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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

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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

By

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A Scholarly Project Submitted to the Graduate Faculty of the

Department of Physical Therapy

School of Medicine and Health Science

University of North Dakota

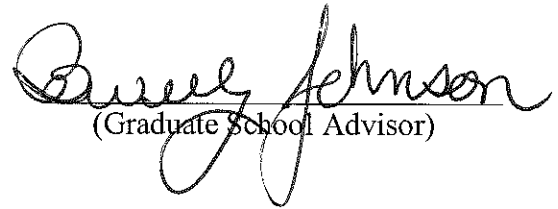
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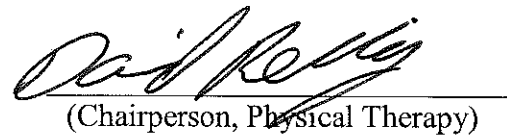
Doctor of Physical Therapy

Grand Forks, North Dakota

May 2015

This Scholarly Project, submitted by Rachel Bothun, Christine Gillespie, Zachariah Kvidt, and Krista Moorman 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)


(Chairperson, Physical Therapy)

PERMISSION

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

Department Physical Therapy

Degree Doctor of Physical Therapy

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ABSTRACT

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. 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.

CHAPTER I INTRODUCTION

Background

Bone Builders is a community-based exercise and education program that began in 1998 as a partnership with Cooperative Extension in Maricopa County, Arizona. Coordination of the program is by the Retired and Senior Volunteer Programs (RSVP), who based their group off of that developed by Tufts University. The purpose of the program is to prevent osteoporosis through changes in diet and exercise habits, as well as increase awareness of the disease and its risk factors. Through 100 various partners and volunteer educators, it is spreading the message of osteoporosis prevention.¹

The number of patients with osteoporosis and sarcopenia continues to increase worldwide due to an overall increase in the population's chronological age.² More than 28 million Americans have osteoporosis or are at high risk for developing it, which correlates with one out of two women suffering from osteoporosis related fractures at some point in their life.¹ It is a disease caused by bone deterioration often described as "porous bone", and defined by medical literature as, "Abnormalities in the amount and architectural arrangement of bone tissue that leads to impaired skeletal strength and an increased susceptibility to fractures."^{1,3} These fractures are most commonly seen in the spine, hip and wrist.²

The prevalence of fractures in elderly women can be correlated with having osteoporosis, falls, or a combination of the two.⁴ Approximately 30% of people 65 years of age and older have

an average of one fall per year, with an increase in fall occurrences each year as one ages.⁵⁻⁹ A fall is defined as one experiencing an unexpected loss of balance resulting in coming to rest on the floor, ground, or an object below knee level.^{2,6} Fifteen percent of falls result from an external event that would cause most people to fall, such as: slippery surfaces, uneven terrain, and footwear.^{6,10} Intrinsic factors relating to falls include lower extremity muscle weakness, generalized illness, medication, visual, vestibular, or proprioceptive impairments.¹⁰ Proper balance strategies rely on addressing these factors to make necessary adjustments for any noted discrepancies.

Major factors associated with increased falls in the elderly are previous falls, balance deficits, and strength limitations. Strength deficits can result from sarcopenia, which is commonly associated with osteoporosis. Sarcopenia is defined as low muscle mass resulting from age related muscle loss.² Low muscle mass in certain muscle groups leads to strength loss which contributes to increased fall risk. MacRae et al.^{2,11} have documented that lower scores on manual muscle testing of the hip abductors, knee extensors, knee flexors, and ankle dorsiflexors are significantly related to an older adult's fall status. Along with these muscle groups, weaker back extensors often result in deformities of the skeleton such as increased kyphosis, or hyperkyphosis. Hyperkyphosis is the leading source of sagittal plane deformity and is associated with reduced gait speed, greater difficulty climbing stairs, and poorer balance which can cause modifications to posture and an increased probability of fall and fracture.^{2,12,13} This information is reinforced by several studies suggesting the deterioration of musculoskeletal function in older adults may play a key role in the observed age-related deficits in balance control.^{2,11,14-18} Balance loss is also caused by reduced proprioceptive abilities in the elderly such as visual, vestibular, somatosensory inputs, CNS processing, and muscular effectors. The reduced sensory

cues, combined with physical decline, leads to upright balance control becoming more difficult for older adults.² Figure 1 depicts the relationships of changes with aging, to poor balance (falls and fractures).

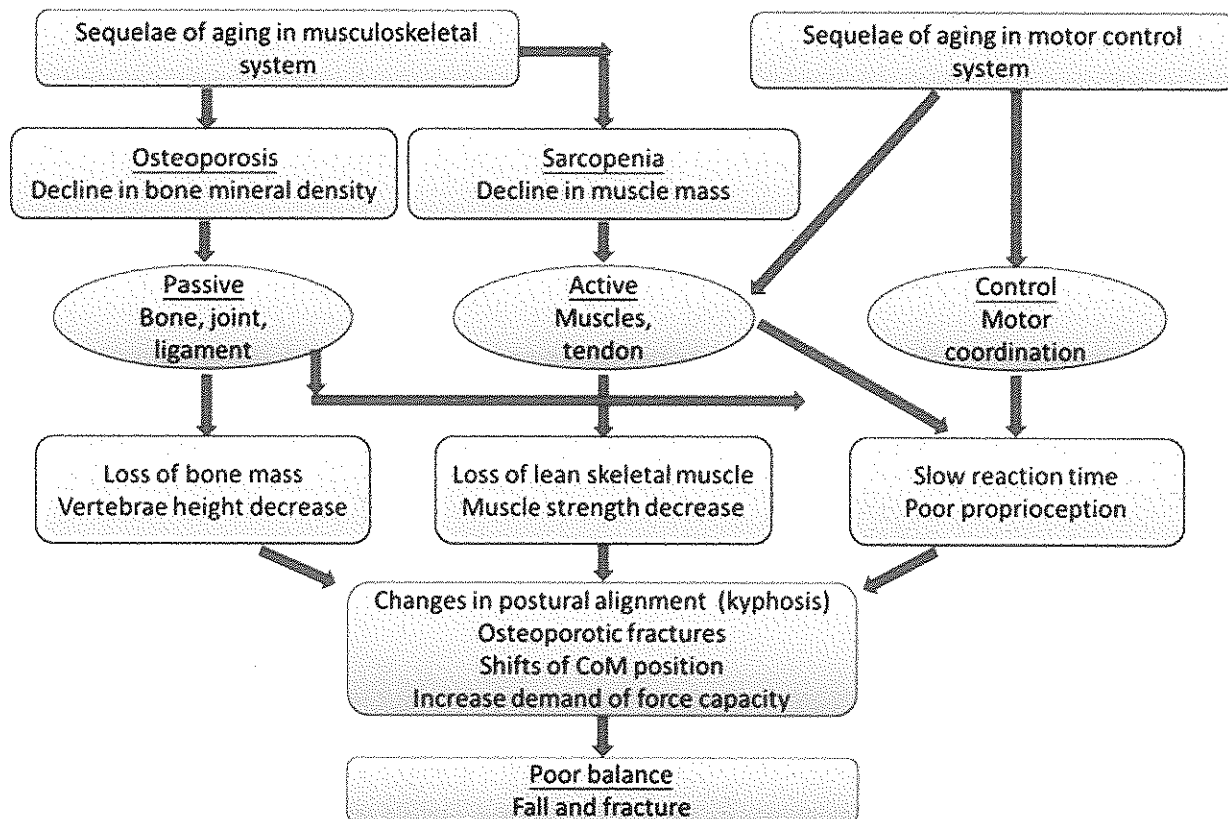


Figure 1 Mechanism of poor balance control in osteoporosis. CoM Z center of mass.²

Various types of exercise and group programs have been shown to be beneficial in overall function and quality of life in the elderly. A study by Hsu et al², showed the importance of muscle quality and postural alignment in balance control, which can in turn reduce fall risk. Most significantly, studies are showing that combined exercise intervention programs addressing both strength and balance function are leading to fall prevention in community dwellers.^{6-10,17,19} A Cochrane review by Gillespie et al⁶, found that the combination reduces rate of falls, but does

not have an effect on fall risk. In particular, a meta-analysis by Sherrington et al⁸, proposed more intensive programs have a larger focus on balance training resulting in the greatest reduction of fall rate and risk of falls by 17%. According to Olsen and Bergland⁴, education regarding fall risks and prevention has been shown to reduce the fear of falling in the elderly. While Bone Builder's does not largely focus on balance training, it does follow evidence by providing an exercise combination of strength training, standing exercises with weights shifts, and an educational component.

Falls create the largest number of deaths and injuries in those greater than 65. It is estimated that falls led to a direct medical cost of more than \$30 billion in 2010 alone.^{19,21} As various exercise and educational interventions improve function and quality of life, health care costs can be decreased as well. Hanley et al.⁷ reported a savings of \$16.9 million over a 4-year period following a multidisciplinary program in New South Wales, Australia.

As bone mass decreases, there arises an increased risk of fractures due to falls. Exercise programs, such as Bone Builders, are designed to provide weight bearing activities, thus preventing excess bone loss through inactivity. These techniques also incorporate muscle strengthening and proprioception in the extremities, which can have positive effects on balance.

The Center for Disease Control (CDC) reports two million adults aged 65 years or older were treated in an emergency room following a fall incident each year.²¹ With high injury rates and medical costs, the CDC is bringing forth information to address the growing issue of falls in this population. The main focus on reducing falls involves addressing medications, vision, home hazards, and inclusion of exercise or weight bearing activities into daily living. They offer fall prevention checklists, posters, and brochures for health care workers and community members to utilize. The CDC has developed a Compendium of Effective Fall Interventions which lists

programs found to be effective in fall prevention for community dwelling older adults. They also discuss various tests and measures that can be performed to determine fall risk. The CDC information is free and open to the public in order to work toward improving safety of all older individuals.²²

Purpose

The purpose of this study was to evaluate the effectiveness of the community based exercise program of Bone Builder's relative to participant satisfaction, quality of life, strength, balance, gait, and fall risk. It was hypothesized that community based exercise for the elderly improves strength, balance, and gait parameters which correlate with a decreased fall risk.

CHAPTER II METHODS

This research is a continuation of the 2013 study conducted by the University of North Dakota Physical Therapy students and the Bone Builder's program in a Midwest community. The Bone Builder's Program has sessions three days per week on Tuesdays, Thursdays, and Fridays at 9:00 am and 3:30 pm. The research team was present for two of these sessions prior to conducting the study in order to obtain a better understanding of the program. Exercises were observed to have specific counting sequences, encouraging continuous breathing and control during movements. Hand and ankle weights were also optional additives to the exercises performed. Following the observation, data was collected during a 3:30 Thursday session and a 9:00 am Friday session. The tests used for gathering data were chosen based on CDC recommendations and measures utilized by the pilot study.

Subjects

Fifty one females gave written consent to participate in the study done at the Grand Forks Senior Center. Inclusion criteria consisted of: age of 60 years or older, community dwelling, currently enrolled in the Bone Builder's Program, ability to ambulate unaided by another individual with or without an assistive device, and ability to understand and follow instructions. The senior center accepts individuals 60 years and older; thus, the inclusion criteria was set to meet these standards and gain a broader perspective of the aging population than that of the pilot study's youngest age of 65. Exclusion criteria consisted of: less than 60 years of age, medically

unstable, or inability to ambulate safely unaided by another individual. All willing participants met the inclusion criteria.

Four-Stage Balance Test

The Four-Stage Balance Test is utilized by the CDC as a measure to assess static balance. Balance positions progressively get more difficult with the four types of balance stances including: narrow base of support (NBOS), modified tandem, tandem, and single limb stance. For safety purposes, a gait belt was applied on each subject. Every subject stood next to a counter they could grab if they felt as though they were losing balance. All tests were done with the participant's eyes open. For all tests, subjects were given instruction that they may move their arms or body to maintain balance, but their feet could not move from the set position.

The subjects were instructed to utilize the counter as needed to achieve each of the four positions. Participants needed to demonstrate independent control of the position without use of the counter before researcher began timing. Initially, the tester described and demonstrated the narrow base of support position with both feet touching one another. Once the subject demonstrated the position independently and had control of their balance, the tester stated, "Ready begin" and the timer was started. The timer was stopped upon movement of the participant's feet from the position, or when the subject grabbed the counter. Upon maintenance of balance, the subject was instructed to stop at 30 seconds. The modified tandem stance was described and demonstrated, with instruction to place the instep of one foot at the big toe of the opposite foot. The subject was allowed to decide which foot would be forward. Once again, the timer began at independent control of that position. A full tandem stance followed the modified, with demonstration and instruction to place one foot in front of the other with the heel touching the toe. The subject used the same foot forward they chose in the modified stance. According to

the CDC, individuals are at a high fall risk if unable to hold this position for 10 seconds.²¹The most difficult assessment of the four stage balance test is the single limb balance. Subjects were given demonstration and instruction to stand with one leg off the floor. The exact location and distance off of the floor of the lower extremity was not instructed, however, it could not be touching or resting on the stance extremity. The participant was allowed to try both legs, before choosing which leg to stand on for the test. The timer was stopped upon the patient placing the non-stance limb on the floor, grabbing the counter, or at the completion of 30 seconds.

Timed Up and Go (TUG)

The Centers for Disease Control and Prevention (CDC) has recommended healthcare professionals administer at least one gait, strength, and balance tests on their community dwelling patients for fall prevention. The TUG is the balance test recommended to evaluate gait, lower body strength, and balance. According to the CDC, if the participant takes longer than 12 seconds to complete the TUG, they are at a higher risk for falls.²²The TUG has been found to have a sensitivity and specificity of 87%. Standard instructions for the TUG were followed using a chair (seat height 46 cm, arm height 67 cm) with arm rests that was placed at the beginning of the walkway. A 10 foot walkway was then measured and marked with a cone for the participant to walk around.²³To address reliability, one researcher performed this test with all participants. The participant was instructed to stand, with or without the use of their arms, walk at a safe and comfortable walking speed around the cone, and sit back down in the chair. Timing began when the tester said “go,” and ended when the participant’s buttocks hit the seat. For safety purposes, a gait belt was placed on every participant. Each subject was given one practice run, and their second attempt was then timed and recorded for data analysis. One participant used a four wheeled walker as an assistive device during this test, which was documented.

The 30 Second Sit-to-Stand Test

The 30 second sit-to-stand test has been shown to be a reliable (0.84-0.92) test for assessing general lower extremity strength and endurance.²⁴ It has been chosen over other tests, such as the five times sit-to-stand test, as it adds an endurance component. When evaluating the elderly population, this becomes important to ensure safety in their environment.²⁹

Subjects were instructed to sit in the middle of an 18 inch chair with their hands placed across their chest and feet flat on the floor. On the command “go,” the subject was to rise to a full standing position, and return to full seated position with their buttock touching the chair each repetition. This was to be repeated as many times as the subject could tolerate in 30 seconds. If the subject required use of his/her arms to stand, the test was stopped and a zero recorded. If the subject was over halfway to a standing position at 30 seconds, this was counted as a full sit-to-stand added to their total score.

Grip Strength

Grip strength has been used as a predictor for overall upper extremity strength, as well as future outcomes in aging adults. Low grip strength is associated with likelihood for premature mortality, increased disability, and prolonged hospital stays.²⁵ To assess grip strength, a Jamar hand dynamometer was used. This instrument has been shown to be reliable (0.85-0.98).^{26,27}

Subjects were instructed to sit up-right with both feet flat on the floor, arm in a neutral position at their side, elbow bent 90 degrees, and wrist in a neutral position. The subject was instructed to squeeze the dynamometer as hard as they could for three seconds. Three tries were given on their dominant hand, and the strongest attempt was recorded. Grip strength was measured in pounds, and compared to age related norms.²⁵

GAITRite Gait Velocity Assessment

For measuring gait speed, the GAITRite system was used. The system includes a ten meter mat and sensors to track the subject's foot placement, recording parameters in a computer program. The program analyzes many features of each gait including footprint analysis, step and stride width, and various gait deviations that may be present. This study focused only on the feature of gait velocity. Two studies, Menzet al.²⁸ and Webster et al.²⁹ elaborated on the GAITRite system being a both a reliable and valid measurement tool to assess gait speed in older adults with reliability ICC between .83-.99 and validity ICC being between .92-.99.

For participant safety, GAITRite mat was placed on tile floor with tape holding down each corner. A piece of tape labeled "start" was placed three feet from the beginning of the mat, and a blue cone was set three feet past the end of the mat. The initial three foot distance was to allow participants to achieve normal walking pace before reaching the mat, while the additional three feet after the mat allowed for constant gait speed during the 10 meter recorded walk. The computer station where the researcher sat and recorded the results was placed off to the side and behind the mat in order to prevent any visual influence during participants' trials. Participants were provided both instructor demonstration and verbal description. They were further instructed to keep head up, eyes focused forward while walking at an everyday walking pace. Following verbal and visual demonstration, the participant was placed at the starting tape and instructed to begin walking once the researcher said "go". Once the participant had completed one trial they were shown the results of gait velocity and this was recorded. Assistive devices were not used by any of the subjects. However, a wheeled walker was pushed along the side of the mat by an assistant in order to hold a participant's oxygen tank during ambulation.

Falls Efficacy Scale-International Assessment

The Falls Efficacy Scale-International (FES-I) is a valid and reliable assessment for determining an older individual's fear of falling level in a quantifiable manner. Upon initial development and validation, the FES-I had excellent internal validity (Cronbach's alpha=0.96) as well as test-retest reliability (ICC=0.96).³⁰

The participants were instructed to be as honest as possible when filling out the form in order to best show their true concern of falling. Participants sat down at a table with a researcher present to answer any questions or to read/explain the questions as needed. Following the survey, the researcher recorded the total score out of 64 possible points. A score of 64 places an individual at the highest fear of falling, whereas the lowest score possible of 16 means the subject has no concern of falling.

Quality of Life Assessment

A quality of life assessment (QOL) was administered to better understand perceived benefits of the Bone Builders community exercise program. The questions covered the length of participation in the program and perspectives on any changes in the following areas: ability to sleep at night, balance, energy level, flexibility, state of mind, strength, and whether they preferred to group to individual exercise. Participants were instructed to fill out the form to the best of their ability. If a participant had any questions or concerns, a researcher was present to assist as needed. It is to be noted that the researchers added in a question about sleep, which they felt was needed to fully understand the participants' total QOL.

CHAPTER III RESULTS

Data was entered into an excel file and transferred to SPSS to be analyzed. Four comparisons were explored during this study. The means were compared for overall first time subject's (2013, 2014) to second time subjects (2014), to determine if longer participation in the program yielded better test scores. Last year's data (2013) was compared to the combined 2013 and 2014 data. Collected mean results versus normative data were assessed (Table 1). Lastly, in order to analyze repeat subjects, means were compared from the participants' first scores (2013) to their second scores (2014).

Age Groupings		30SecSTS	Grip	Gait Speed	TUG*	4stage3**	4stage4***
60-64	Mean	15	43 lbs.	1.0 m/sec	8 sec	> 10 sec	25.1 sec
65-69		14					
70-74	Mean	13	37.4 lbs.	0.9 m/sec	9 sec	> 10 sec	11.3 sec
75-79		12					
80-84	Mean	11	36.5 lbs.	0.8 m/sec	11 sec	> 10 sec	7.1 sec
85-89		10	30.3lbs.				
90-94		8					

*TUG: >12 seconds to complete the TUG are at a high risk for falling
 **An older adult who cannot hold the tandem stance (stage 3) for at least 10 seconds is at increased risk of falling. There are not normative values available for stages 1 or 2 for the 4 stage balance test.
 ***Participants unable to perform the one-leg stand for at least 5 seconds are at increased risk for injurious fall.

Demographics

The study consisted of 51 female participants, within the age range 60-90, who are enrolled in the Bone Builders exercise program. The length of participation in this program

ranged from zero months to 48 months. The age group 60-69 had 11 subjects, 70-79 had 26 subjects, and 80-90 had 14 subjects. The entire sample consists of 2013 and 2014 data for first and second time participants in order to build a larger sample size for greater precision. Included in this sample are eight repeat subjects who participated in both the 2013 and 2014 studies (Table 2).

Age Groupings		FES	30 sec STS	Grip	Gait Speed	TUG	4stage1	4stage2	4stage3	4stage4
60-69	Mean	19.67	17.33	50	1.6033	7.24	30	30	30	17.7833
	N	3	3	3	3	3	3	3	3	3
	Min	18	13	25	1.4	6.5	30	30	30	9.82
	Max	22	21	75	1.71	8.03	30	30	30	30
70-79	Mean	20.25	14.50	44.25	1.1125	10.1475	30	30	28.6575	18.27
	N	4	4	4	4	4	4	4	4	4
	Min	14	11	25	.96	9.03	30	30	24.63	5.10
	Max	28	18	70	1.26	11.63	30	30	30	30
80-90	Mean	18	12	52	1.09	9.57	30	30	22.03	1.96
	N	1	1	1	1	1	1	1	1	1
	Min	18	12	52	1.09	9.57	30	30	22.03	1.96
	Max	18	12	52	1.09	9.57	30	30	22.03	1.96
Total	Mean	19.75	15.25	47.38	1.2938	8.985	30	30	28.3325	16.0488
	N	8	8	8	8	8	8	8	8	8
	Min	14	11	25	.96	6.50	30	30	22.03	1.96
	Max	28	21	75	1.71	11.63	30	30	30	30

There were a total of two subjects, one in each test, who opted out of the 30 second sit-to-stand and grip strength due to osteoarthritis of the knee and rheumatoid arthritis of hands, respectively. In addition, one subject utilized a four wheeled walker when performing both the timed up and go and the GAITRite assessment. The 4 stage balance test was added to the study in 2014, and therefore had a total of 19 participants.

30 Second Sit-to-Stand

In a review of both 2013 and 2014 data, all age groups fell within the normative data range, with the 80-90 year old age group being slightly above average, at 11.79 stands. Overall 2014 data displayed a decrease in stands within all age groups, compared to 2013's data. The 8 repeat subjects, on average, improved by 2.5 stands. However, two subjects declined from the previous study by an average of 1.5 stands, while one participant maintained at their previous level (Table 3). The eight repeat subjects scored higher, on average, than overall first time subjects.

Table 3: 2013 vs 2014 Repeat Data

Subject	FES		30 Second Sit to Stand		Grip Strength		Gait Speed		Timed Up and Go	
	2013	2014	2013	2014	2013	2014	2013	2014	2013	2014
1	20	19	12	13	46.7	25	1.85	1.7	7.9	6.5
12	24	19	14	12	25.3	25	1.2	1.23	8.18	9.84
14	36	20	15	18	27.3	42	1.01	1.26	8.88	9.03
15	19	22	14	18	65.7	75	1.45	1.71	6.72	7.19
17	24	18	13	12	59	52	1.15	1.09	9.47	9.57
19	17	14	17	17	70	70	1.1	1.0	9.72	11.63
20	16	18	19	21	41.7	50	1.29	1.4	7.18	8.03
22	27	28	10	11	48.3	40	0.89	0.96	11.91	10.09

Timed Up and Go (TUG)

All age groups averaged less than 12 seconds to complete the test indicating a low to moderate risk for falls. The age groups 60-69 and 70-79, on average, had mean scores greater than the age group normative data. The 80-89 group, on average, had mean scores below the norm (Table 1). The age groups 60-69 and 80-89 required more time to complete this test, while the 70-79 group required less time, than the prior study (Table 4). Of the eight repeat subjects, two saw an improvement in their TUG score by an average of 1.61 seconds and six subjects

required more time to perform this test by an average of 0.85 seconds (Table 3). The eight repeat subjects took less time to complete the test than overall first time subjects.

Age Groupings	30 Second Sit to Stand		Grip Strength		Gait Speed		Timed Up and Go	
	2013	2013-2014	2013	2013-2014	2013	2013-2014	2013	2013-2014
60-69	16.25	14.73	60.8	52.17	1.43	1.19	7.71	8.86
70-79	13	11.56	43.83	46.38	0.95	1.07	11.11	10.76
80-90	16.67	11.79	54.2	44.86	1.11	1.04	9.22	10.93

Grip Strength

All age groups, on average, fell within the normative data range for grip strength. On average, the age groups 60-69 and 80-89 displayed a decrease in grip strength, while the 70-79 group had an increase, in comparison to the prior study data (Table 3). For the eight repeat subjects, three demonstrated an improvement in their grip strength by an average of 10.77 pounds, one had no strength change, and 4 had an average decrease of 9.33 pounds (Table 4). Second time subjects in age groups 60-69 and 70-79, on average, had a decrease in overall grip strength on their dominant hand compared to first time participants. However, those in the age group 80-89, on average, had an increase in overall grip strength on their dominant hand.

4 Stage Balance

The 4 stage balance test as of now does not have specific normative data for each age group; however, there are norms for tandem stance and single leg stance (Table 1). All age groups were able to perform the tandem stance (stage 3) for at least 10 seconds and the single leg stance for at least five seconds, placing them in a low fall risk category.

The previous year did not perform the 4 stage balance, thus, there is no data comparison. This test was chosen over the tandem stance used in the previous year, as the 4 stage balance provides more detail and is promoted by the CDC.

Gait Speed

All age groups fell within normative data ranges. The age groups 60-69 and 80-89 displayed a slower gait speed than the previous year's data and the age group 70-79, on average, had a faster gait speed (Table 3).

For the eight repeat subjects, three had an increased gait speed by an average of 0.10 seconds, and five subjects' gait speed decreased by an average of 0.14 seconds (Table 4). On average, second time study participants had faster gait speeds than first time participants.

Falls Efficacy Scale (FES)

A researcher individually sat down with each subject to assist in filling out the FES questionnaire. A lower score on the FES indicates an overall lower concern for falls. A higher score indicates high concern for falls in the subject's daily life. On average, the 60-69 age group scored 19.45/64, 70-79 scored 24.58/64, and 80-90 scored 26.64/64. This trend indicates that as the subjects' age increases, their concern for falling also increases. However, further investigation on the accuracy of self-reported concerns is needed as FES scores did not always correlate with scores on balance and gait assessments. They appear to have more confidence in their abilities than they physically displayed during the study.

The second time study participants overall rated their concern for falls less than or equal to first time study participants.

Quality of Life Questionnaire (QOL)

A researcher individually sat down with each subject to assist in filling out the quality of life questionnaire. The form asks the subjects' perception on how much improvement they have had on sleep, balance, energy level, flexibility, state of mind, and strength since joining the Bone Builders program. Each section was to be rated on a scale of 1-3, with 1 being no change, 2 slight improvements, and 3 significant improvements. First time study participants reported the least improvement in sleep and the most improvement in strength. Second time study participants reported sleep as the area with the least improvements as well, but reported flexibility as the highest area of growth (Table 5).

Age Groupings		Sleep	Balance	Energy	Flexibility	State of Mind	Strength
60-69	Mean	1.27	2.27	1.91	2.18	2.27	2.09
	N	11	11	11	11	11	11
70-79	Mean	1.60	2.05	2.15	2.15	1.90	2.25
	N	20	20	20	20	20	20
80-90	Mean	1.67	1.71	1.71	1.71	1.71	1.86
	N	6	7	7	7	7	7
Total	Mean	1.51	2.05	2.00	2.08	1.97	2.13
	N	37	38	38	38	38	38

The QOL questionnaire also has a section where subjects can comment on areas of concern, medication use, preference of exercise setting, and the benefits of community exercise programs. Listed below are some written answers:

“I feel the Bone Builders class is very beneficial and continuing on a regular basis is necessary to maintain your optimum strength as you age.”

“Good to be able to work at the individual’s own pace.”

“Group therapy keeps you going regularly and the social aspect is good for your well-being.”

“I think I’m getting a lot more flexible and significantly stronger.”

“It’s helped my balance.”

Table 6: 2013 and 2014 data for all first time study subjects

Age Groupings		FES	30 sec STS	Grip	Gait Speed	TUG	4stage1	4stage2	4stage3	4stage4
60-69	Mean	19.45	14.73	52.173	1.18636	8.8609	30	30	30	12.18
	N	11	11	11	11	11	4	4	4	4
	Min	16	9	34.7	.740	6.72	30	30	30	5.58
	Max	23	20	80	1.850	13.13	30	30	30	30
70-79	Mean	24.58	11.56	46.376	1.06627	10.7577	30	30	23.8236	10.8382
	N	26	25	25	26	26	11	11	11	11
	Min	16	0	25.3	.510	6.44	30	30	7.57	0
	Max	42	17	70	1.480	22.53	30	30	30	30
80-90	Mean	26.64	11.79	44.857	1.0355	10.9279	30	30	22.295	9.07
	N	14	14	14	14	14	4	3	4	4
	Min	16	7	24.3	.84	7.5	30	30	9.4	0
	Max	40	22	59	1.25	15.59	30	30	30	30
Total	Mean	24.04	12.32	47.226	1.08373	10.3953	30	30	24.8021	10.7484
	N	51	50	50	51	51	19	19	19	19
	Min	16	0	24.3	.51	6.44	30	30	7.57	0
	Max	42	22	80	1.85	22.53	30	30	30	30

CHAPTER IV DISCUSSION

Bone Builders is a community based exercise program aimed at preventing or slowing the progression of osteoporosis. The purposes of the study was to follow-up the pilot study and determine an individual's risk for falls after having participated in a consistent exercise program. It was hypothesized that Bone Builders participants have a decreased risk for falls, as well as improved mobility. In addition, researchers expected that repeat participants would improve or maintain their previous scores from the pilot study data (2013). As predicted, all subjects' scores were above the normative data in all assessments performed. However, repeat participants' scores only showed improvement in the 30 second sit to stand, and, on average, had a small decline in all other assessment. The scores may be affected by assessment deviations due to human error between the 2013 and 2014 researcher groups. Based on this information and the small number of repeat subjects, no significant relation can be made to the entire Bone Builders population.

As with every study, there are limitations that appear. Interrater reliability between the 2013 and 2014 research groups causes data between the two studies to be skewed. Energy levels may have been affected due to outlying factors such as some participants being tested before, during, or after their exercise class. Assessment order administration is another outlying factor that may have caused fatigue, due to some tests being more physically demanding than others. Finally, there was a vast difference of the quantity of participants in each age group. The

70-79 age group had significantly more subjects than 60-69 and 80-90, which may skew age group data comparisons.

Four Stage Balance Test

The four stage balance test is a new assessment tool utilized in this study to evaluate static balance with four different foot positions. It was added to the 2014 research because it is listed by the CDC as a tool to assess balance and measure an individual's fall risk. Also, using four levels of measurement allows the researcher to record specific areas of balance deficits. Older subjects were expected to have the greatest balance limitation which would manifested in difficulty with tandem stance and single leg stance. Results are consistent with this hypothesis, as the age group 80-89 was unable to hold a single leg stance (stage 4) for greater than ten seconds. One limitation to this test is possible environmental distractions such as background noise, and researcher-subject conversation which may disrupt the participant's focus on balance. In addition, the test has a high learning curve due to inexperience of these four foot positions. There was not a formal practice test, thus, test stance time may have been less than the participants' true capability. Finally, each stance was to be held for 30 seconds, with the most challenging test performed last. Therefore, fatigue is a possible limitation as well.

Timed Up and Go (TUG)

The purpose of the timed up and go is to assess dynamic gait along with transitions and turning balance. It was expected that older subjects would require more time to complete the test than younger subjects. Table 1 displays this trend, as the age group 60-69 took an average 8.86 seconds, the age group 70-79 took on average 10.76 seconds, and the age group 80-90 took on average 10.93 seconds. A limitation of this test is the one's interpretation of the instructions, "to

walk at their normal speed.” There is ambiguity in the participants’ perception of the definition of normal gait velocity, which may alter the walking time for each individual.

30 Second Sit-to-Stand

The purpose of the 30 second sit-to-stand is to assess general lower extremity strength and endurance. Researchers expected that as one ages, they will have fewer sit to stands caused by a decrease in lower extremity strength and endurance. The 80-90 age group was able to perform more sit to stands than the 70-79 age group, which contradicts the researchers’ hypothesis as stated above. The 80-89 age group, having fewer participants, may have played a role in the higher overall average. A lack of subject understanding when instructed to control movement throughout the sit to stand is a possible limitation. Due to this, using momentum as a compensation pattern to stand was observed, along with lack of control during the eccentric decent. The use of these two patterns may render a higher score, rather than displaying a lack of lower extremity strength or control that could be present.

Grip

Grip is a good predictor of overall upper extremity strength and future health of aging adults.²⁵ As predicted, a slight reduction in grip strength with increasing age was noted. However, on average, all the age groups displayed numbers above the normative data. Although both hands were tested, due to subject curiosity, only data from the dominant hand was recorded to remain consistent with the pilot study data collection. The main limitations are hand injuries or arthritis, causing a reduced grip strength score. A lower score may have led the researcher to believe one had decreased upper extremity strength and endurance when true deficits weren’t present.

Gait Speed

Gait speed is shown to be correlated with fall prediction in the older population. Increased age was hypothesized to produce decreased gait speeds, and therefore, an increased risk for falls. Results support the above hypothesis. The 60-69 age group on average ambulated 1.19 m/s, the 70-79 age averaged 1.07 m/s, and the 80-90 age ambulated 1.04 m/s. Due to reliability, validity, and elimination of human error, there are very few limitations with this test using the GAITRite system. However, one possible limitation is environmental distractions to the participant. Other movement occurring in the room may have caused the subject to shift their gaze, causing small variations in the gait pattern. This may not be a limitation though, since it mimics real world situations for normal gait. A comparison of assessments done in different environments would be beneficial.

Quality of Life Survey

The purpose of this survey was to determine the subjects' perception of improvement in the five categories, previously stated in the methods section, since starting the Bone Builder's program. It was hypothesized that the participants' views of their quality of life (QOL) would improve following involvement in the Bone Builder's Program. Both 2013 and 2014 study groups reported there to be improvements in various aspects of life. Participants' testimonials regarding the Bone Builder's program support the above hypothesis, as physical improvements and over well-being are both written of. Limitations to the survey included subjectivity, participants' mood while filling out the survey, and their understanding of the questions in the survey.

Functional Efficacy Scale-International

The reasoning behind the Functional Efficacy Scale-International (FES-I) was to assess the participants' personal concern for falls. The researchers expected that concern for falls increases as one ages generating a higher score on the FES-I. Results show this trend to be consistent with the initial hypothesis developed. Subjective views of the participants are a limitation, as their self-perception did not always hold true to their observed abilities. As with the QOL, the FES-I is also limited by the participants' understanding of the questions.

Suggestions for Improvement

To improve this study, there is a need for consistency in test utilization from year to year to allow for better comparison of data between successive studies. One area of measurement to include in the future, is recording both the dominant *and* non-dominant hand to determine if hand pathologies, such as arthritis, have an effect on grip strength.

At this time, with such a few number of repeat subjects, researchers mainly studied comparisons to normative data and scores between age groups. In order to create a cross sectional study, researchers should gather data every three months versus annual testing to gain more repeat subjects. This provides the opportunity for analysis of the effects of group exercise in determining if long term exercise leads to a decrease in fall risk and an improvement in mobility among the aging population.

Conclusion

A community based exercise program, such as Bone Builders, has a positive effect on participation with exercise, as well as improving the fall risk and safety in older adults. Participants in Bone Builders, on average, scored above the normative data range in all

assessments, which is indicative of a decreased fall risk and a higher level of mobility. All of the participants reported enjoyment with group exercise as it provides a social outlet, while also working on maintaining a healthy lifestyle. As the overall population of this age group continues to increase, implementation of community exercise programs for older adults is beneficial, and worth advocating for in more communities.

APPENDIX A
(CONSENT)

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: <u>MAR 26 2014</u>
Expiration Date: <u>MAR 25 2015</u>
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: MAR 26 2014
Expiration Date: MAR 15 2015
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: <u>MAR 26 2014</u>
Expiration Date: <u>MAR 25 2015</u>
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: MAR 26 2014
Expiration Date: MAR 25 2015
University of North Dakota IRB

Date _____
Subject Initials _____

APPENDIX B
(IRB)

RESEARCH PROJECT REVIEW AND PROGRESS REPORT
UNIVERSITY OF NORTH DAKOTA INSTITUTIONAL REVIEW BOARD



DATE March 12, 2014 DEPARTMENT/COLLEGE 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

CONTINUING APPROVAL, EXPEDITED CATEGORY 497

NEXT REVIEW REQUIRED BEFORE: MAR 25 2015

CONTINUING APPROVAL, BASED ON FULL BOARD REVIEW

NEXT REVIEW REQUIRED BEFORE: _____

SUSPEND APPROVAL, PENDING INVESTIGATION

APPROVAL TERMINATED

COMMENTS OF REVIEWER: _____

Chair/Vice Chair/Member, IRB: Kathy Smart

cc: Chair, Physical Therapy Approval Date: March 26, 2014

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:
19 since the date of last approval, and
19 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.

None

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.

Participants have expressed appreciation for the education on fall risks and reported continuing with the recommendations noted as part of the testing. Subjective and qualitative data is being analyzed.

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.

Participants had difficulty with completing the "before starting community program" portion of the Falls Efficacy Scale. Even with assistance it is questionable the information is accurate. Propose to delete this portion of the form and have participants fill out only their current status. Comparison information is captured in the "Quality of Life/Satisfaction Questionnaire. Even though this is not as detailed it seems to be more accurate. Minor modification to the static balance component to incorporate CDC recommended 4-Stage Balance Test.

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

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.
None

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

Falls are especially prevalent in the older population, which contributes to decreased health status and increased medical costs. The benefits of activity are well known to decrease balance deficits and increase overall quality of life. This study examines the effects of a community exercise program on improving quality of life, decreasing risk of falls, and an overall satisfaction of the program. Subject protection continues as noted in the initial IRB. Risks remain minimal and continue to be addressed as noted in the initial IRB.

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 / Under PA Date 3/13/14

Current email address: beverly.johnson@med.und.edu

Current Address: Dept Physical Therapy PO Box 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

Introduction. Falls are especially prevalent in the older population, which contributes to decrease health status and increased medical costs. The benefits of activity are well known to decrease balance deficits and increase overall quality of life. This study examines the effects of a community exercise program on improving quality of life, decreasing risk of falls, and an overall satisfaction of the program.

Methods. Nineteen community-dwelling older adults (68-83 years) were recruited from the Bone Builders community exercise program. A quality of life/satisfaction questionnaire, Falls Efficacy Scale-International (FES-I), 30-second sit-to-stand, Timed Up and Go (TUG), grip strength, tandem stance, and gait speed were assessed. Assessment scores were collected and compared to industry norms for each age group. Minor change being made to incorporate CDC 4-Stage Balance Test. Change is being made to the informed consent to address this modification. The standard Falls Efficacy Scale International (FES-I) will continue to be used and the reflection piece asking participants to remember how they felt prior to the program is being deleted; this will not require a change in the informed consent.

Results. The 65-69 and 80-89 age groups' mean scores were at or better than the age norms on all tests. The 70-79 age group's mean scores were at or better than the age norm on all assessments except gait speed and TUG. In comparison to other age groups, the 70-79 age group scored the lowest on the majority of the tests; this group also had the highest concern about fear of falling on the FES-I retrospectively and currently. On the quality of life/satisfaction survey, the majority of participants reported social and psychological benefits.

Conclusion. Researchers found this community exercise program to be beneficial in improving quality of life, and a possible influencing factor in increasing strength and reducing some of the risk factors associated with falls. Plan is to continue to evaluate current participants on a yearly basis to addressing quality of life and functional assessments related to fall risk as noted in the methods section. Every three months new members to the Bone Builder's class will be invited to participate in the study to increase the number of subjects. Subjects will continue to benefit from the balance assessment at no cost to increase awareness and education.

REPORT OF ACTION: PROTOCOL CHANGE
University of North Dakota Institutional Review Board

Date: 4/3/2014

Project Number: IRB-201304-292

Principal Investigator: Johnson, Beverly; Danks, Meridee

Department: Physical Therapy

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

The above referenced project was reviewed by a Designated Member for the University's Institutional Review Board on MAR 26 2014 and the following action was taken:

Protocol Change approved. Expedited Review Category No. 497

Next scheduled review must be before: MAR 25 2015

Copies of the attached consent form with the IRB approval stamp dated MAR 26 2014 must be used in obtaining consent for this study.

Protocol Change approved. Exempt Review Category No.

This approval is valid until _____ as long as approved procedures are followed. No periodic review scheduled unless so stated in the Remarks Section.

Copies of the attached consent form with the IRB approval stamp dated _____ must be used in obtaining consent for this study.

Minor modifications required. The required corrections/additions must be submitted to RDC for review and approval. This study may NOT be started UNTIL final IRB approval has been received. (See Remarks Section for further information.)

Protocol Change approval deferred. This study may not be started until final IRB approval has been received. (See Remarks Section for further information.)

Protocol Change disapproved. This study may not be started until final IRB approval has been received.

REMARKS: Any unanticipated problem or adverse occurrence in the course of the research project must be reported within 5 days to the IRB Chairperson or RDC by submitting an Unanticipated Problem/Adverse Event Form.

Any changes to the Protocol or Consent Forms must receive IRB approval prior to being implemented (except where necessary to eliminate apparent immediate hazards to the subjects or others).

PLEASE NOTE: Requested revisions for student proposals MUST include adviser's signature. All revisions MUST be highlighted and submitted to the IRB within 90 days of the above review date.

Education Requirements Completed. (Project cannot be started until IRB education requirements are met.)

cc: Chair, Physical Therapy



Signature of Designated IRB Member
UND's Institutional Review Board

3-26-14

Date

If the proposed project (clinical medical) is to be part of a research activity funded by a Federal Agency, a special assurance statement or a completed 310 Form may be required. Contact RDC to obtain the required documents.

(Revised 10/2006)

Appendix C
(Bone Builders Data Sheet)

Subject # _____
Age _____

Bone Builders Data Sheet- Spring 2014

___ 1. Questionnaire Completed

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

___ 3. 30 Second Sit to Stand Test Number of Stands _____

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

Subject # _____

Age _____

4 Stage Balance: fall risk < 10 seconds

Date ()

- | | | | |
|---------------|---------------------|-----------------|----------------------------|
| 1. | Narrow Based Stance | Score: ____ sec | |
| 2. | Semi-Tandem Stance | Score: ____ sec | Right or Left foot forward |
| 3. | Tandem Stance | Score: ____ sec | |
| 4. | Single Leg stance | Score: ____ sec | Right or Left |
| Date () | | | |
| 1. | Narrow Based Stance | Score: ____ sec | |
| 2. | Semi-Tandem Stance | Score: ____ sec | R or L
foot forward |
| 3. | Tandem Stance | Score: ____ sec | |
| 4. | Single Leg stance | Score: ____ sec | R or L |

Appendix D
(QOL)

Subject # _____

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

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.

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)?

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 E
(FES)

C

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

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