

EFFECTIVENESS OF ADVANCED STAY STRONG, STAY HEALTHY IN  
COMMUNITY SETTINGS

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By  
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The undersigned, appointed by the dean of the Graduate School, have examined the thesis  
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**EFFECTIVENESS OF ADVANCED STAY STRONG, STAY HEALTHY IN  
COMMUNITY SETTINGS**

presented by Emily M. Crowe,

a candidate for the degree of Master of Science, and hereby certify that, in their opinion, it is  
worthy of acceptance.

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# EFFECTIVENESS OF ADVANCED STAY STRONG STAY HEALTHY IN COMMUNITY SETTINGS

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## ABSTRACT

**Introduction.** The Advanced Stay Strong, Stay Healthy (ASSSH) program was developed in 2009 by a team of MU Extension Specialists to meet the increasing need for a follow-up program to the Stay Strong Stay Healthy (SSSH) program. The goal of the program is to build on the fitness base acquired from SSSH by adding new and more complex exercises. The neuromuscular system quickly adapts to stressors and loads and must be constantly challenged for gains in strength, flexibility and balance to continue. Thus, it is necessary to alter the exercise routine regularly. Advanced SSSH is designed to challenge older adults in new and different ways to help staleness and plateaus, and to improve activities of daily living (ADL's). Loss of muscular strength, flexibility, and balance are strong predictors of falls in the elderly.

**Purpose.** The primary purpose of this research was to investigate the effectiveness of the MU Extension program Advanced Stay Strong, Stay Healthy. It was hypothesized that the program can improve physical parameters of health including strength, balance, and flexibility which indicate the risk of falling among seniors.

**Methods.** Twenty eight older adults volunteered to participate in this study. Matched pairs t-tests were used to compare differences in measures of the physical indicators of strength, flexibility, and balance. Two-way analysis of variance (ANOVA) was conducted to examine the age effects on the increments in measures of the physical indicators of strength from pre to post. Dual X-Ray absorptiometry (DXA) scans were conducted before and after the 10-week exercise intervention to identify changes in body composition (lean mass and fat mass) and changes in percent body fat (%BF).

**Results.** Twenty three subjects (21 female, 2 male; 50-76 y) successfully completed the 10 week training protocol and were included in the analysis. Following a 10-week structured strength program, participants significantly improved strength, flexibility, and balance ( $p<0.05$ ). Results from the DXA indicated improvements in body weight and whole body composition ratio displayed by a decrease in body fat (g) and an increase in lean body mass (g), however, no significant differences were observed. Subjects showed a significant decrease in %BF following 10 weeks of programming. No significant changes in bone mineral content (BMC) or bone mass density (BMD) were observed.

**Conclusion.** The community-based MU Extension program ASSSH can significantly improve muscular strength, flexibility, balance and, ultimately, reduce risk factors of falling among seniors. Although subjects showed statistically significant improvement in strength, flexibility and balance measures, 10 weeks appeared to be too short to achieve significant changes in BMC, BMD and changes in lean body mass and fat mass.

Nevertheless, the positive trends observed in body composition and BMD suggest that analysis of a longer intervention period to elicit observable changes in bone turnover (i.e. 12 months or greater) is warranted.

## INTRODUCTION

Unexpected falls are a frequent and serious problem facing people aged 65 and older. Injuries resulting from falls in older adults represent a significant health burden (89) since approximately 30% of those aged 65 years and older experience at least one fall each year and half of those fall recurrently (12, 88). The mortality rate for falls increases dramatically with age in both sexes and in all racial and ethnic groups, with falls considered the sixth leading cause of death in persons 65 years and older (62). One in ten falls results in injuries such as hip fractures, subdural hematoma, serious soft tissue injuries and head injuries (53) and are the leading cause of injury-related visits to emergency departments in the United States (86).

Despite randomized control trials (13, 19, 87) and clinical guidelines (1) showing that fall-prevention interventions can be successful, falls and fall-related injuries continue to rise along with associated healthcare costs. A systematic review estimating the economic burden of falls of older adults living in the community was shown to be \$23.3 billion in the US alone (25). By 2050, the annual number of hip fractures occurring globally is expected to be 6.26 million (68). Identifying strategies to reduce the number of falls, and thus hip fractures remains a topic of international importance, given the anticipated treatment costs and a 1-year mortality rate of up to 33% following hip fractures (91).

**Risk Factors for Falls.** The skeletal and muscular organ systems are tightly intertwined. The strongest mechanical forces applied to bone are those created by muscle contraction that increase bone density and strength (16). It is not surprising, therefore, that the decrease in muscle strength leads to lower bone strength. One of the hallmark features

of the aging process and significant risk factors for falls is sarcopenia. The term sarcopenia first proposed by Irwin Rosenberg in 1989 describes the age-related loss of skeletal muscle mass and strength (74). Ten years later, Baumgartner et al (8) introduced a clinical definition of sarcopenia defined as a value of lean body mass 2 SD below the average value calculated in healthy, young men and women. This strategy is equivalent to that used to define osteoporosis in adults. Degenerative processes in the neuromuscular system, reduced food intake, and physical inactivity are the most important causes of sarcopenia (11). The declining muscle mass of sarcopenia occurs at the alarming rate of 4-5% per decade (81) and results in impaired quality of skeletal muscle, leading to increased muscle weakness (93). Such weakness is a strong predictor of falls in the elderly, a significant contributor to decreased quality of life, and associated with an increased morbidity and mortality in this population (59). It is still unclear what factors affect the magnitude of the force generated by muscle tissue, but some data suggest that behavioral and environmental factors are more important than genetic predisposition (84), implying that proper dietary and lifestyle interventions are perhaps more effective at preventing sarcopenia.

**Health Benefits of Strength Training.** Research over several decades has shown compelling evidence supporting the benefits of targeted physical activity programs for older adults (17, 75). Strength training is considered a promising intervention for reversing the loss of muscle function and the deterioration of muscle structure that is associated with advanced age. This reversal is thought to result in improvements in functional abilities and health status in the elderly by increasing muscle mass, strength and power and by increasing BMD (40). Several studies have shown these improvements in bone density with regular strength training in older adults, women in particular (21, 46, 61).

In 1994, Nelson et al. conducted a long-term strength-training study in women aged 50 to 70 years old. After one year of strength training two days per week, middle-aged women became stronger, gained muscle mass, and had improvements in bone density above and beyond the control group (61). Reducing the signs and symptoms of osteoporosis in older adults is also advantageous for improving quality of life. In 2001, Baker et al. (4) studied the impact of strength training in older adults aged  $\geq 55$  with clinically diagnosed osteoarthritis. After four months, the strength-training group had significant reductions in pain and improvements in muscular strength, functional performance, physical abilities, quality of life and self-efficacy (2).

**Falls Prevention Programs.** The benefits of physical exercise in improving the functional capacity of frail, older adults have been the focus of considerable research in recent years (31, 45, 92). Exercise intervention strategies including supervised resistance training, balance training, coordination training, and multi-component exercises (i.e., combination strength, endurance, and balance training) have shown effective in reducing falls in elderly at risk persons (7, 28, 49, 50, 58, 78, 94). Exercises that improve lower body strength and balance have also been shown to reduce the risk of falls and fall-related injuries among frail individuals living in nursing homes (1, 65, 79). In addition to strength training, exercise programs, particularly those including balance training, have been shown to reduce the risk of falls by 10%–49% (76).

However, research on falls and fall prevention can often be difficult and problematic. There are inherent logistic difficulties in performing and interpreting these types of studies. From a clinical standpoint, hospitals and outpatient clinics that measure outcome variables such as number of falls and fallers recorded by staff members may

produce observation and recording biases (65). Also, a consistent lack of follow-up after studies also makes it difficult to identify the effects the interventions have on actual rates of falling. In addition, subjects with certain medical or pre-existing conditions (i.e., physical frailty, sarcopenia) who have a higher risk of falling, are often excluded from these types of intervention studies.

Despite the challenges associated with falls-related research, multifactorial interventions conducted by skilled community health professionals have consistently shown effective in preventing falls (18), particularly those programs targeting persons at risk (33) and include several intervention strategies (26). Certain fall risk factors mentioned above including impaired balance, abnormal gait patterns (24, 51), and muscle weakness (63) respond favorably to physical activity (14, 32). Data suggests that people with leg weakness have a 4-to-5 fold increase in risk for falls, and people with impaired gait or balance have approximately a 3-fold increase (76). An example of an evidence-based program that has been implemented by MU Extension professionals in community settings is Stay Strong Stay Healthy (SSSH), a targeted strength training program geared for older adults with higher fall risk. The SSSH program content was modeled after the Strong Woman program developed at Tufts University (61). Each class of approximately 20 participants consists of group strength training, balance and flexibility one to two times a week for 10 weeks. Translational research has shown that following programming, participants of SSSH demonstrated statistically significant improvements in strength, balance, coordination and flexibility (6).

Following the success of SSSH, the Advanced Stay Strong, Stay Healthy (ASSSH) program was developed in 2009 by a team of MU Extension Specialists as the

need for a follow-up program to the SSSH program increased. The goal of the Advanced SSSH program is to build on the fitness base acquired from SSSH by adding new and more complex exercises and one additional training session per week (two days per week total). Until now, the efficacy of this real-world community based and Extension delivered program has not been evaluated.

**Purpose.** The purpose of this research was to investigate the effectiveness of the MU Extension program Advanced Stay Strong, Stay Healthy. It is hypothesized that the program can improve physical parameters of health including strength, balance, and flexibility which are significant indicators of an individual's fall risk profile.

## METHODS

**Subjects.** Figure 1 shows the timeline of events in the experimental design. Procedures in this research study were approved by the University of Missouri's Health Sciences Institutional Review Board. Subjects were recruited via flyers, online newsletters and word of mouth on the University of Missouri's campus. To be eligible for the study, participants were between the ages of 50-85 y, post-menopausal (women only), and met least one of the following criteria: a) completed the Stay Strong Stay Healthy program and/or b) have been regularly participating in strength training activities for the past three months or greater. Once recruited, subjects were scheduled for a preliminary meeting. Subjects were presented with a consent form outlining the rationale for the study, the participant description, procedure, possible risks and benefits of the study, and their rights as a participant. Screening took place in the Exercise Physiology Lab in McKee Gymnasium on the University of Missouri's campus. Volunteers were screened for any medical problems that might affect their ability to complete the study using the Physical

Activity Readiness Questionnaire (PAR-Q) (Public Health Agency of Canada, 2002).

Following written consent, subjects completed the personal contact and information form, and provided proof of medical clearance from their doctors, if necessary. Qualified subjects were then scheduled for a second meeting at McKee Gymnasium to collect anthropometric data, complete the DXA scan and the physical fitness assessment outlined below.

**DXA.** Body composition was assessed by the DXA (QDR 4500A, Hologic., Inc., Bedford, MA, USA) using fan beam technology on the second visit. Each subject completed a whole body DXA scan pre and post intervention. Subjects were instructed to wear minimal clothing and have no metal objects on or near their body. The subject was asked to lie supine on the DXA table and positioned by the technician. Body composition was estimated using computer software (QDR Software for Windows XP, Hologic, Inc., Bedford, MA). Bone mass, fat mass, and lean tissue mass were represented in pounds; %BF was calculated by the software and represented as fat mass(g)/total mass (g) x 100.

**DXA reliability.** All DXA scans were analyzed by the same technician. Normal and standard DXA quality control measures, equipment checks, and calibrations as recommended by the manufacturer will be performed prior to testing. DXA is a three-compartment model that estimates bone mineral mass, lean tissue mass, and fat tissue mass. Although DXA was originally developed as a tool for measuring bone mineral content, it has been accepted as a valid method for measuring body composition, specifically percent body fat (10, 54). DXA gives estimates of whole body and lean muscle mass with a precision of error equal to or smaller than other non-invasive methods, thus providing the rationale for its use and purpose in this study.

**Physical Fitness Assessment.** Four fitness measures from the Senior Fitness Test (6) were evaluated pre and post strength training intervention. The primary outcome measures included the “chair stand test” assessing lower body strength and muscular endurance; the “8-foot up-and- go” assessing balance and coordination while moving; the “chair sit and reach” assessing lower body flexibility; and the “back scratch” assessing upper body flexibility; Balance was assessed using a graded balance test (4). Detailed descriptions of each test are provided below and outlined in Table 1.

**Chair Stand Test.** Lower body strength and muscular endurance were assessed using the chair stand test. Participants were instructed to sit on a chair with their arms crossed on their chest and stand to a fully standing position and sit down successfully as many times as they can in 30 seconds. Time was measured by a stop watch to the nearest 0.01 seconds. The score recorded was the total number of stands executed correctly in 30 s. For the Chair Stand Test, high test-retest reliability has been shown (ICC=.89) (85).

**8-Foot Up-and-Go.** Balance and coordination while moving were assessed using the 8-foot-up-and-go test. Time was recorded with a stopwatch to the nearest 0.01 second. Before testing, trained personnel provided verbal instructions regarding the test procedure. Participants began seated and were instructed to walk 8 feet, turn around a cone, walk back to the chair and sit down. The stopwatch was started on the command “ready-set-go” and stopped as the participant sits down. Subjects were asked to walk as quickly as possible without running. The 8-foot-up-and-go (or timed up and go (TUG)) has shown excellent test-retest reliability (ICC=0.99) in older adults (70).

**Chair Sit and Reach.** Lower body flexibility was assessed using the Chair Sit and Reach test. Participants were instructed to sit on the edge of a chair placed against a wall for safety. One foot must remain flat on the floor. The other leg is extended forward with the knee straight, heel on the floor, and ankle bent at 90°. Subject was instructed to place one hand on top of the other with tips of the middle fingers even and to inhale, and then as they exhale, reach forward toward the toes by bending at the hip, keeping the back straight and head up and hold the reach for 2 seconds. Study personnel measured between the tip of the fingertips and the toes. If the fingertips touch the toes then the score is zero. If they do not touch, the distance between the fingers and the toes was measured as a negative score (in inches). If they overlap, test personnel measured by how much and recorded a positive score. Test was performed on both the left and right leg.

**Back Scratch.** Upper body flexibility was assessed with the Back Scratch test. While in the standing position, the subject was instructed to place one hand behind the head and back over the shoulder, and reach as far as possible down the middle of your back with your palm touching your body and the fingers directed downwards. Placing the other arm behind your back, palm facing outward and fingers upward and reach up as far as possible attempting to touch or overlap the middle fingers of both hands. The distance between the tips of the middle fingers was measured using a ruler or tape measure. If the fingertips touch, then the score was zero. If they do not touch, the distance between the middle finger tips was recorded as a negative score (inches). If they did overlap, the distance of overlap was measured and recorded as a positive number.

**Graded Balance Test.** Balance was assessed using a graded balance test. Subjects were asked to perform a series of six balance tests with increasing difficulty. Subjects were

asked to hold all positions for 10 seconds before progressing to the next test: (1) Standing in a “mountain pose” – standing in an upright position with feet closed and eyes looking straight ahead without swaying; (2) Tandem stand – standing with one foot directly in front of the other. The heel of the front foot should be touching the toes of the back foot (3) One-legged stand – Shift all your weight to one foot. Bend the knee on the other leg to bring that foot up in the back. (4) Remain in tandem pose but with eyes closed; (5) Tandem stand with eyes closed and head turning – Same as test (4) but turn head slowly to the right, then slowly all the way to the left, and then return to face the front; (6) One-legged stand with eyes closed – This is the same as test 3, except eyes were closed. Score was assigned by the stage(s) of the balance test they successfully passed on a scale of 1-5.

**Timed 25-Foot Walk Test.** Walking performance was assessed with the 25-foot walk test. All participants started in a standardized standing “start position”, which was 5 inches behind the starting line indicated by a black line on the floor. Each participant received the following standard instructions “I’d like you to walk 25 feet as quickly as possible, but safely. Do not slow down until after you’ve passed the finish-line. Ready? Go”. The time to complete the task was assessed with a stopwatch and calculated from the initiation of the instruction to start and ends when the participant reached the 25-foot mark. The task is immediately administered again by having the patient walk back the same distance. The 25-foot walk test has shown excellent test-retest reliability (ICC = 0.94) (48).

**Exercise Intervention.** Participants who met the inclusion criteria and were able to commit to the 10 weeks of strength training were included for participation in the study. The exercise intervention consisted of a 10-week resistance training program consisting of two class sessions per week. All exercise training sessions were conducted at McKee

Gymnasium on the University of Missouri's campus under the supervision of trained exercise personnel. Participants were asked to maintain their usual activity levels outside of the training intervention for the duration of the program.

The resistance-training intervention involved a combination of stretching, balance, and strengthening exercises. Sessions began with a 5 minute warm-up period, followed by two sets of 10 repetitions of eight to 10 various strength exercises including (but not limited to) wide leg squat, standing leg curl, lunge, biceps curl, overhead press, toe stand, front raise, rear raise, one arm row, chest press, chest fly and bent forward fly. Classes finished with a 5 minute cool down period including light stretching and balance exercises. The flexibility program included commonly used stretching activities for the major muscle groups including two stretches each for the hamstrings, quadriceps, back, shoulder and chest muscles. Each session lasted 45-60 min. Standby or hand supports were only used when required. A large portion of the class was performed while standing. Each stretch was held for a period of 20 s and repeated twice.

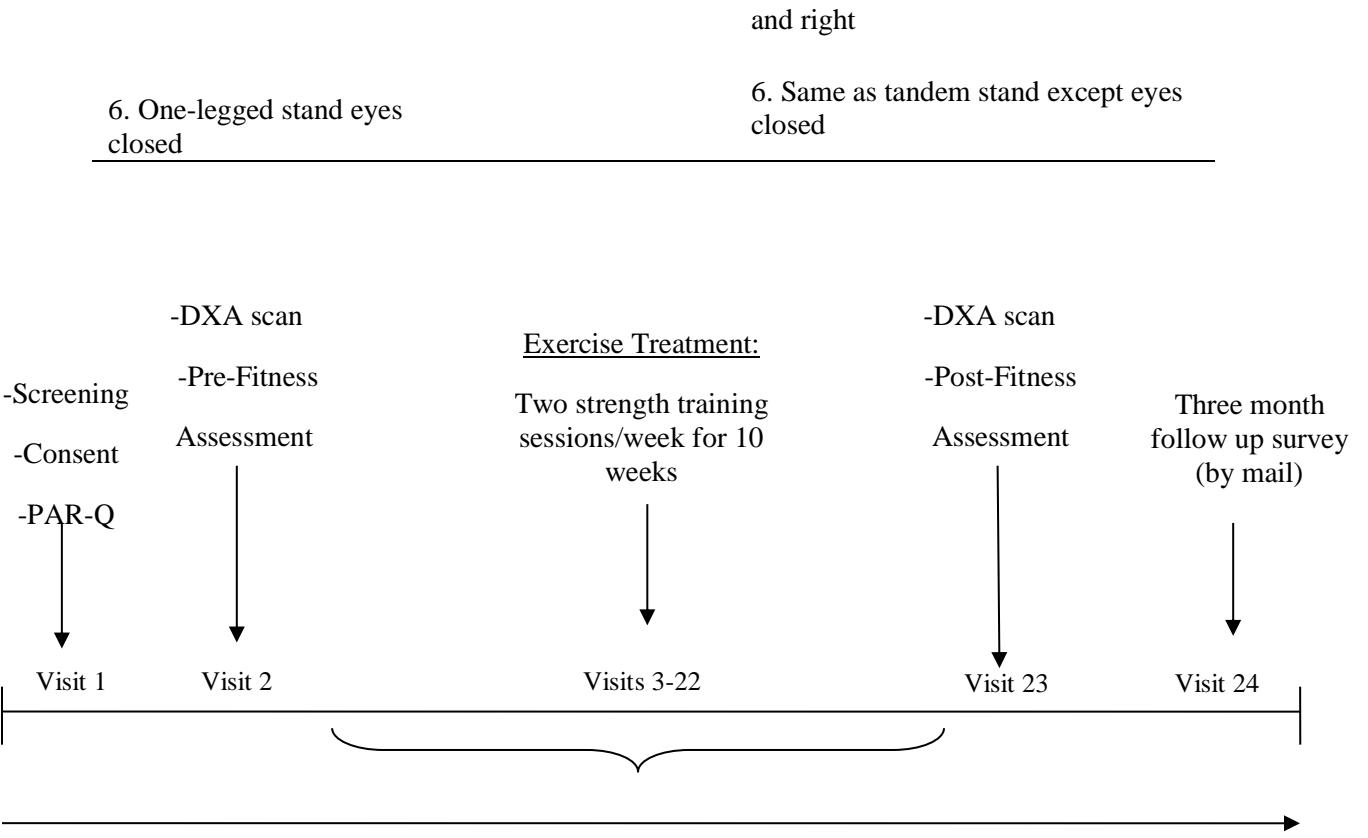
Exercise equipment available for this program included dumbbells (2, 3, 4, 5, 8 and 10 lb) and chairs. Progression in the program was individualized. Whenever participants felt that the last three repetitions of a set were "easy", they were encouraged to increase the amount of resistance by using the next-size-heavier dumbbell. For exercises using only the resistance of the participants body weight (i.e. chair squats), participants were encouraged to progress by either adding weight by holding a pair of dumbbells or adding additional repetitions to the set.

**Statistical analysis.** Data was analyzed using SPSS for Windows (version 20.0).

Descriptive statistics were generated for variables of interest including age, weight and height and were expressed as mean  $\pm$  standard deviation. Matched pairs t-Tests, using an alpha level of .05 and 95% confidence interval (CI), was used to compare differences in measures of the physical indicators of strength, flexibility, and balance. Two-way analysis of variance (ANOVA) was conducted to examine the age effects on the increments in measures of the physical indicators of strength, flexibility, and balance from pre to post-testing. All data was collected at the same laboratory.

**Table 1. Data Collected to Assess Physical Strength**

Physical performance test	Purpose	Description
30-s chair stand	Assess lower body strength	Number of full stands that can be completed in 30 seconds with arms folded across chest
Chair sit-and-reach left and right	Assess lower body flexibility	Distance in centimeters between extended hand and toes when seated at edge of chair with leg extended; negative number indicated inability to reach toes
Back scratch left and right	Assess upper body flexibility	Distance in centimeters between one hand reaching over shoulder and second hand reaching up the middle of the back
8-foot up-and-go	Assess agility/dynamic balance	Number of seconds required to get up from a seated position, walk 8 feet, return to seated position
Balance tests performed in order of difficulty:	Sequentially assess balance	
1. Mountain Pose		1. Ability to stand for 10 seconds with feet side by side and touching, without using hands for support
2. Tandem stand		2. Ability to stand for 10 seconds with heel of one foot touching toe of other foot, one hand touching wall for support.
3. One-legged stand		3. Ability to stand for 10 seconds on one leg
4. Tandem stand eyes closed		4. Same as mountain pose with eyes closed
5. Tandem stand eyes closed head turning		5. Same as tandem stand with eyes close with head turning slowly left



**FIGURE 1. Experimental design describing milestones within exercise intervention.**

## RESULTS

**Participants.** Twenty-eight older adults (26 women, 2 men) volunteered to participate in this study. Twenty-three subjects completed the 10-week training program. Five subjects were unable to complete the program, with most drop-outs being due to scheduling conflicts and persistent joint pain. The mean age was 60.5 y (Range 50-76 y), height 167.6 cm, and a weight of 92.3 kg for the male subjects and 74.7 kg for female subjects at baseline. Subjects in this study were apparently healthy community-dwelling older adults with no mobility restrictions.

All participants completed at least 16 of the 20 face-to-face exercise training sessions except for one participant. Average attendance was 89.5% (Attended 17.9 out of 20 sessions). Subjects occasionally missed classes due to illness and conflicting appointments. Those who missed the face-to-face class sessions were sent a list of specific exercises they missed to complete at home. At the next training session, subjects self-reported if they completed the at-home exercises or not. Of the six subjects that missed training sessions, four completed the routine at home, increasing the overall adherence rate to 90.5% for the total number of strength sessions completed during and outside of class (Mean = 18.1 out of 20 total sessions).

**Total body weight.** Pre and post measures of body composition were examined and analyzed by the DXA. Table 2 displays all pre and post-test measures of body composition. All results are displayed as means  $\pm$  SD. At baseline, mean body weight (lbs) was  $165.3 \pm 29.7$ . After the intervention, total body weight decreased slightly to  $165.1 \pm 30.2$ . There was no significant change in total body weight from pre to post-exercise intervention.

**%BF.** Subjects significantly reduced their %BF following the strength training intervention ( $p < .05$ ). At baseline, the mean %BF for all subjects was  $36.9 \pm 5.5$ . After the intervention, mean %BF was  $33.31 \pm 5.9$ , a decrease in %BF by an average of 3.62%.

**Lean Mass.** At baseline, average lean mass (lbs) for all subjects was  $103.6 \pm 18.6$ . After the intervention, lean mass increased to  $104.6 \pm 19.0$ . Overall, subjects increased their lean mass by 1.0 lbs, however, there was no statistical significance observed from pre to post-exercise intervention.

**Fat Mass.** At baseline, the mean fat mass was  $56.9 \pm 15.6$ . After the intervention, fat mass decreased by 1.24 lbs to  $55.6 \pm 16.2$ . However, there was no significant change in fat mass from pre to post-intervention.

**BMD.** At baseline, the mean BMD for all subject was  $1.115 \pm 0.1$ . After the intervention, BMD increased slightly to  $1.118 \pm 0.1$ , showing no significant change in BMD from pre to post exercise intervention (Table 1).

**Fitness Tests.** Participants showed statistically significant improvement from pre to post assessment in each of the seven markers used to assess strength and flexibility (Table 3). Results from two-way ANOVA showed that younger participants, that is, those less than 60 years old ( $n=12$ ) significantly reduced their %BF ( $p<0.05$ ), increased lean body mass, slightly increased their BMD more than the older adults (60+ years old). However, there was no significant difference between age groups when comparing the physical measures of fitness.

**Attendance.** All exercise sessions were supervised and recorded by trained study personnel to assure consistency and completion. Compliance to the aforementioned protocols was excellent. Average attendance was 89.1% for the 10 weeks of strength training sessions (Mean attendance= 17.9 out of 20 total sessions). Subjects did occasionally miss classes due to illness, scheduling conflicts, etc. Those who missed the face-to-face class sessions were sent a list of specific exercises they missed to complete at home. At the next training session, subjects self reported if they completed the at-home exercises or not. Of the six subjects that missed training sessions, four completed the routine at home, increasing the overall adherence rate to 90.5% for all strength sessions completed (Mean = 18.1 out of 20 total sessions). Six of the 23 total subjects attended

100% of the exercise sessions. When comparing data from the participant's in the upper quartile for attendance (Attendance = 100%; n=6) to those in the lower quartile for attendance (attendance = 81%; n=6), those with greater adherence to the exercise sessions had more significant improvements in the sit-and-reach test ( $P=.03$  vs.  $.06$ ), balance test ( $P=0.004$  vs.  $0.01$ ), and several measures of body composition. Subjects with higher adherence also had more significant reductions in fat mass ( $p=0.09$  vs.  $0.3$ ), lean mass ( $p=0.28$  vs.  $0.31$ ), total body mass ( $p<0.05$  vs.  $0.39$ ), and %BF ( $p=0.23$  vs.  $0.26$ )

**Table 2. Pre and Post Differences in Group Means for Body Composition**

Physical Measure	Pre Mean	Post Mean	P value (95%CI)
Weight (lb)	165.4	165.1	0.75
%BF	36.9	33.3*	0.02
Lean Mass (lb)	103.6	104.6	0.18
Fat Mass (lb)	56.9	55.6	0.07
BMD (g/cm <sup>2</sup> )	1.115	1.118	0.99

\* p<0.05  
n=23

**Table 3. Pre and Post Differences in Group Means from Physical Fitness Test**

Physical Measure	Pre Mean	Post Mean	Percent Change	P value (95% CI)
Chair stand	18.48	23.91*	29.38%	<0.001
Chair sit & reach (right)	1.57	3.59*	128.66%	0.002
Chair sit & reach (left)	1.32	3.41*	158.33%	0.003
Back scratch (right)	-1.93	-0.41*	78.76%	0.016
Back scratch (left)	-3.87	-2.67*	31.01%	0.019
8-foot up-and-go	5.21	4.38*	15.93%	<0.001
Balance test score	3.48	5.14*	47.70%	<0.001

\* p<0.05  
n=23

## **DISCUSSION**

### **Main Findings**

The results of our analysis show that the ASSSH program significantly improved several parameters of physical fitness including lower body strength. This was demonstrated by the improvement in the chair stand test, in which participants were able to perform 5.43 more stands (on average) in 30 s after 10 weeks of programming. It is worth mentioning that the physical fitness of the participants in this study was much higher than the national average for this age population. The national range of scores for men in chair stands is 12-19 stands for adult men age 60 and older. By comparison, the range of chair stands completed by the men (Range 63-69 y) at baseline was 15.5 (Range 11-20 stands), roughly average for the age group. However, the women in this study performed above the national average. The range of scores for women in chair stands is 10-17 stands adult women aged 60-74 y. By comparison, the chair stands completed by the women in this study (Range 50-76 y) at baseline was 18.8 (Range 8-35), which is considered above average for the 60+ age group. This comparative data highlights the fact that the subjects recruited for this study were of above average fitness compared to the national averages.

Participants also significantly improved the time to complete the 8-foot up-and-go test (-0.83 s), which demonstrates an improvement in balance and coordination while moving. The 0.83 s improvement was not only statistically significant, but clinically relevant and meaningful in this population. Poor balance is strongly coordinated with an increased risk of falls for older adults (52), and although balance training was not a major component of the intervention, balance and coordination improved as a result of the strength training. In addition, improvements in balance performance have been shown to be attributable to increases in strength. Subjects in this study improved their balance test

score by 47.7%. These findings are consistent with previous research showing how strength training can improve balance in older adults (66).

Participants also significantly improved upper and lower body flexibility as shown by the change in chair sit and reach and the back scratch tests. Subjects improved their chair sit-and-reach measures by 2.02 inches (in.) on the right side and 2.09 in. on the left. Subjects were also able to improve their upper body mobility shown by an improvement in the back scratch test by 1.52 in. on the right side and 1.2 in. on the left side. Although strength training was the primary focus on the intervention, stretching was incorporated daily into the training sessions, so an improvement in flexibility (upper and lower body) was expected.

### **Strengths of the Study Design**

The present study had several strengths. All exercise sessions were supervised and recorded by trained study personnel to assure consistency and completion. Compliance to the aforementioned protocols was excellent. Average attendance was 89.1% for the 10 weeks of strength training sessions (Mean attendance= 17.9 out of 20 total sessions). Subjects did occasionally miss classes due to illness, scheduling conflicts, etc. Those who missed the face-to-face class sessions were sent a list of specific exercises they missed to complete at home. At the next training session, subjects self-reported if they completed the at-home exercises or not. Of the six subjects that missed training sessions, four completed the routine at home, increasing the overall adherence rate to 90.5% for all strength sessions completed (Mean = 18.1 out of 20 total sessions). Six of the 23 total subjects attended 100% of the exercise sessions.

The 10 week community-based exercise intervention showed participants significantly reduced their %BF. It is worth mentioning that four subjects displayed negative trends in body composition from pre to post intervention (increased body fat, %BF, and decreased lean body mass). Although resistance training exercise is recognized as the primary method for increasing muscle mass across the lifespan and reducing sarcopenia in older adults, not all people respond the same way to resistance training stimuli, nor do they experience the same degree of chronic adaptations such as hypertrophy. This hypertrophic variability may be affected by gender, age, diet, physical activity level, previous training status and various factors related to genetic predisposition (30). It has been previously distinguished that those people who positively respond to a training program/stimuli fall under a “responders” category, while those that do not experience any chronic adaptation after identical training processes have been identified as “non-responders”. When removing the “non-responders” from the data set, there was a statistically significant improvement in fat mass ( $P<0.001$ ), lean mass ( $P=0.02$ ) and %BF ( $p<.001$ ). For the majority of subjects who completed the 10 week intervention, it is important to realize that participants made substantial individual improvements in their body composition when comparing lean mass and fat mass. As a whole, body fat decreased by 1.24 lbs. and lean mass increased by an average of 1.0 lb. It has been found that human muscle can exert a force of 6 kilograms per square centimeter of cross-sectional area, which is equivalent to 85 lbs. per square inch. Given that muscle mass and strength are significant indicators of fall risk, the increase in lean mass in these subjects is likely to be biologically significant, if not statistically significant, in this relatively small cohort.

The trends observed in the present study were similar to the outcomes observed in a study by Carter et al. (15) examining the efficacy of a community-based 10 week exercise intervention to reduce fall risk factors in women with osteoporosis. The results of their study showed that 10 weeks did not significantly reduce fall risk factors in women with osteoporosis, however, there were trends towards improvement in key independent risk factors for falling (15). This does not exclude the possibility that a longer intervention may achieve such a result.

Apart from contributions of muscles weakness and deficits in balance, low bone mass is also a risk factor for fracture (20, 39). The present strength training intervention did not show significant improvements on total body bone mineral or regional BMD. Year-long studies of high-intensity resistance training have shown an increase or maintenance of BMD in postmenopausal women. However, given the time course of bone remodeling (47), it was unlikely that a detectable change in BMD would occur following the 10-week training period. Although there was a lack of sedentary control group in this study, it is likely that this exercise intervention avoided BMD attenuation, and without exercise, BMD would have likely decreased in these subjects as a result. Research by Shah et al. (80) supports this concept in their study examining the independent and combined effects of weight loss and resistance training on bone metabolism in relation to changes in BMD in obese older adults. The results showed that bone loss at the total hip was relatively less in the diet-exercise group (-1.1%) than in the diet group (-2.6%), whereas BMD increased in the exercise group (1.5%) (between-group  $p < 0.001$ ). These data showed that exercise training combined with diet-induced weight loss not only ameliorates frailty but also attenuates the weight loss-induced reduction in BMD and lean body mass,

suggesting that a combination of weight loss and exercise training may be important therapy for obese older adults.

Although there was no measurable test for cognitive skills in this study, the participant's attitudes about exercise in general appeared to improve. Participants' enthusiasm for exercise increased over the course of the 10 week study as they began to increase strength and take note of the benefits of the program. Qualitative data from the participants' feedback forms indicated that they felt more confident in their physical abilities, enjoyed the class and deemed it worthwhile. The instructor observed the participants strong attendance was influenced by the social interaction and encouragement to participate by their peers, an observation consistent with the literature that social support from family, friends, or experts tend to adhere better to exercise behaviors (71).

### **Study Limitations**

There were several limitations to our study design. Most of the study's limitations stemmed from the community-based design. Community-based exercise programs such as ASSSH do not follow suit with traditional methods and ideal research design, environment and methods. The best approach to this type of study is to randomize subjects after recruitment and baseline testing to a control group and intervention groups. This, unfortunately, was not feasible. The lack of control group in our current study limits the level of evidence our data can provide. Had we recruited a pure, non-exercise control group, between-group differences might have been more marked.

Second, we relied on field measures of strength, balance and flexibility to assess fall risk, which may be limiting by ceiling effects, rather than laboratory-based objective measures which would require inaccessible, expensive equipment such as a force-plate,

perturbation platform or sway meter (22). The use of the wide array of field tests may, however, be considered a strength of this study because it allows testing in settings that are convenient to the participants and more feasible for this type of community-based program.

Third, this study did not measure changes in aerobic endurance of the participants. It has been shown that resistance training alone can increase aerobic capacity of older adults (92), so while there was no aerobic component in this particular exercise intervention, it can be assumed that aerobic capacity increased as a result of the strength training. The addition of a test to measure aerobic fitness would strengthen the credibility of the program and provide a more comprehensive look at the individual's overall fitness level. One example of such test is the 2-minute step test and is measured by the number of full steps completed in two minutes, raising each knee to a point midway between the patella (kneecap) and iliac crest (top hip bone). The score is the number of times the right knee reaches the proper height (72). This is a safe, functional alternative to the 6-minute walk test and would be a good addition to the existing measures in the ASSSH program.

Exercise intervention studies appeal to those who are already healthy and motivated (67), and the participants who volunteered for this study were already particularly fit for their age. This limits the population to which results can be generalized. However, the positive results shown in this study with an already fit group of participants would imply that if a group of unfit individuals recruited and endured the same 10-week intervention, there is the potential for even greater improvements. It is also worth mentioning that improving a fall risk factor does not guarantee a fall reduction. There is a need for a larger study of this design to evaluate the effect that is powered to detect a treatment effect on falls, and ideally, injurious falls and fractures (44).

In addition, the results of this study showed subjects did not significantly improve their body composition as a whole. There are several possible explanations for this finding. First, this study did not have a dietary component. Subjects were not asked to keep a dietary log and dietary education was not provided to subjects. This may have caused subjects to overestimate the caloric expenditure of the added activity and as a result, overcompensate by increasing their daily caloric intake, providing one possible explanation for the minimal weight loss and lack of significant changes in body composition. Recent research has supported this overcompensation effect following exercise. A study by Finlayson et al. (2009) examined hedonic and homeostatic mechanisms involved in the acute effects of exercise on food intake. After exercise, compensators (C) increased their EI, rated the food to be more palatable, and demonstrated increased implicit wanting (29). An enhanced implicit wanting for food after exercise may help to explain why some people overcompensate during acute eating episodes. Some individuals could be resistant to the beneficial effects of exercise due to a predisposition to compensate for exercise-induced energy expenditure. Also, subjects lost 1.24 lbs. of fat mass overall but gained 1.0 lbs. of lean body mass, equaling a weight loss of only 0.24 lbs, demonstrating that although some subjects gained weight, the weight gained was lean body mass and not fat mass. This statistic also highlights the importance and primary goal of strength training which is to improve overall body composition, not decreasing total body weight per se.

Another study limitation is the lack of fall tracking. Prospective reporting of falls using fall calendars are considered the gold standard (37), but are not possible when establishing fall rates before commencing a study. Thus, the potential preventative role of these programs warrants longer term investigation in a larger sample to determine the

impact on fall rates. The small sample size also limited the power to detect small between-group differences, suggesting that a larger sample may be warranted for future research.

## **Future Directions for Research**

A reduction in fall occurrence and fall risk is important in older adults. A prospective study such as ours with a larger sample size and a broader cohort documenting improved postural stability, reduced fall occurrence, and reduced fall risk as a result of multifactorial exercise intervention is needed. Although our research plan and data gathering were prospective, we relied on some self-reported data and did not report participants fall history over time. A similar method should be applied to a sample of people at risk for falls, with a daily telephone follow-up of fall history as the gold standard.

As declining muscle strength and balance promote falls and fracture in older adults, we suggest that a high-intensity progressive resistance training program of only one session per week may prove useful in reducing the risk of falls and, hence, fracture and that additional research should be directed at this possibility. In addition, the primary study outcome was fall risk, as opposed to falls. Thus, future research using falls as the primary outcome measure is needed to confirm the persisting beneficial effect of different types of exercise on falls in those with low bone mass and/or sarcopenia.

As mentioned above, compliance to the aforementioned protocols in the present study was excellent. Average attendance was 89.1% for the 10 weeks of strength training sessions (Mean attendance= 17.9 out of 20 total sessions). It is well documented that adherence to an exercise program, regardless of type, intensity, volume, is key to improving acute and long-term health outcomes. Morey et al. (2002) reported that among older adults enrolled in a physical activity program for over 10 years, participants classified

as adherent had a long-term survival benefit by time compared to a non-adherent group (60). Other research has shown that individuals who are more adherent to the regular exercise programs, compared to those who are less adherent, experience greater improvements in fitness, physical function, quality of life, and disease-specific outcomes (9). Despite the compelling evidence, older adults have lowest rates of participation in formal exercise programs among all age groups (82). Long-term weight loss is a difficult task, and most individuals who start with good intentions and commit to change their behavior fail to continue. However, long-term adherence to physical activity is essential for the maintenance of health benefits. MU Extension professionals can use behavior change strategies to enhance participants' motivation and adherence to regular physical activity and healthy diet, rather than only focusing on weight changes. In addition, flexibility programs may be useful as an alternative exercise program for older adults who do not find resistance training manageable or appealing. The benefits of including flexibility programs on alternate days with resistance training is an interesting potential area for future research and warrants further investigation.

## **CONCLUSION**

The purpose of this study was to determine the effectiveness of the MU Extension program Advanced Stay Strong Stay Healthy on reducing fall risk. Older adults are the fastest growing segment of American society. Those that maintain good muscular strength, flexibility, and balance by exercise participation have a lower risk of falls, enjoy a better quality of life, and generally live longer than their inactive counterparts. Unfortunately, there are few community based exercise programs targeted at older adults. Most community professionals lack the training, skills, and confidence to lead exercise classes.

Not surprisingly, many have avoided using exercise as a means to improve the health of their community. ASSSH is a viable option for community professionals interested in helping older adults maintain independence through improved muscular strength, flexibility, and balance.

There is an increasing demand for exercise studies to clearly define the dimensions of exercise needed to ameliorate health. In the present study, we evaluated a 10-week community-based strength training program that focuses on three major intrinsic fall risk factors: balance impairments, gait instabilities, and muscle weakness. The proposed exercises require relatively low supervision and material costs. The clinical implication of this study is that appropriately supervised community based exercise classes can be safe for older adults prone to osteoporosis, osteopenia and risk of falling. Although subjects showed statistically significant improvement in strength, flexibility, balance measures, 10 weeks appears to be too short a time period to achieve significant changes in body composition. Nevertheless, the positive trends observed in this study suggest that analysis of a longer intervention is warranted

We acknowledge that improving a fall risk factor profile does not necessarily guarantee fall reduction. There is a need for a larger study to evaluate the effect of this type of intervention in a high risk group that is powered to detect a treatment effect on falls and ideally, injurious falls and fractures. Nevertheless, the clinical implications of this study are significant. With the growing aging population, the number of falls will likely increase in years to come. Decades of experimental research has shown that exercise appears to play an important role in preventing falls among older adults. However, currently there is a limited availability of low-cost, exercise-intervention programs to help

increase strength, flexibility and balance in older adults prone to falls. The demand for this type of organized community program will continue to grow as the aging “baby boomer” population grows older over the next several decades. ASSSH showed significant and meaningful improvements in strength, balance, and flexibility and is a functional option for older adults looking to maintain independence and improve their quality of life for years to come.

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**APPENDIX A:**  
**EXTENDED LITERATURE REVIEW**

## **BENEFITS OF STRENGTH TRAINING ON FALL RISK AND BONE HEALTH IN OLDER ADULTS: A SYSTEMATIC REVIEW**

Osteoporosis and related fractures are a serious public health problem worldwide because of the associated morbidity, mortality and health care costs. In 2011, 1.2 million Americans were diagnosed with osteoporosis and another 5.4 million had osteopenia and are therefore at risk of fragility fracture (38). Due to the demographic trend towards an ageing population, the incidence of osteoporosis-related conditions is projected to rise to three million people by 2021, with a fracture occurring every three and a half minutes unless effective prevention strategies are implemented. For those that sustain a hip fracture, it is estimated that more than 20% will die within 6 to 12 months post fracture (36), almost 50% will require long-term nursing care and up to 80% of those who survive will fail to regain their pre-fracture level of function (90).

Since most osteoporotic fractures are due to a fall or minimal trauma (77) there is considerable interest in identifying safe, effective and widely accessible community-based strategies for addressing multiple fracture-related risk factors, particularly reduced bone density, muscle wasting and weakness, poor balance and impaired gait and mobility which increase the risk of falling.

Despite randomized control trials (13, 19, 87) and clinical guidelines (1) showing that fall-prevention interventions can be successful, falls and fall-related injuries continue to rise, along with associated healthcare costs. A systematic review estimating the economic burden of falls of

older adults living in the community was shown to be \$23.3 billion in the US alone (25).

By 2050, the annual number of hip fractures occurring globally is expected to be 6.26 million (68). Identifying strategies to reduce the number of falls, and thus hip fractures remains a topic of international importance, given the anticipated treatment costs and a 1-year mortality rate of up to 33% following hip fractures (91).

Therefore, the aim of this review was to summarize the health benefits of strength training for older adults. This review will also cover the effects of different types of intervention programs on decreasing fall risk factors older adults and elderly people as a starting point for developing future interventions that maintain a healthy bone mass and higher quality of life in people throughout their lifetime

**Effects of Strength (Resistance) Training on Elderly.** Research over several decades has shown compelling evidence supporting the benefits of targeted physical activity programs for older adults (17, 75). Strength training can also help reduce the symptoms of various chronic diseases such as arthritis, depression, type-2 diabetes, osteoporosis, sleep disorders and heart disease (11- 19). Several studies have shown improvements in bone density with regular strength training in older adults, women in particular (21, 46, 61). Nelson et al. conducted a long-term strength-training study in women aged 50 to 70 years old. After one year of strength training two days per week, middle-aged women became stronger, gained muscle mass, and had improvements in bone density above and beyond the control group (7). Reducing the signs and symptoms of osteoporosis in older adults is also advantageous for improving quality of life. In 2001, Baker et al (4) studied the impact of strength training in older adults

aged > 55 with clinically diagnosed osteoarthritis. After four months, the strength-training group had significant reductions in pain and improvements in muscular strength, functional performance, physical abilities, quality of life and self-efficacy (2).

**Falls Prevention Programs.** The benefits of physical exercise in improving the functional capacity of frail, older adults have been the focus of considerable research in recent years (31, 45, 92). Exercise intervention strategies including supervised resistance training, balance training, coordination training, and multi-component exercises (i.e., combination strength, endurance, and balance training) have shown effective in reducing falls in elderly at risk persons (7, 28, 49, 50, 58, 78, 94). Exercises that improve lower body strength and balance have also been shown to reduce the risk of falls and fall-related injuries among frail individuals living in nursing homes (1, 65, 79). In addition to strength training, exercise programs, particularly those including balance training, have been shown to reduce the risk of falls by 10%–49% (76).

However, research on falls and fall prevention can often be difficult and problematic. There are inherent logistic difficulties in performing and interpreting these types of studies. From a clinical standpoint, hospitals and outpatient clinics that measure outcome variables such as number of falls and fallers recorded by staff members may produce observation and recording biases (65). Also a consistent lack of follow-up after studies also makes it difficult to identify the effects the interventions have on actual rates of falling. In addition, subjects with certain medical or pre-existing conditions (i.e., physical frailty, sarcopenia) who have a higher risk of falling, are often excluded from these types of intervention studies.

Despite the challenges associated with falls-related research, multifactorial interventions conducted by skilled community health professionals have consistently shown effective in preventing falls (18), particularly those programs targeting persons at risk (33) and include several intervention strategies (26). Certain fall risk factors mentioned above including impaired balance, abnormal gait patterns (24, 51), and muscle weakness (63) respond favorably to physical activity (14, 32). Data suggests that people with leg weakness have a 4-to-5 fold increase in risk for falls, and people with impaired gait or balance have approximately a 3-fold increase (76). An example of an evidence-based program that has been implemented by Extension professionals in community settings is Stay Strong Stay Healthy (SSSH), a targeted strength training program geared for older adults with higher fall risk. The SSSH program content was modeled after the Strong Woman program developed at Tufts University (61). Each class of approximately 20 participants consists of group strength training, balance and flexibility one to two times a week for ten weeks. Translational research has shown that following programming, participants of SSSH demonstrated statistically significant improvement from pre to post assessment in each category measuring strength, balance, coordination and flexibility (6).

**Risk Factors for Falls.** The skeletal and muscular organ systems are tightly intertwined. The strongest mechanical forces applied to bone are those created by muscle contraction that increase bone density and strength (16). It is not surprising, therefore, that the decrease in muscle strength leads to lower bone strength. One of the hallmark features of the aging process and significant risk factor for falls is sarcopenia. The term sarcopenia first proposed by Irwin Rosenberg in 1989 describes the age-related loss of skeletal muscle mass and strength (74). 10 years later, Baumgartner et al (8) introduced a clinical

definition of sarcopenia defined as a value of lean body mass 2 SD below the average value calculated in healthy, young men and women. This strategy is equivalent to that used to define osteoporosis in adults. Degenerative processes in the neuromuscular system, reduced food intake, and physical inactivity are the most important causes of sarcopenia (11).

The declining muscle mass of sarcopenia occurs at the alarming rate of 4-5% per decade (81) and results in impaired quality of skeletal muscle, leading to increased muscle weakness (93). Such weakness is a strong predictor of falls in the elderly, a significant contributor to decreased quality of life, and associated with an increased morbidity and mortality in this population (59). It is still unclear what factors affect the magnitude of the force generated by muscle tissue, but some data suggest that behavioral and environmental factors are more important than genetic predisposition (84), meaning proper dietary and lifestyle interventions are perhaps more effective at preventing sarcopenia.

**Duration and Frequency of Strength Training in Elderly.** Despite the widespread acceptance among experts that strength training is necessary, even at an older age, numerous aspects of the dose-response relation have not been explained conclusively (3, 23, 57, 66, 69). Activities of daily living (i.e. walking, feeding, bathing, home making) are not sufficient as a training stimulus for the muscles. Elderly men and women who do not undergo additional training will lose body strength and the strength of the arms to a disproportionate extent (56). Typically, strength (resistance) training aiming for hypertrophy is done at least 3 times a week for 8 to 12 weeks; a longer training period increases a more sustained effect (69).

The view that with advancement in age, load bearing intensity should be reduced in order to avoid injuries and chronic overuse is widespread. However, this effect is not supported by current evidence in the literature, and several studies have pointed out the need for higher intensities for elderly as well as young people. In a meta-analysis of 29 randomized controlled studies including a total of 1313 subjects older than 65 years, Steib et al. showed a notable dependence of the improved strength capacity on the intensity of the weight training (83). High-intensity strength training (>75% of the maximal strength capacity) thus triggers higher increases in strength than training of medium or low intensity. More distinguished recommendations regarding the duration and frequency were recommended in a review article by Mayer et al. and are described in detail in the table below (40).

**TABLE**

**Effects and examples of recommended training dosages and possible organizational approaches to different forms of strength training for elderly people**

Objectives	Possible effects of training	Dosage	Possible organizational approaches
Increase in muscle strength	Increase in muscle mass	8–12 repetitions per muscle group in 70–85 % of the one-repetition-maximum; 3 sets; 2–3 training units per week; at least 8–12 weeks	Fitness studio; gymnasium, home program, initially under instruction, later independently
	Training of intramuscular coordination	Up to 8 repetitions per muscle group with intensities of more than 80% of the one-repetition-maximum; 3–5 sets; 3 training units per week; several weeks	Fitness studio; gymnasium, home program, under instruction
	Training of intermuscular coordination	Several repetitions; up to daily training units; high speed of movement, among others	Training on uneven surfaces with or without additional weights; under instruction, later independently
Reduction of sarcopenia	Increase in muscle mass	8–12 repetitions per muscle group in 60–80% of the one-repetition-maximum; 3 sets, 3 training units per week, at least 8–12 weeks	Fitness studio; gymnasium, home program, initially under instruction, later independently
Adaptation of tendons and bones	Increase in net synthesis of collagen; reduction in bone density loss	Medium to high intensities (>60–80% of the one-repetition-maximum, >body weight); several training units per week; weeks to months	Fitness studio; gymnasium, under instruction
Prevention of falls and injuries	Optimizing postural control; training of intermuscular coordination	Several repetitions; up to daily training units; high speed of movement	Training on uneven surfaces with or without additional weights; under instruction, later independently
	Training of intramuscular coordination	Up to 8 repetitions per muscle group in intensities of more than 80% of the one-repetition-maximum; 3–5 sets; 3 training units per week; several weeks	Fitness studio; gymnasium, home program, under instruction

**Falls Prevention Programs.** A variety of physical activity (i.e., exercise) programs have been used to improve the physical parameters associated with fall risk. The benefits of physical exercise in improving the functional capacity of frail, older adults have been the focus of considerable research in recent years (31, 45, 92). Regular exercise is associated with many health-related improvements within this population. For example, physical activity can reduce or prevent the need for medical treatment, or it can be an important addition to medical treatment. Furthermore, regular physical activity improves the functioning of the cardiovascular, respiratory, metabolic, endocrine, and immune systems. By doing this, it greatly reduces risk factors associated with coronary artery disease, and may also prevent the development of, or effectively treat, diseases such as non-insulin- dependent diabetes mellitus, osteoarthritis, osteoporosis, obesity, colon cancer, peripheral vascular occlusive arterial disease, arthritis, and hypertension. Regular physical activity also reduces body fat stores, increases muscle strength and endurance, strengthens bones, and improves mental health (73).

Specifically, exercise intervention strategies including supervised resistance training, balance training, coordination training, and multi-component exercises (i.e., combination strength, endurance, and balance training) have shown effective in reducing falls in elderly at risk persons(7, 28, 49, 50, 58, 78, 94). Exercises that improve lower body strength and balance have also been shown to reduce the risk of falls and fall-related injuries among frail individuals living in nursing homes (1, 65, 79). In addition to strength training, exercise programs, particularly those including balance training, have been shown to reduce the risk of falls by 10%–49% (76).

In addition to the numerous health benefits of physical activity, many of these benefits may have a positive effect on balance in older adults as well. Several studies have examined the effects of general exercise programs on balance. Cress et al. randomly assigned older adults to a control or combined (aerobic and strength exercise) group and observed no changes in balance measures in either group upon completion of a 6-month training program. In another study, static balance on one foot with eyes closed was significantly improved in older adults following a 1-year training program consisting of back extension exercises, strength training, and flexibility/relaxation exercises (47). Other resistance training studies have utilized more balance-specific training programs. Wolfson et al. assigned elderly adults into four different training groups: a strength training group, a balance training group, a balance plus strength training group, or an educational control group. Changes in single-stance balance, strength, and loss of balance measures were evaluated before and after 3 months of training. Loss of balance was significantly less in the balance group than in the control, strength training, and balance plus strength training groups (97). Both the balance and balance plus strength groups showed significant improvements in single-stance time after 3 months of training, demonstrating the importance of multi-factorial intervention program to see improvements in overall balance.

**Impact on Bone and Joint Health.** Osteoporosis, a disease characterized by low bone mass and micro-deterioration of bone tissue (2), is increasingly common with advancing age. Bone loss and structural damage lead to bone fragility. This increase in skeletal fragility, along with a rise in fall risk, results in an increased susceptibility to fractures with aging known as ‘fragility fractures’ (27). One of the major risk factors for fragility fracture is low bone mass (27). In the current clinical practice setting, the

identification of low bone mass in an older patient without a personal history of fragility fracture is usually based on measurement of bone mineral density (BMD). The World Health Organization defines osteoporosis as a hip BMD 2.5 or more standard deviations (SD) below the mean for young white adult women (i.e. femoral neck T score  $-2.5$  SD or below using the National Health and Nutrition Examination Survey III referent population of women aged 20–29 years) (41). The prevalence of low bone density in older adults is significant and widespread across all genders, race, and cultural groups. Osteopenia, which is the precursor to osteoporosis, is characterized by a BMD between 2.5 and 1.0 SD below the young adult mean. Since bone strength is defined as its resistance to fracture, and lower bone is related to increased fracture risk, both of these conditions can increase an individual's fall risk (5).

Several training methods have been used to improve bone mineral content (BMC) and BMD in prospective studies. However, not all forms of exercise have the same positive effects on bone mass and because of that the studies that evaluated the role of exercise programs on bone-related variables in elderly people have obtained conflicting results (34). Kelley et al. (42) showed through a meta-analysis that some types of exercise training do not improve femoral neck BMD in postmenopausal women and, recently, in a systematic review and meta-analysis, Nikander et al (64) did not find any significant effects of exercise on bone strength from any training program, which may partly be explained by the short duration and inadequate power of the few published trials. Guadalupe-Grau et al (35) reported that studies performed in older adults show only mild increases, maintenance or just attenuation of BMD losses in postmenopausal women. Nevertheless, other meta-analyses showed very consistently that exercise training program have benefits in both the

lumbar spine and femoral neck in postmenopausal women (43, 96) Moreover, a systematic review found that both impact and non-impact exercises have a positive effect on bone (95) and another recent article by Martyn-St James and Carroll (55) suggested that impact exercise in the form of jogging when combined with other low impact activity, such as stair climbing and walking, and program combining impact exercise with high-magnitude exercise in the form of resistance training, have a positive effect on preserving BMD in postmenopausal women. Thus, it is suggested that each kind of exercise program has different effects on bone mass and risk of fracture in elderly people. Nevertheless, the literature still remains controversial on the topic.

**Future Directions & Conclusions.** Reviewing the literature on strength training and elderly, there are a few significant holes in the research. Most noticeably, there is very limited data specific to very old adults. Most randomized controlled trials focus on older adults with an average age of 55–70 years, so studies detailing fall-related habits of the elderly population are rare. Therefore, no reliable conclusions as to the effect of exercise during senescence can be reported. The majority of the longitudinal studies have been performed in older women due to the importance of maintaining bone health and preventing osteoporosis in this population. As a result, studies accounting for bone health in aging men are few and far between. Future research in this population is necessary to know the potential effects of exercise in this gender and age group.

Although the strongest studies included in this review (and in general scientific literature) are randomized controlled trials, there were also several non-randomized studies. The latter condition may have created self-selection in group assignment of the participants, which is particularly important in exercise trials where individuals may be

more or less predisposed, or motivated, to participate in exercise research. And lastly, the relatively short term of some of the aforementioned strength training trials could possibly mask a positive effect of exercise on bone content.

As stated above, there are several future directions in this area of research. Possibilities for future research proposals include: (a) long-term exercise training programs that allow muscle and bone to adapt to the mechanical stress of training; (b) trials including men and older participants (70+ yrs); (c) trials comparing the influence of sex and age in training response(s); (d) the inclusion of diet parameters as covariates in the analysis; and (e) research, which assesses the effect of detraining after exercise intervention.

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**APPENDIX B:  
INFORMED CONSENT**

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## CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

INVESTIGATOR'S NAME: STEPHEN D. BALL  
PROJECT #: 1209026

STUDY TITLE: ADVANCED STAY STRONG, STAY HEALTHY

### INTRODUCTION

This consent may contain words that you do not understand. Please ask the investigator or the study staff to explain any words or information that you do not clearly understand.

This is a research study. Research studies include only people who choose to participate. As a study participant you have the right to know about the procedures that will be used in this research study so that you can make the decision whether or not to participate. The information presented here is simply an effort to make you better informed so that you may give or withhold your consent to participate in this research study.

Please take your time to make your decision and discuss it with your family and friends.

You are being asked to take part in this study because you are a healthy adult who has completed the Stay Strong, Stay Healthy program and/or have been strength training for six months or longer.

This study is being sponsored by MU Extension.

In order to participate in this study, it will be necessary to give your written consent.

### WHY IS THIS STUDY BEING DONE?

A variety of health promotion interventions have been shown to be effective in maximizing the health and independence of older adults. The most effective programs target the important risk of falls prevention and focus on improving muscle strength, minimize muscle loss and increase strength significantly. Resistive exercise (such as strength training) also improves bone density and helps to minimize osteoporosis. These improvements in muscle and bone help prevent falls and allow older adults to maintain independence and enjoy better quality of life. The purpose of this research is to determine the effectiveness of the MU Extension Advanced Stay Strong, Stay Healthy program at improving muscular strength, flexibility and ultimately risk of falling among older adults.

### How Many People Will Take Part In The Study?

About 20 people will take part in this study

### WHAT IS INVOLVED IN THE STUDY?

If you take part in this study, you will have the following tests and procedures:

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UMC, HS IRB: CONSENT

HS IRB USE ONLY

Approval Date:

Expiration Date:

1 of 6

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#### **Visit 1: Screening and Consent**

Once the consent form has been signed, all participants will be screened to determine if they are eligible to participate. Screening will take place in the Exercise Physiology Lab in McKee Gymnasium and will take 1 hour. During the screening, study personnel will answer any questions the participants may have about the study. Participants will be asked to complete the following forms: participant contact information, physical authorization by a personal physician (where applicable), and a physical activity questionnaire (PAR-Q). Qualified subjects will be scheduled for visit 2 will take place at McKee Gymnasium.

#### **Visit 2: DXA Scan and Pre-Fitness Assessments**

Qualified subjects will come back to McKee Gymnasium for a second visit to complete a dual X-ray absorptiometry (DXA) scan. The DXA scan will require you to lie still for approximately 10 minutes during the procedure. Subjects will be exposed to a small amount of radiation during the scan, equivalent to 1/10th the radiation of a chest X-ray and about 1/1000 of a similar Computed Tomography scan. All study participants will undergo an additional DXA scan following the conclusion of the 10-week program. Subjects will be provided with the results of their scan. If you have any questions about the results, you will need to contact your personal provider. Interpretation of the results of your DXA scan must be performed by a physician.

In addition to demographic data, four fitness outcomes will be evaluated before and after the 10 week program using measures from the Senior Fitness Test (17). Measures include the “chair stand test” assessing lower body strength and muscular endurance; the “8-foot up-and-go” assessing balance and coordination while moving; the “chair sit and reach” assessing lower body flexibility; and the “back scratch” assessing upper body flexibility. Balance will be assessed using a graded balance test.

#### **Visits 3-21: Exercise Intervention**

All exercise training sessions will be conducted at the McKee Gym Fitness Center under the supervision of trained exercise personnel. The class of approximately up to 20 participants will consist of group strength training, balance and flexibility twice a week for ten weeks. Each session begins with a 5 minute warm-up period, followed by two sets of ten repetitions of eight strength exercises including, but not limited to, wide leg squat, standing leg curl, side hip raise, knee extension, biceps curl, overhead press, toe stand, and bent forward fly. Exercises are subject to change and will vary with each individual as needed. Classes end with a 5 minute cool down period including light stretching and balance exercises.

#### **Visit 22: DXA scan and Post-Assessment**

Following the conclusion of the 10 week training period, subjects will repeat the same Senior Fitness Assessment tests and DXA scan. The procedure for this visit will be the same as Visit 2.

A follow up survey will be mailed to the participants 3 months following the 10 week training period. Subjects will not need to schedule a visit to complete this form.

#### **HOW LONG WILL I BE IN THE STUDY?**

You will be in the study for approximately 22 weeks. The study will involve 10 weeks of strength training classes plus a follow-up survey 3 months post-training.

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UMC, HS IRB: CONSENT

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Approval Date:

Expiration Date:

2 of 6

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The investigator and/or your doctor may decide to take you off this study, if in their judgment that it is in your best interest.

**You can stop participating at any time. Your decision to withdraw from the study will not affect in any way your medical care and/or benefits. If you decide to stop participating in the study, you are encouraged to discuss your decision with your doctor.**

### **WHAT ARE THE RISKS OF THE STUDY?**

While on the study, you are at risk for the side effects described below. You should discuss these with the investigator and/or your doctor. There may also be other side effects that we cannot predict. Many side effects go away shortly after the exercise session has ended, but in some cases side effects can be serious or long-lasting or permanent.

Risks and side effects related to the procedures in this study include:

#### **The Dual Energy X-ray Absorptiometry (DXA)**

You will be exposed to a small amount of radiation. The DXA scan is equivalent to 1/10th the radiation of a chest X-ray and about 1/1000 of a similar Computed Tomography scan. Radiation effects are cumulative. You should always inform future doctors of your participation in this study.

**Reproductive risks:** The effects of the DXA on the female or male reproductive systems or on a developing fetus are unknown but could cause harm. For this reason, women of child-bearing age will be excluded from this study to ensure no harm will be done.

#### **Resistance Exercise Training:**

Resistance training may cause musculoskeletal soreness and injury (particularly in the first few exercise sessions) and the possibility of muscle and joint injury as a result of participating in the weight lifting exercises. Participants will be instructed in the safe and proper procedures for all exercise activities and supervised by exercise personnel at all times. All exercise sessions will include warm-up and cool-down procedures to further minimize the risk of injury.

For the reasons stated above the investigator will observe you closely while giving the treatment described and, if you have any worrisome symptoms or symptoms that the investigator or his associates have described to you, notify the investigator immediately. Dr. Stephen Ball's telephone number is 573-268-2696. For more information about risks and side effects, ask the investigator or contact the study coordinator at 573-882-2334.

### **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

If you agree to take part in this study, there may or may not be direct medical benefit to you. You may expect to benefit from taking part in this research to the extent that you are contributing to medical knowledge. We hope the information learned from this study will benefit other patients hoping to improve their muscular strength, flexibility, balance and, ultimately, reduce their fall risk in the future.

### **WHAT OTHER OPTIONS ARE THERE?**

An alternative is to not participate in this research study.

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UMC, HS IRB: CONSENT

**HS IRB USE ONLY**

Approval Date:

Expiration Date:

3 of 6

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Please discuss these and other options with the investigator and your doctor.

#### **WHAT ABOUT CONFIDENTIALITY?**

Information produced by this study will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law. If the investigator conducting this study is not your primary, or regular doctor, he/she must obtain your permission before contacting your regular doctor for information about your past medical history or to inform them that you are in this trial.

Results of this research may be published and reports may be made to government agencies, funding agencies, manufacturers, or scientific groups, but you will not be identified in any such publication report. In addition, the Federal Food and Drug Administration, Health Sciences MU IRB, or other government agencies may inspect and copy your medical records that apply to this research. In all cases, information about you will be treated confidentially.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission.

#### **WHAT ARE THE COSTS?**

There is no cost to you for participating in the study.

All costs for the measurements and procedures that are part of this research study will be paid by the MU Exercise Physiology Laboratory. Your only cost will be traveling to the laboratory on a regular basis.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

#### **WILL I BE PAID FOR PARTICIPATING IN THE STUDY?**

You will receive no payment for taking part in this study.

#### **WHAT IF I AM INJURED?**

It is not the policy of the University of Missouri to compensate human subjects in the event the research results in injury. The University of Missouri, in fulfilling its public responsibility, has provided medical, professional and general liability insurance coverage for any injury in the event such injury is caused by the negligence of the University of Missouri, its faculty and staff. The University of Missouri also will provide, within the limitations of the laws of the State of Missouri, facilities and medical attention to subjects who suffer injuries while participating in the research projects of the University of Missouri. In the event you have suffered injury as the result of participation in this research program, you are to contact the Risk Management Officer, telephone number (573) 882-1181, at the Health Sciences Center, who can review the matter and provide further information. This statement is not to be construed as an admission of liability.

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### **WHAT ARE MY RIGHTS AS A PARTICIPANT?**

**Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate.** If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future care at the University of Missouri. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. In addition, the investigator of this study may decide to end your participation in this study at any time after he has explained the reasons for doing so and has helped arrange for your continued care by your own doctor, if needed.

### **WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

If you have any questions regarding your rights as a participant in this research and/or concerns about the study, or if you feel under any pressure to enroll or to continue to participate in this study, you may contact the University of Missouri Health Sciences Institutional Review Board (which is a group of people who review the research studies to protect participants' rights) at (573) 882-3181.

You may ask more questions about the study at anytime. For questions about the study or a research-related injury, contact the study coordinator at 573-268-2696.

A copy of this consent form will be given to you to keep.

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**Signature**

I confirm that the purpose of the research, the study procedures, the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. I have read this consent form and my questions have been answered. My signature below indicates my willingness to participate in this study.

---

Subject/Patient\*

Date

---

Legal Guardian/Advocate/Witness (if required)\*\*

Date

---

Additional Signature (if required) (identify relationship to subject)\*\*\* Date

\*A minor's signature on this line indicates his/her assent to participate in this study. A minor's signature is not required if he/she is under 7 years old. Use the "Legal Guardian/Advocate/Witness" line for the parent's signature, and you may use the "Additional Signature" line for the second parent's signature, if required.

\*\*The presence and signature of an impartial witness is required during the entire informed consent discussion if the patient or patient's legally authorized representative is unable to read.

\*\*\*The "Additional Signature" line may be used for the second parent's signature, if required. This line may also be used for any other signature which is required as per federal, state, local, sponsor and/or any other entity requirements.

"If required" means that the signature line is signed only if it is required as per federal, state, local, sponsor and/or any other entity requirements.

**SIGNATURE OF STUDY REPRESENTATIVE**

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered questions regarding the study to the best of my ability.

---

Study Representative\*\*\*\*

Date

\*\*\*\*Study Representative is a person authorized to obtain consent. Per the policies of the University of Missouri Health Care, for any 'significant risk/treatment' study, the Study Representative must be a physician who is either the Principal or Co-Investigator. If the study is deemed either 'significant risk/non-treatment' or 'minimal risk,' the Study Representative may be a non-physician study investigator.

**APPENDIX B:  
PROTOCOL**

**STUDY TITLE: ADVANCED STAY STRONG, STAY HEALTHY**

PROJECT #: 1209026

DATE: 09-25-13

VERSION #: 2

**PRIMARY INVESTIGATOR: STEPHEN D. BALL, PH.D**

113 McKee Hall

Columbia MO 65211

Phone: 573.882.2334

Fax: 573.884.4885

**INTRODUCTION**

Among the elderly, an important musculoskeletal disease is the development of sarcopenia, loss of skeletal muscle mass. The declining muscle mass of sarcopenia occurs at the alarming rate of 4-5% per decade (7) and results in impaired quality of skeletal muscle, leading to increased muscle weakness (8). Such weakness is a strong predictor of falls in the elderly, a significant contributor to decreased quality of life and increased morbidity and mortality in this population (5). A variety of health promotion interventions have been shown to be effective in maximizing the health and independence of elderly populations (1). The most effective of these programs target the important risk of falls prevention and focus on improving muscle strength (3). These programs include resistive exercise, that is, strength training, which help attenuate muscle loss and increase strength significantly (5). Resistive exercise also improves bone density and helps to minimize osteoporosis (2). These improvements in muscle and bone help prevent falls and allow older adults to maintain independence and enjoy better quality of life.

Minimal follow-up has been done to assess the outcomes of clinical trials that are implemented in general community practice. Additionally, the efficacy of this community based and Extension delivered program has not been evaluated. The goal of this research is to validate the effectiveness of the Advanced SSSH program implemented by Extension professionals across the state of Missouri.

**RISKS**

Throughout the study, participants are at risk for the side effects described below. Participants should discuss these with the investigator and/or their doctor. There may also be other side effects that we cannot predict.

**The Dual Energy X-ray Absorptiometry (DXA)**

Participants will be exposed to a small amount of radiation. The DXA scan is equivalent to 1/10th the radiation of a chest X-ray and about 1/1000 of a similar Computed Tomography scan. Radiation effects are cumulative. Participants should always inform future doctors of their participation in this study.

Reproductive risks: The effects of the DXA on the female or male reproductive systems or on a developing fetus are unknown but could cause harm. For this reason, women of child-bearing age will be excluded from this study to ensure no harm will be done.

### Resistance Exercise Training:

Resistance training may cause musculoskeletal soreness and injury (particularly in the first few exercise sessions) and the possibility of muscle and joint injury as a result of participating in the weight lifting exercises. Participants will be instructed in the safe and proper procedures for all exercise activities and supervised by exercise personnel at all times. All exercise sessions will include warm-up and cool-down procedures to further minimize the risk of injury.

### **BENEFITS**

If participants agree to take part in this study, there may or may not be direct medical benefits to the participant. Subjects may expect to benefit from taking part in this research to the extent that they are contributing to medical knowledge. We hope the information learned from this study will benefit other patients in the future looking to improve their muscular strength, flexibility, balance and, ultimately, reduce their fall risk.

Other benefits include participating in a supervised exercise program and body composition analysis.

Subjects may also acquire additional benefits of exercise not describe herein.

### **TRIAL OBJECTIVES AND PURPOSE**

The specific aims of this project will include the following:

*Specific Aim 1:* To validate the effectiveness of the MU Extension Advanced Stay Strong, Stay Healthy program through improvements in muscular strength, flexibility, and ultimately, decrease the risk of falling among seniors.

### **STUDY DESIGN**

*Primary endpoints:* Significant improvements in muscular strength, flexibility, body composition and decreased risk of falls after 10 weeks of strength training using the Senior Fitness Assessments as clinical markers.

#### *Subject Recruitment:*

Participants will be recruited via flyers, word of mouth, and advertisement through the University of Missouri campus organization Healthy for Life. Approximately 20 people will participate in this study. Because this is an organized exercise class with potential research implications, we are only allowing the class to have a maximum of 20 participants to maintain high quality individualized care.

### **Visit 1: Screening and Consent**

Once consent has been obtained, all participants will be screened to determine if they are eligible to participate. Screening will take place in the Exercise Physiology Lab in McKee Gymnasium and will last approximately 1 hour. During the screening, study personnel

will answer any questions the participant may have about the study and will complete the following forms: participant contact information, participant consent, physical authorization (where applicable), and a physical activity questionnaire (PAR-Q). Qualified subjects will be scheduled for visit 2 which will take place at McKee Gymnasium.

### **Visit 2: DXA Scan and Pre-Fitness Assessments**

Qualified subjects will come back to McKee Gymnasium for a second visit to complete a DXA scan. The DXA scan will require subjects to lie still for approximately 10 minutes during this procedure. Subjects will be exposed to a small amount of radiation during the scan, equivalent to 1/10th the radiation of a chest X-ray and about 1/1000 of a similar Computed Tomography scan. All study participants will undergo an additional DXA scan following the conclusion of the 10-week Advanced SSSH program. Subjects will be provided with the results of their scan. If subjects have any questions about the results of their scan, they will need to contact their family practitioner. Interpretation of the results of the DXA scan must be performed by a physician.

In addition to demographic data, four fitness outcomes will be evaluated pre and post the 10 weeks of strength training using measures from the Senior Fitness Test (6). Measures include the “chair stand test” assessing lower body strength and muscular endurance; the “8-foot up-and- go” assessing balance and coordination while moving; the “chair sit and reach” assessing lower body flexibility; and the “back scratch” assessing upper body flexibility. Balance will be assessed using a graded balance test (4). These tests will be repeated following the 10-week training period.

### **Visits 3-22: Exercise Intervention**

All exercise training sessions will be conducted at McKee Gymnasium under the supervision of trained exercise personnel. The class of approximately 10-20 participants will consist of group strength training, balance and flexibility twice a week for ten weeks. Each session begins with a 5 minute warm-up period, followed by two sets of ten repetitions of eight strength exercises including, but not limited to, wide leg squat, standing leg curl, side hip raise, knee extension, biceps curl, overhead press, toe stand, and bent forward fly. Exercises are subject to change and will vary with each individual as needed. Classes end with a 5 minute cool down period including light stretching and balance exercises.

### **Visit 23: DXA scan and Post-Assessment**

Following the conclusion of the 10 week training period, subjects will repeat the Senior Fitness Tests and DXA scan. The procedure for this visit will be the same as Visit 2.

A follow up survey will be mailed to the participants 3 months following the 10 week training period. Subjects will not need to schedule a visit to complete this form. All data will be coded and not include the participants name.

## Visit Information

A. Number of total visits  
23 visits

B. Frequency of visits:  
Two days per week

C. Length of visits:  
60-75 minutes

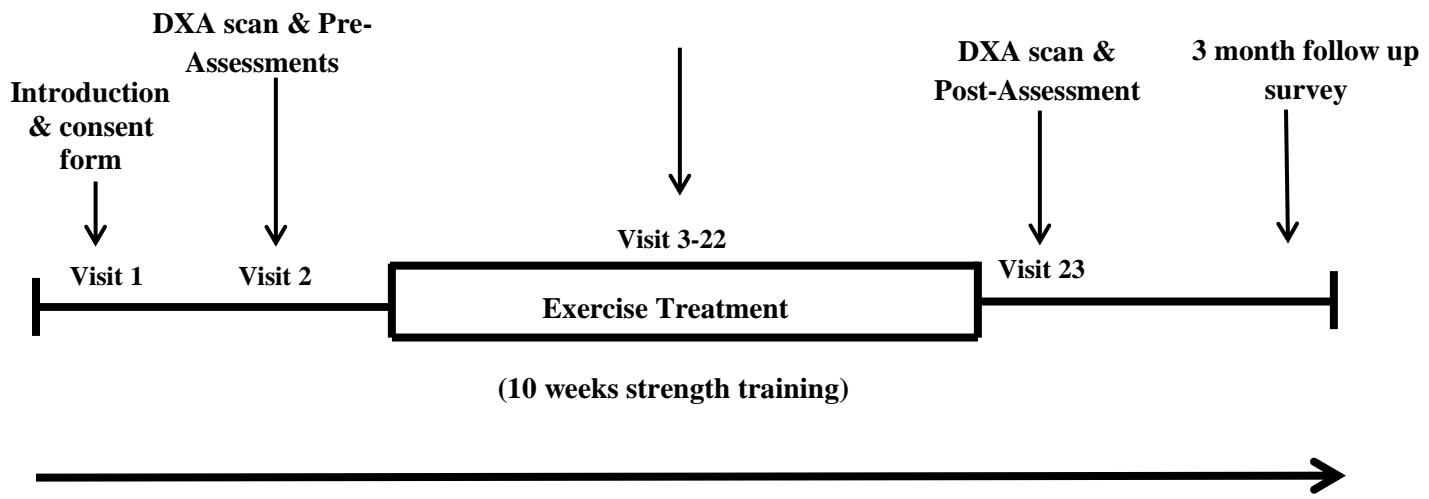


Figure 2. Experimental Design

**Table 1. Senior Fitness Assessments**

<b>Physical Performance Test</b>	<b>Purpose</b>	<b>Description</b>
30-second chair stand*	Assess lower body strength	Number of full stands that can be completed in 30 seconds with arms folded across chest
Chair sit-and-reach left and right*	Assess lower body flexibility	Distance in centimeters between extended hand and toes when seated at edge of chair with leg extended; Negative number indicates inability to reach toes.
Back scratch left and right*	Assess upper body flexibility	Distance in centimeters between one hand reaching over shoulder and second hand reaching up the middle of the back
8-foot up-and-go*	Assess agility/dynamic balance	Number of seconds required to get up from a seated position, walk 8 feet, return to seated position
Balance tests performed in order of difficulty 1. Mountain pose 2. Tandem stand 3. One-legged stand 4. Tandem stand eyes closed 5. Tandem stand eyes closed head turning 6. One-legged stand eyes closed	Sequentially assess balance	1. Ability to stand for 10 seconds with feet side by side and touching, without using hands for support 2. Ability to stand for 10 seconds with heel of one foot touching toe of other foot, one hand touching wall for support. 3. Ability to stand for 10 seconds on one leg 4. Same as mountain pose with eyes closed 5. Same as tandem stand with eyes close with head turning slowly left and right 6. Same as tandem stand except eyes closed

## **COMPLIANCE STATEMENT**

*This research will be conducted in compliance with the protocol, Good Clinical Practice (GCP), and the applicable regulatory requirement(s).*

## **SELECTION CRITERIA**

Inclusion criteria will include the following:

1. Subjects must be middle-aged or older adults (ages 50-85) who have completed the Stay Strong, Stay Healthy program and/or have been strength training for 3 months or longer.

Exclusion criteria will include the following:

1. Women of child-bearing potential

## **Subject withdrawal criteria and procedures specifying:**

- a. When and how to withdraw subjects from the trial / investigational product treatment.

*If the participant is unable to make 60% of the scheduled exercise sessions, we will have to withdraw the participant from the study.*

*If subjects are unable to complete the assigned exercises, we will have to withdraw the subject from the study.*

- b. The type and timing of the data to be collected for withdrawn subjects.  
*All data collected from subjects will be recorded and locked in the office of the primary investigator.*
- c. Whether and how subjects are to be replaced.  
*To replace a withdrawn subject, we will recruit another one through email and flyer advertisements.*
- d. The follow-up for subjects withdrawn from investigational product treatment/trial treatment.  
*There will be no follow-up for withdrawn subjects.*

## **TREATMENT OF SUBJECTS**

Participants will remain in the lab during most of the testing procedures to assure compliance. All exercise sessions will be supervised by trained exercise personnel. Testing will stop and the IRB will be notified immediately in case of adverse event and current illnesses. The participants will be contacted via phone to determine if they have recovered from their adverse event.

## **STATISTICS**

Statistical analyses will be performed using the IBM SPSS statistical software version 20 (IBM Corporation, Armonk, NY, USA). Descriptive statistics will be generated and matched pair T-tests will be used to compare differences in measures of the physical indicators of strength, flexibility, and balance. Two-way analysis of variance (ANOVA) will be conducted to examine the gender and age effects on the increments in measures of the physical indicators of strength from pre to post assessments in the Senior Fitness Tests. Significance will be set at  $P \leq 0.05$ .

The level of significance to be used:  $P \leq 0.05$

## **REFERENCES**

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**APPENDIX C:**  
**DATA COLLECTION FORMS**



## PAR-Q: PHYSICAL ACTIVITY READINESS QUESTIONNAIRE

Regular exercise is associated with many health benefits, yet any change of activity may increase the risk of injury. Completion of this questionnaire is a first step when planning to increase the amount of physical activity in your life. Please read each question carefully and answer every question honestly:

Yes	No	1) Has a physician ever said you have a heart condition and you should only do physical activity recommended by a physician?
Yes	No	2) Do you feel pain in your chest when you do physical activity?
Yes	No	3) In the past month, have you had chest pain at a time when you were not doing physical activity?
Yes	No	4) Do you ever lose consciousness or do you lose your balance because of dizziness?
Yes	No	5) Do you have bone or joint problems (back, knee or hip) that may be made worse by a change in your physical activity?
Yes	No	6) Is a physician currently prescribing medications for your blood pressure or heart condition?
Yes	No	7) Are you 69 years of age or older?
Yes	No	8) Do you know of any other reason you should not exercise or increase your physical activity?

If you answered "yes" to any of the above questions, talk with your doctor **before** you become more physically active. Tell your doctor your intent to exercise and to which questions you answered "yes."

If you honestly answered "no" to all questions, you can be reasonably positive that you can safely and **gradually** increase your level of physical activity.

Note: This PAR-Q is valid for a maximum of 12 months from the date it is completed. If at any time your medical condition changes, you must complete a new PAR-Q and the previous one becomes invalid.

Participant signature\_\_\_\_\_ Date\_\_\_\_\_

Stay Strong, Stay Healthy



UNIVERSITY OF MISSOURI  
**Extension**

***Advanced Stay Strong, Stay Healthy Program  
Physician Authorization Form***

Patient Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Phone Number: \_\_\_\_\_

\_\_\_\_\_ Yes, my patient can participate.

\_\_\_\_\_ Yes, my patient can participate with the following limitations:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_ No, my patient cannot participate at this time due to his/her medical conditions and health status.

Physician's Signature: \_\_\_\_\_

Print Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Phone Number: \_\_\_\_\_ FAX Number: \_\_\_\_\_

This form may be given to patient, faxed, or scanned and returned back to:

**Emily Crowe  
Room 106 McKee Gymnasium  
Columbia, MO 65211  
Phone: 573-228-3808  
Fax #: 573-884-4885  
Email: [emcdkc@mail.missouri.edu](mailto:emcdkc@mail.missouri.edu)**

Please return this form by: \_\_\_\_\_



**Participant Contact Information**

Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

County: \_\_\_\_\_ Daytime phone number or cellphone: \_\_\_\_\_

Email: \_\_\_\_\_

Age and year of birth: \_\_\_\_\_ Gender: \_\_\_\_\_

Program site: \_\_\_\_\_ Start date: \_\_\_\_\_

**In case of emergency, please call:**

Name: \_\_\_\_\_ Relationship: \_\_\_\_\_

Phone number: \_\_\_\_\_ OR

Name: \_\_\_\_\_ Relationship: \_\_\_\_\_

Phone number: \_\_\_\_\_

**Follow-up survey:**

Are you willing to participate in a three-month follow-up survey?  Yes or  No

If yes, do you prefer that the survey is sent via e-mail?  Yes or  No, please send via mail

If yes, please provide e-mail address: \_\_\_\_\_

University of Missouri Extension wants to make sure that we are presenting our programs to a wide range of participants. This information is voluntary and confidential and will be used to identify our audiences in general.

**Race**

- American Indian/Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Islander
- White
- Two or more races/Other
- Unknown

**Hispanic**

- Yes
- No

**Veteran status**

- Non veteran
- Veteran
  - Vietnam Veteran
  - Other

**Disabled**

- Yes
- No

**I need to tell you...**

Here's where you can put any pertinent comments that you think I need to know.

Adapted From  
The StrongWomen Program  
A National Fitness Program for Women



John Hancock Center for Physical Activity and Nutrition  
Friedman School of Nutrition Science and Policy  
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## Advanced Stay Strong, Stay Healthy Fitness Assessment



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Assessments	Pre	Post
<b>Chair Stand</b> (No. of Stands in 30 sec.)		
<b>Chair Sit/Reach</b> (No. of in. +/-)	R	
<b>Back Scratch</b> (No. of in. +/-)	L	
<b>8-Foot Up-&amp;-Go</b> (No. of seconds)	R	
<b>25 Foot Walk Test</b> (No. of seconds)	L	

Name \_\_\_\_\_

Age \_\_\_\_\_ M \_\_\_\_\_ F \_\_\_\_\_

Location: \_\_\_\_\_

Pre Assessment Date: \_\_\_\_\_

Post Assessment Date: \_\_\_\_\_

Balance Tests Record the time in seconds. If participant cannot complete a test for 10 seconds, do not proceed to the next test.	Pre	Post	If the highest test you could pass was:	Your Balance is considered:
Mountain Pose (seconds)			Unable to pass any test	Very Poor
Tandem Stand (seconds)			Test 1: Tandem stand	Poor (challenging for frail 80-90 year olds)
One-Legged Stand (seconds)			Test 2: One-legged stand	Fair (expectation for 50-80 year olds)
Tandem Stand w/eyes closed (seconds)			Test 3: Tandem stand with eyes closed	Good (expectation for healthy 35-50 year olds)
Tandem Stand w/eyes closed & head turning (seconds)			Test 4: Tandem stand with eyes closed/head turning	Very Good (expectation for <35 year olds)
One-Legged Stand w/eyes closed (seconds)			Test 5: One-legged stand with eyes closed	Excellent (expectation for fit <35 year olds)

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## Stay Strong, Stay Healthy Program Feedback

**Name of Instructor:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Location:** \_\_\_\_\_

**Personal Information: Gender:** M \_\_\_\_\_ F \_\_\_\_\_

**Age:**  <40       40-50       51-60       61-70       71-80       81-90       over 90

1) Hand Weights Currently Using (lbs):  0     1-4     5-7     8-10     11 or more  
2) Ankle Weights Currently Using (lbs per ankle):  0     1-2.5     3-5.5     6-8.5     9 or more

3) Overall, were you satisfied with the class? \_\_\_\_\_ Not at all \_\_\_\_\_ Somewhat \_\_\_\_\_ Very much

4) Was your instructor helpful? \_\_\_\_\_ Not at all \_\_\_\_\_ Somewhat \_\_\_\_\_ Very much

**5) After participating in "Stay Strong"....**

....do you feel that your health is better because of the program? \_\_\_\_\_ Yes \_\_\_\_\_ No  
Comments:

...do you feel physically stronger? \_\_\_\_\_ Yes \_\_\_\_\_ No  
Comments:

...do you feel that you have more energy? \_\_\_\_\_ Yes \_\_\_\_\_ No  
Comments:

...do you sleep better? \_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_ Not an issue for me  
Comments:

...are your joints any less painful? \_\_\_\_\_ Yes \_\_\_\_\_ No \_\_\_\_\_ Not an issue for me  
Comments:

...do you feel more flexible? \_\_\_\_\_ Yes \_\_\_\_\_ No  
Comments:

6) Have you added any other physical activities to your weekly schedule (i.e., walking, water aerobics, PACE, etc.)? \_\_\_\_\_ Yes \_\_\_\_\_ No  
Examples:

7) Since beginning this program, have you purchased weights or do you currently own weights?

\_\_\_\_\_ Yes \_\_\_\_\_ No

8) In addition to doing the exercises in class, did you perform the strength training exercises at home?

\_\_\_\_\_ Yes; if answered yes, how many more times per week? \_\_\_\_\_

\_\_\_\_\_ No additional times, I just did the exercises during class.

9) How confident are you that you will be able to continue the strength training exercises you have been learning the past few weeks?

very confident     confident     somewhat confident     not confident

10) How did you hear about the Stay Strong, Stay Healthy program?

- from a friend, family member, or coworker
- Stay Strong, Stay Healthy website
- newspaper ad
- flyer
- other

11) What prompted you to enroll in the Stay Strong, Stay Healthy program? (Check all that apply)

- needed to improve strength & balance
  - reduce risk for osteoporosis
  - social interaction of a group motivates me to exercise
  - less intimidating than a fitness center or exercise gym
  - don't have access to any other way to improve my strength
  - affordable, the price was right
  - other
- 

12) Would you recommend this program to anyone else?  Yes  No  
 Unsure

13) Before I participated in this program, my knowledge skills, or understanding was

None     A little     Some     A lot     A great deal

14) After I participated in this program, my knowledge, skills, or understanding was

None     A little     Some     A lot     A great deal

15) Please share two (2) ways this program has improved your life:

16) How could this program be improved?

17) Additional comments are welcome:

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