2 that did not improve only stood one less time compared to their original number of stands.

Table 13. Age range averages comparing each year

Age Range	30 Second Sit to Stand				Grip Strength (lbs.)				Gait Speed (meters/second)				TUG (sec.)			
	Norms	2013	2014	2016	Norms	2013	2014	2016	Norms	2013	2014	2016	Norms	2013	2014	2016
65-69 (n=1)	14	16.25	14.73	12	43	60.8	52.17	40	1.0	1.43	1.19	.945	8.1	7.71	8.86	10.47
70-79 (n=15)	13 12*	13	11.56	12.07	37.4	43.83	46.38	44.39	0.9	0.95	1.07	1.30	9.2	11.11	10.76	9.09
80-89 (n=6)	11 10**	16.67	11.79	9.83	36.5 30.3**	54.2	44.86	42.42	0.8	1.11	1.04	1.04	11.3	9.22	10.93	10.69

*2 different age groups norms (70-74 and 75-79)

**2 different age group norms (80-84 and 85-89)

Table 14. Repeat Subject Data

Subject	Age when first tested	FES			30 second sit to stand			Grip Strength			Gait Speed			TUG		
		2013	2014	2016	2013	2014	2016	2013	2014	2016	2013	2014	2016	2013	2014	2016
1	68	20	19	21	12	13	12	46.7	25	28	1.85	1.7	1.665	7.9	6.5	6.65
5	79	30	-	19	8	-	10	*	-	*	.90	-	0.92	12.37	-	11.97
35	65	-	22	19	-	13	12	-	36	40	-	.83	.945	-	10.97	10.47
40	83	-	21	25	-	10	12	-	40	38	-	1.05	.927	-	10.25	10.15
41	75	-	20	19	-	11	11	-	42	41.7	-	1.01	.957	-	9.1	11.41
43	76	-	22	21	-	17	16	-	45	44	-	1.29	1.27	-	6.44	7.97
47	74	-	25	27	-	13	13	-	40	43.3	-	1.14	1.23	-	9.0	10.19
52	74	21	-	21	9	-	9	46.6	-	39.7	.976	-	1.01	13.47	-	10.46

*Could not perform due to progressed Rheumatoid Arthritis

-Did not participate in study this year

CHAPTER IV

DISCUSSION

Bone Builders is a free, community based exercise program targeted for individuals who want to reduce their risk of developing osteoporosis and maintain a healthy lifestyle. This research study was conducted to compare participant's results with the two previous studies conducted in 2013 and 2014. The purpose was to determine if each participant's fall risk was decreased after having participated in the program. The researchers predicted that not only would the participants have a decreased risk of falling, but also that the repeat subjects would maintain their scores or improve their scores from the previous years.

Overall, the majority of participants were above the normative data for each assessment. However, some assessments (discussed below) showed scores lower than the norms, especially the 30 second sit-to-stand test. This could be due to multiple different limitations that will be discussed further. As far as repeat subjects, the majority improved or stayed the same, but some did worsen in each assessment, particularly for grip strength and gait speed. For grip strength and gait speed, there were a total of four of the eight repeat participants that scored lower than in the 2013 or 2014 studies. Reasons for this could be due to inter-rater reliability between the 2013, 2014, and present study, along with other factors such as fatigue, instructions, normal aging process, and order of assessment.

When looking at the differences between each specific age group for all participants in the present study, the group that overall had the most scores above the norms were ages 70-79. They scored higher than the age group in every assessment except for the TUG. However, this age group had the most participants (15), versus the 65-69 group that only had one and the 80-89 group that only had six. The difference in the number of participants could easily skew the data.

Currently, there is no research on specifically the Bone Builders exercise program and its ability to increase bone mineral density. However, one study found that after 4 years of participating in an exercise program and taking calcium supplements, postmenopausal women had an increased bone mineral density in the femur trochanter, femur neck, lumbar spine, and total body.³⁴ The exercise program consisted of exercising three times per week, and included 60-75 minute sessions with stretching, balance, weight-bearing, and weight-lifting exercises. It's important to point out that this study focused on prevention of osteoporosis, and not on improving bone density once already diagnosed with osteoporosis. It also includes higher impact exercises than Bone Builders. Another study found that the most important component to any exercise program is exercise frequency. With low enthusiasm to exercise regularly, and as people age they participate less in exercise programs, exercising at least two times a week can improve bone health or maintain it.³⁵ One thing that our study has shown with the quality of life questionnaire is that Bone Builders provides social motivation and support, which helps each person continue to participate in the

program. This is extremely beneficial, as increased attendance and exercise can play a role on bone health. It's important to vary exercises and intensity. Bone Builders offers a variety of different exercises, but they do the same exercises in the same order each session. They could change their order around occasionally to possibly provide more excitement and motivation. It is also important to increase intensity, and most of the women do not increase their weights, so this could be promoted through the program as well.

Another important component with preventing osteoporosis is to maintain an adequate nutrition. Vitamin D and calcium supplementation can assist in bone nutrition. Those diagnosed with osteoporosis have supplement doses that are higher than for the general population. Menopause can lead to estrogen deficiency-induced loss in bone mass, and replacing these nutrients for bone health is important. Bone Builders could offer education classes to promote appropriate nutrition to further prevent osteoporosis on a more consistent basis.³⁶

Exercise has been shown to improve balance in elderly women.³⁷ With this study, it has been shown that repeat subjects (especially those that are in the older 80-89 age group) have mostly maintained their scores from previous studies, indicating that Bone Builders could have an influence on balance maintenance. The women of this program reported on the questionnaire that they enjoy participating in the program because of its positive social aspects and overall motivation. This motivation can improve their attendance to the program, which can continue to provide health benefits.

Each assessment in some way showed a positive result. The review of the quality of life questionnaire from this study and previous studies has shown that participants report a positive psychological and social aspect from this program. (2013, 2014, and present). Balance, flexibility, and strength had the most improvements across all the age groups. Although the results of the 30 second sit-to-stand were different than predicted, it was shown that the 80-89 age group had more sit to stands than the younger groups. Each person demonstrated accurate technique such as not using momentum, and using good control during eccentric decent. In the grip strength measurement, the 70-79 year old average and 80-89 year old average were both above the norms for their respective age groups.

Gait speed is known as the sixth vital sign and can be used as a universal measure for a wide range of diagnoses.²⁶ It is indicative of an individual's functional capacity and general health status, cognitive function, mortality, as well as fall risk.²⁶ It was predicted that there would be a decrease in gait speed and age increased. This was untrue for this study as the 70-79 age group had the fastest mean gait speed. The one individual in the age 65-69 age group was the only subject below the norm for her age group. Though there were two individuals in the 70-79 age group that walked over 1.6 m/s which may have shifted the mean, it is still apparent that every participant was above the norm. All subjects in the 80-89 age group also scored above the norm. There were no subjects that used walking aids.

The subjects during this year's TUG test did not follow the expected trend. In the TUG, the 70-79 year old age group had the fastest average time, followed by the 65-69 year old age group, followed by the 80-89 year old age group.

As shown in the previous study, older subjects had more difficulty advancing through each stage of the 4 Stage Balance Test including holding the single leg stance for more than ten seconds. However, only one person in this study (from the 80-89 age group) was unable to hold tandem stance for longer than 10 seconds, which indicates an increased risk of falling.

Limitations

It would be ideal to have more than one participant in each age group. In this year's study, there was only one participant in the 65-69 year old age group. This made it difficult to generalize the averages. This was one of the main limitations of our study this year.

Limitations of the quality of life survey/questionnaire included subjectivity, if each participant understood the question and time constraint. The survey was given out after all the fall risk testing, so some participants may have wanted to return to their exercise class.

The FES-I is limited by the participants' understanding of the questions, as well as their self-perception, which did not always coordinate with their observed abilities.

For the 30 second sit-to-stand test, the CDC standard instructions were used, which states "On Go, rise to a full standing position and then sit back down

again. Repeat this for 30 seconds." It was clear participants were doing this test similar to how they do the exercise in class, which is slowly. Verbal cueing was used to try and increase the speed of the stands, but they still did not stand as quickly or as many times as possible. In future studies, careful consideration of wording of instructions should be used, with obvious instructions on the difference between the test and their exercise. In addition, changing the class to include varying speeds may be beneficial for functional activities.

The main limitation of the grip strength measurement for this age group is arthritis of the hand, which could cause a reduced grip strength score while true strength deficits may not be present.

The TUG and gait speed measurement is limited by the interpretation of "normal walking speed" by the participants. Some participants may define their "normal" walking speed as much faster or slower than what it actually is.

Limitations of the 4 stage balance test include possible environmental distractions, conversing with the participant while completing the assessment, and fatigue after each measurement. In future studies, a trial/test run could be done, so that each participant fully understand the foot positioning prior to testing.

To improve this study, a greater number of repeat subjects would provide the ability to analyze if exercise, on a more long term scale, leads to decrease in fall risk among the aging population.

Conclusion

Bone Builders, a community based exercise program for older adults, has a positive effect on participation in exercise, as well as improving the fall risk and safety of the participants. On average, the participants in Bone Builders scored above the normative data for their age groups in our tests, which is indicative of a decreased fall risk and higher level of mobility. The women also reported enjoyment with group exercises, providing for social interaction and accountability among participants. Although there is currently no evidence to show the effects that Bone Builders has on osteoporosis risk, this study demonstrated that the program is an excellent way to allow the older adult community to come together and exercise in a social environment. As the overall population continues to age, implementation of community exercise programs like Bone Builders is highly beneficial. The program is worth advocating for to not only decrease fall risk, but also to improve the participant's overall quality of life.

Appendix A
Outline of Exercise Program

RSVP Bone Builders- Sample Group Session

- Set Up
- Check- In (5 minutes)
- Warm-up/ Balance Training (15 minutes)
 - Warm Up: Head, Eyes, Face, Shoulders, Hands, Upper Body, Ankles, Wrists, Scrunch your toes, Toe and Heel Raise
 - Balance Training
 - Chair Stand
 - Calf Raises
 - Toe Raises
 - Tandem Stand or Walk
- Weight/Strength Training (45 minutes)
 - Standing Leg Exercises
 - Standing Front Leg or Seated Leg Lift
 - Standing Back Leg Lift
 - Standing Side Leg Lift
 - Arm Exercises
 - Hug a Tree
 - Zipper/Upward Row
 - Backward Press
 - Overhead Arm Lift
 - Arm Curls
 - The Shelf/Upward Press
- Cool-Down (5 minutes)
- Clean-Up (5 minutes)

Appendix B
Consent Form

INFORMED CONSENT

TITLE: Evaluation of program satisfaction, quality of life, strength and fall risk of community-dwelling older adults participating in a community exercise program.

PROJECT DIRECTOR: Beverly Johnson, PT, DSc, GCS and Meridee Danks, DPT, NCS

PHONE #: 701-777-3871

DEPARTMENT: UND – 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 and meet study criteria (older than 65 years old, community dwelling, male and female, ability to walk unaided 200-400 meters without resting, and ability to follow and understand instructions). Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

PURPOSE OF THIS STUDY AND YOUR PARTICIPATION

You are invited to be in a research study evaluating program satisfaction, quality of life, strength and fall risk of community-dwelling older adults participating in a community exercise program. Falls are common in the older population and often contribute to decreased health status and increase in medical costs. Activity can improve balance and increase overall quality of life. In our study, we will examine the effect of a community exercise program on improving quality of life, decreasing risk of falls, and look at overall satisfaction of the program. Your participation in the study will be a one-time assessment lasting no longer than an hour. A minimum of twelve people will take part in this study.

Approval Date:	JUN 14 2016
Expiration Date:	JAN 13 2017
University of North Dakota IRB	

Date _____
Subject Initials _____

WHAT WILL HAPPEN DURING THIS STUDY?

In random order you will complete seven tests:

1. The Timed Up and Go (TUG) test was developed as a brief screen for mobility and falls risk. The TUG measures, in seconds, the time it takes for an individual to stand up from a standard arm chair, walk a distance of 3 meters, turn, walk back to the chair, and sit down again. The participant wears his/her regular footwear and uses his/her customary walking aid (none, cane, or walker). No physical assistance is given. A safety belt will be used when performing this assessment. One minute to complete.
2. The 4-Stage Balance Test assesses static balance with a narrow base of support. The participant will be asked to stand in up to four positions with feet close together including tandem stance (one foot in front of the other, touching heel to toe) and to stand on one foot unsupported. The researcher records the amount of time the participant is able to stand in the positions stopping after 30 seconds or when the participant steps out of position. A safety belt will be used when performing this assessment. Less than one minute to complete.
3. Walking speed has been shown to be predictive of falls and overall functional ability. Speed will be calculated either manually having the participant walk up to 20 feet or by using GAITRite, a computerized system. The GAITRite is an electronic walkway that participants will walk over up to 3 times and calculates the speed of motion. Testing requires about 5 minutes for setup and testing and has minimal to no risk requiring no safety device.
4. 30 second sit-to-stand is an assessment to measure a person's endurance and general strength in the lower extremities. Poor lower extremity endurance can lead to decreased mobility in the community and a decrease in activities of daily living. The participant is instructed to go from a sit-to-stand position repeated as many times as the individual is able within a 30 second timeframe. The assessment generally takes under three minutes to complete.
5. Grip strength has been correlated to overall health and wellness as well as increased quality of life. As a person ages, a decrease in grip strength can cause a lack of participation in regular activities and is a sign of overall frailty. The participant is instructed to hold a handheld dynamometer and squeeze as hard as the individual is able for approximately a few seconds. The researcher will record the measurement on the dynamometer. This process will be repeated three times for each hand. The assessment generally takes under three minutes to complete.

Approval Date: <u>JAN 14 2016</u>
Expiration Date: <u>JAN 13 2017</u>
University of North Dakota IRB

Date _____
Subject Initials _____

6. The Falls Efficacy Scale-International is a short, easy to administer tool that measures the level of concern about falling during social or physical activities inside and outside the home whether or not the person actually does the activity. The level of concern is measured on a four point scale. (1 = not at all concerned, 4 = very concerned).
7. The quality of life/satisfaction questionnaire is a short survey compiled by the research team that assesses the participant's perception and satisfaction of the overall program and perceived benefits from the program.

This study involves questionnaires and balance assessments and you are free to skip any questions or activities you do not feel comfortable completing.

WHAT ARE THE RISKS OF THE STUDY?

There may be some risk from being in this study such as loss of balance. This will be reduced by providing close supervision with safety belts and a spotter during balance activities. You may choose to stop any activity they do not feel comfortable with. Rest periods will be provided between tests as needed.

WHAT ARE THE BENEFITS OF THE STUDY?

A brochure will be provided to educate and provide awareness to participants on fall prevention. You will also receive the score from their balance assessment at no cost. We hope our research will contribute to literature concerning the role of activity in preventing falls.

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. Investigators and our statistician will have access to the information. Your study record may be reviewed by government agencies, 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 destroying any links between you and your information. Any information used for this study will not include identifying factors.

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.

Approval Date:	JAN 14 2016
Expiration Date:	JAN 13 2017
University of North Dakota IRB	

Date _____
Subject Initials _____

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. You will not have any direct costs for being in this research study. Indirect costs include transportation and your time.

CONTACTS AND QUESTIONS?

The researchers conducting this study are Beverly Johnson and Meridee Danks. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact **Beverly Johnson at 701-777-3871 or Meridee Danks at 701-777-3861** or the Physical Therapy Department at 701-777-2831.

If you have questions regarding your rights as a research participant 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 if 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.

Subject's Name _____

Signature of Subject

Date

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

Signature of Subject

Date

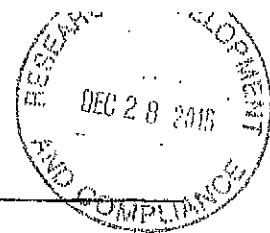
Approval Date:	JAN 14 2016
Expiration Date:	JAN 13 2017
University of North Dakota IRB	

Date _____
Subject Initials _____

Appendix C

IRB

Research Project Review and Progress Report
University of North Dakota Institutional Review Board



DATE: 11/30/2015 DEPARTMENT: Physical Therapy

PRINCIPAL INVESTIGATOR: Johnson, Beverly; Danks, Meridee

PROJECT TITLE: Evaluation of Program Satisfaction, Quality of Life, Strength and Fall Risk of Community-Dwelling Older Adults Participating in a Community Exercise Program

PROPOSAL NUMBER: IRB-201304-292

IF MEDICAL COMPONENT, PLEASE GIVE PHYSICIAN'S NAME:

IRB USE ONLY

FULL BOARD REVIEW REQUIRED, EVEN THOUGH ORIGINAL APPROVAL WAS EXPEDITED

CONTINUED APPROVAL, "EXPEDITED" CATEGORY 4,7

NEXT REVIEW REQUIRED BEFORE: JAN 13 2017

CONTINUED APPROVAL, BASED ON FULL BOARD REVIEW.

NEXT REVIEW REQUIRED BEFORE: _____

SUSPEND APPROVAL, PENDING INVESTIGATION

APPROVAL TERMINATED

COMMENTS OF REVIEWER: _____

Signature of Chair/Vice Chair or Designee: K. Brant

cc: Chair, Physical Therapy Approval Date: 1.14.16

1. Is project complete? Yes No

2. Is project ongoing? Yes No

If No, explain below and indicate if continued approval and continuing review is desired.

3. How many subjects have been enrolled in the research project?

32 since the date of last approval, and
51 since the initial approval

4. Is the research permanently closed to the enrollment of new subjects? Yes No

Have all subjects completed all research-related interventions? Yes No

Does the research remain active only for long-term follow-up of subjects? Yes No

5. Is data analysis complete? Yes No

*** If the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, the research does not need to remain active for long-term follow-up of subjects, and all data analysis is complete, please sign here that you would like the IRB to terminate approval for this project, and finish filling out the rest of this form.

Please terminate IRB approval for this research project _____
Signature of Principal Investigator Date

6. Has any additional grant money been awarded for this project in the past year? Yes No
If yes, submit a copy of the grant along with this completed form.
7. Describe any adverse events and/or unanticipated problems involving risks to subjects or others that have occurred since the last approval. If you did not report the adverse event or unanticipated problem previously, a separate Unanticipated Problem/Adverse Event Form must be submitted to RD&C with this form.
No adverse events or problems
8. Have any additional risks with this research been identified? Yes No
Describe all benefits experienced by participants, and include a current risk/benefit assessment based on study results.
9. Have there been any changes or deviations from the approved protocol since the most recent approval? Yes No If Yes, elaborate below, and submit a separate Protocol Change Form to the RD&C indicating proposed protocol changes.
- a. Have any of these changes been implemented already? Yes No
If yes, please describe fully.
- b. Are any protocol changes being planned for later implementation? Yes No
If yes, please describe fully. A separate Protocol Change Form must be submitted to RD&C for approval before the proposed protocol changes can be implemented.
10. Have any subjects withdrawn from the research? Yes No
If yes, state how many have withdrawn and describe the circumstances.

11. Have there been any complaints about the research since the last IRB review? Yes No
If yes, please report and summarize the complaints and your response/action.

12. Summarize any multi-site trial reports relevant to your research.

NA

13. Summarize any recent literature, findings, or other information relevant to your research, especially information about risks associated with the research.

No new findings in recent literature

14. Have all PI's involved with the research completed the IRB Educational Requirements?
Yes No (Educational requirements must be completed before the IRB can grant continued approval for the research project.)

15. On a separate piece of paper, provide a thorough protocol summary (approximately 300 words) giving a concise summary of the protocol's progress to date and the reasons for continuing the study or reasons for asking the IRB to terminate approval. The summary should include, for instance, an explanation of any complaints about the research, relevant multi-site trial reports, participant benefits, or a current risk-benefit assessment based on study results. Sufficient information is required in the summary so that the IRB can determine whether the proposed research continues to fulfill the criteria for approval.

16. A copy of the current informed consent document(s) (with the IRB Approval stamp), as well as a clean copy of the consent document(s) (with no IRB Approval stamp) must be submitted with this report.

17. Have there been any changes in the conflict of interest statement or situation for the Principal Investigators, research staff involved in the study, or each individual's respective family members in the last 12 months?
Yes No If yes, please describe fully on a separate sheet of paper.

Signature of Principal Investigator *Beverly Johnson* Date *12/23/15*

Current email address: *bev.johnson@med.und.edu*

Current Address: *Dept. of Physical Therapy* *Stop 9037*

This completed form should be returned to the IRB, University of North Dakota, 264 Centennial Drive Stop 7134, Grand Forks, ND 58202-7134.

#15 Protocol Summary

Background and Purpose: Exercise programs aimed at prevention of osteoporosis are effective in fall prevention and improving mobility in older adults. This trial examined whether the Bone Builder's community exercise program decreases fall risk and improves mobility in community dwelling females over the age of 60.

Methods: Fifty one females ages 60-90 who currently are participating in the Bone Builder's program volunteered to participate in four different assessments as well as two questionnaires. Tests included: the 4-stage balance, timed up and go, gait speed (measured with the GAITRite system), 30 second sit-to-stand, and grip strength. The Functional Efficacy Scale-International (FES-I) and the Quality of Life survey were the two questionnaires used to assess participants' subjective views of fall concern and improvement of living quality.

Analysis: Data was entered into an excel file and transferred to SPSS to be analyzed. Analysis is pending a larger N. Descriptive statistics were performed to investigate trends and compare to industry norms for each age group.

Results: Overall, all participants were within the normative data ranges on all tests. The eight repeat subjects, on average, scored higher on the tests in comparison to first time study subjects. However, these eight repeat subjects saw a decline from 2013 to 2014 in all tests, except the 30 second sit-to-stand test.

Conclusion: Participation in community exercise programs for older adults is beneficial in decreasing fall risk, improving mobility, and improving overall quality of life. As shown by the data, implementing exercise programs and promoting participation in more communities may have a positive effect on the overall safety and well-being of older individuals. This will continue to become increasingly important as the longevity of life is rising, and the baby boomer generation ages and becomes an increased risk for falls.

Appendix D
Bone Builders Data Sheet

Subject # _____

Age _____

Bone Builders Data Sheet- 2016

____ 1. Questionnaire Completed

____ 2. Falls Efficacy Scale Completed-International (FES-I) Total Score _____

____ 3. 30 Second Sit to Stand Test Number of Stands _____
Arms Crossed? Y/N _____

Age	60-64	65-69	70-74	75-79	80-84	85-89	90-94
Men	16	15	14	14	12	11	10
Women	15	14	13	12	11	10	8

____ 4. Grip Strength Dominant Hand _____ Non-dominant Hand _____

Norms at Age		60-69	70-79	80-85	>85
Men	DH	78.5	64.9	53.2	47.9
	Non-DH	70.5	58.7	47.9	44.6
Women	DH	43	37.4	36.5	30.3
	Non-DH	38.5	36.5	31.9	26.18

____ 5. Gait Speed Gait Speed in meters/second _____

Age	Gender	Mean Comfortable Walking Speed (Bohannon 2008)
50-59	Male	1.1 m/sec
	Female	1.1 m/sec
60-69	Male	1.0 m/sec
	Female	1.0 m/sec
70-79	Male	1.0 m/sec
	Female	0.9 m/sec
80-89	Male	0.8 m/sec
	Female	0.8 m/sec

____ 6. Timed Up and Go Test (TUG) Time required to complete test _____

≥ 12 seconds to complete the TUG are at a high risk for falling

___7. Tandem Stance

1. Narrow Based Stance (10 sec total)

Time: ____ sec

Support into position Y/N _____
 Support out of position Y/N _____

2. Semi-Tandem Stance (10 sec total)

Time: ____ sec Right or Left Foot Forward

Support into position Y/N _____
 Support out of position Y/N _____

3. Tandem Stance (20 sec total)

Time: ____ sec Right or Left Foot Forward

Support into position Y/N _____
 Support out of position Y/N _____

4. Single Leg Stance (10 sec total)

Time: ____ sec Right or Left Foot

Support into position Y/N _____
 Support out of position Y/N _____

Increased risk of falls if unable to hold tandem stance ≥ 10 seconds

Test	Initial	Re-Check 1	Re-Check 2
# Falls			
# Prescriptions			
Falls Efficacy Scale			
30 Sec Sit to Stand			
Grip Strength			
Gait Speed			
TUG			
Tandem Stance (Narrow, Semi, Tandem, SLS)			

Appendix E
Quality of Life Questionnaire

Quality of Life/Satisfaction Questionnaire

By providing answers to these questions, you will be helping researchers and program facilitators to better understand the perceived benefits of the community exercise program. We thank you in advance for your participation!

Age: _____

Sex: Male or Female (Circle one)

How long have you been participating in the community exercise program:

_____ Weeks OR _____ Months OR _____ Years

Do you use any weights when participating in this exercise program?

_____ YES _____ NO (Check one)

If YES, please check if you use weights for your arms, legs, or both, and write how many pounds you use for each arm or leg.

_____ ARMS _____ LEGS _____ BOTH (Check one)

Pounds used for each ARM: _____ #

Pounds used for each LEG: _____ #

Please circle any changes you believe have resulted from your participation in the program:

Ability to sleep at night: 1) No Change 2) Slight improvement 3) Significant Improvement

Balance: 1) No Change 2) Slight improvement 3) Significant Improvement

Energy Level: 1) No Change 2) Slight improvement 3) Significant Improvement

Flexibility: 1) No Change 2) Slight improvement 3) Significant Improvement

State of mind: 1) No Change 2) Slight improvement 3) Significant Improvement

Strength: 1) No Change 2) Slight improvement 3) Significant Improvement

Please provide any specific comments you have about any of the categories listed above.

How many different prescription medications do you currently take? (Please list number of medications/drugs, not number of pills or dosage)

Since being in the program, have you had any changes in your medication, including vitamins and over the counter medications (dosage increase/decrease, began a new medicine, or quit taking a current medication)?

Have you had any previous falls? _____ YES _____ NO (Check one)

If YES, how many falls within the last year have you had?

Do you prefer exercising in a group? _____ YES _____ NO (Check one)

Please state why or why not.

Please provide any additional comments on the benefits you feel the community exercise program has provided you.

Thank you for your time and participation!

Appendix F

FES-I

Falls Efficacy Scale-International (English)

Below are some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently don't do the activity (for example, if someone does your shopping for you), please answer to show whether you think you would be concerned about falling IF you did the activity. For each of the following activities, please check the box which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

		Not at all concerned 1	Somewhat concerned 2	Fairly concerned 3	Very concerned 4
1	Cleaning the house (for example, sweep, vacuum or dust)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
2	Getting dressed or undressed	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
3	Preparing simple meals	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
4	Taking a bath or shower	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
5	Going shopping	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
6	Getting in or out of a chair	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
7	Going up or down stairs	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
8	Walking around in the neighborhood	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
9	Reaching for something above your head or on the ground	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
10	Going to answer the telephone before it stops ringing	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
11	Walking on a slippery surface (for example, wet or icy)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
12	Visiting a friend or relative	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
13	Walking in a place with crowds	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
14	Walking on an uneven surface (for example, rocky ground, poorly maintained pavement)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
15	Walking up or down a slope	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
16	Going out to a social event (for example, religious service, family gathering or club meeting)	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
TOTAL SCORE=		<i>add all 1's</i>	<i>add all 2's</i>	<i>add all 3's</i>	<i>add all 4's</i>

SCORING: Low Concern: 16–19; Moderate Concern: 20–27; High Concern: 28–64

Appendix G
CDC Standard Instructions

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

The Timed Up and Go (TUG) Test

Purpose: To assess mobility

Equipment: A stopwatch

Directions: Patients wear their regular footwear and can use a walking aid if needed. Begin by having the patient sit back in a standard arm chair and identify a line 3 meters or 10 feet away on the floor.

Instructions to the patient:

When I say **"Go,"** I want you to:

1. Stand up from the chair
2. Walk to the line on the floor at your normal pace
3. Turn
4. Walk back to the chair at your normal pace
5. Sit down again

On the word **"Go"** begin timing.

Stop timing after patient has sat back down and record.

Time: _____ **seconds**

An older adult who takes ≥ 12 seconds to complete the TUG is at high risk for falling.

Observe the patient's postural stability, gait, stride length, and sway.

Circle all that apply: Slow tentative pace ■ Loss of balance ■
Short strides ■ Little or no arm swing ■ Steadying self on walls ■
Shuffling ■ En bloc turning ■ Not using assistive device properly

Notes:

For relevant articles, go to: www.cdc.gov/injury/STEADI



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

STEADI Stopping Elderly
Accidents, Deaths & Injuries

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

The 30-Second Chair Stand Test

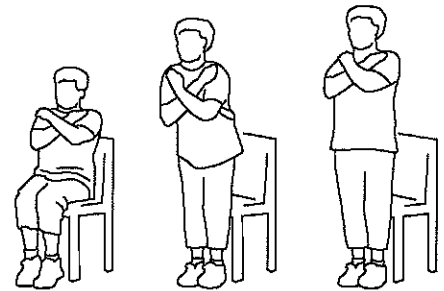
Purpose: To test leg strength and endurance

Equipment:

- A chair with a straight back without arm rests (seat 17" high)
- A stopwatch

Instructions to the patient:

1. Sit in the middle of the chair.
2. Place your hands on the opposite shoulder crossed at the wrists.
3. Keep your feet flat on the floor.
4. Keep your back straight and keep your arms against your chest.
5. On **"Go,"** rise to a full standing position and then sit back down again.
6. Repeat this for 30 seconds.



On **"Go,"** begin timing.

If the patient must use his/her arms to stand, stop the test. Record "0" for the number and score.

Count the number of times the patient comes to a full standing position in 30 seconds.

If the patient is over halfway to a standing position when 30 seconds have elapsed, count it as a stand.

Record the number of times the patient stands in 30 seconds.

Number: _____ **Score** _____ **See next page.**

A below average score indicates a high risk for falls.

Notes: _____

For relevant articles, go to: www.cdc.gov/injury/STEADI



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

STEADI Stopping Elderly Accidents, Deaths & Injuries

Chair Stand—Below Average Scores

Age	Men	Women
60-64	< 14	< 12
65-69	< 12	< 11
70-74	< 12	< 10
75-79	< 11	< 10
80-84	< 10	< 9
85-89	< 8	< 8
90-94	< 7	< 4

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

The 4-Stage Balance Test

Purpose: To assess static balance

Equipment: A stopwatch

Directions: There are four progressively more challenging positions. Patients should not use an assistive device (cane or walker) and keep their eyes open.

Describe and demonstrate each position. Stand next to the patient, hold his/her arm and help them assume the correct foot position.

When the patient is steady, let go, but remain ready to catch the patient if he/she should lose their balance.

If the patient can hold a position for 10 seconds without moving his/her feet or needing support, go on to the next position. If not, stop the test.

Instructions to the patient: I'm going to show you four positions.

Try to stand in each position for 10 seconds. You can hold your arms out or move your body to help keep your balance but don't move your feet. Hold this position until I tell you to stop.

For each stage, say "**Ready, begin**" and begin timing.

After 10 seconds, say "**Stop.**"

See next page for detailed patient instructions and illustrations of the four positions.

For relevant articles, go to: www.cdc.gov/injury/STEADI



Centers for Disease
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National Center for Injury
Prevention and Control

STEADI Stopping Elderly
Accidents, Deaths & Injuries

Instructions to the patient:



1. Stand with your feet side by side.

Time: _____ **seconds**



2. Place the instep of one foot so it is touching the big toe of the other foot.

Time: _____ **seconds**



3. Place one foot in front of the other, heel touching toe.

Time: _____ **seconds**



4. Stand on one foot.

Time: _____ **seconds**

An older adult who cannot hold the tandem stance for at least 10 seconds is at increased risk of falling.

Notes:

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