PENNSTATE

HRP-591 - Protocol for Human Subject Research

Protocol Title:

Patient Centered Exercise Coaching into Primary Care

Short title: Working to Increase Stability through Exercise (WISE) Study

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1.0 Objectives

1.1 Study Objectives

AIM 1. To compare the effectiveness of exercise coaching with enhanced usual care in reducing serious fall-related injuries (SFRI), including fragility fractures from a fall, among older adults with a prior fragility fracture. We hypothesize that 13% of control subjects will experience a SFRI versus 7% of exercise subjects after the 36 months.

AIM 2. To compare the effectiveness of exercise coaching versus enhanced usual care on other patient-centered outcomes (loneliness, physical function, muscle strength, bone density, and muscle mass) that patients told us they were interested in. We hypothesize that exercise coaching will significantly improve each of these outcomes.

AIM 3. To examine heterogeneity of treatment effects (HT-1) with regard to key participant factors (age, gender, race, ethnicity, osteoporosis medication use, intervention engagement, patient choice of exercise location – in-home v. community). We hypothesize that sub-groups can be identified for whom a particular intervention approach is most effective, to help inform patient-, provider- and key stakeholder decision makers. Of note, many of these subgroup analyses are not fully powered, particularly given the reduction in sample size from the original 2100 to the modified 1130. There is, as a result, less than 80% power to detect significant differences for most of these subgroup analyses. These analyses will, however, suggest where differences lie that can be further evaluated in future studies.

1.2 Primary Study Endpoints

Serious Fall-Related Injuries (SFRI), including Fragility Fractures from a fall

To identify our main outcome (SFRI, including FF), we will collect main outcome data every 4 months and during the assessment (12, 24, 36 months) using a fall calendar to record all fall events (e.g., date, location). This will help participants to recall falls during the 4 month period. Subjects will be asked, for example, *"Have you fallen in the past 4 months (or since last contact)? Were you injured in any fall in the past 4 months (or since last contact)?" "Did you land on the floor, ground or other lower level when you fell?" "When you fell, did you break or fracture a bone? or "Were you told by a doctor, or other health professional "*. For any new events, the circumstances regarding the incident (i.e., what occurred) will be recorded for use in adjudicating whether the injury was related to a FF (i.e., "low-trauma" or fall from standing height or less). The dates of injuries and the name of the institution will be recorded, so that medical records can be sought using the authorization form signed by all patients at baseline.

For any SFRI (including FF) or hospitalization/ED visits noted quarterly or during the 12, 24 or 36 months assessment, medical records will be obtained, including outpatient notes, emergency department notes, hospital discharge summary reports and radiologic notes. These records will be collected and presented, blinded to treatment condition, 14 days before the monthly meeting to the Outcomes Committee (Jan De Beur-Chair, Jonson, Fox, Stewart, Greenspan). For each event, the Outcomes Committee will be charged with determining whether it was 1) a fracture related to a fall from standing height or less, 2) a non-traumatic fracture not related to a fall, 3) a serious fall related injury without a fracture, 4) a traumatic fracture (e.g., MVA) , 5) a non-serious fall related injury, or 6) none. A vote is made for each event. If there is not agreement, if will be opened for discussion and another vote. If

consensus is not possible, the case will be presented to Dr. Jan De Beur for final adjudication, given her vast experience with this process (34, 77, 78).

We will additionally request permission from subjects to access their claims through RESDAC or a similar company and PaTH network. This will allow for comprehensive collection of data for our primary outcome. We will need the participant's health insurance claim (HIC) number for RESDAC.

1.3 Secondary Study Endpoints

Self-Reported Falls and Fall-Related Injuries: We will examine the number of falls, and fall-related injuries using two questions from the Behavioral Risk Factor Surveillance System (BRFSS) at baseline, and using the STRIDE questionnaire for all 4-month follow-up assessments (34).

Self-Reported Health, Physical Function, Fatigue, Pain, Sleep Disturbance, Ability to Participate in Social Roles and Activities, Depression, Anxiety, Loneliness: We will use 33 self-reported questions to assess key patient centered outcomes that the intervention may improve: self-reported health (1 question), depression (4 questions), anxiety (4 questions), physical function (4 questions), ability to participate in social roles and activities (4 questions), fatigue (4 questions), pain (5 questions), sleep disturbance (4 questions), ability to participate in social roles and activities and loneliness (3 questions). We will use depression, anxiety, fatigue, pain, sleep disturbance and physical function scales from the NIH-supported Patient Reported Outcomes Measurement Information System (PROMIS). We will also use the single-item measure of self-reported health, which is strongly predictive of many health outcomes (37, 38). We will use a 3-item loneliness questionnaire which has high 12-month test-retest reliability (r = 0.73)(39) and is predictive of future functional decline and death (40). To assess physical function, we will use the 4-item PROMIS measure of physical functioning that includes ability to *walk*, *do chores*, *run errands* and *go up and down stairs*, key physical functions. Dr. Joshua Smyth, a clinical psychologist and Professor at Penn State with experience in clinical trials to improve anxiety and depression (41-44), will oversee the analysis of these survey results.

Body composition: Bone Mass, Muscle Mass, Bone architecture: Body composition will be determined by dual energy X-ray absorptiometry (DXA) as done in routine clinical care and overseen across sites by the Body Composition Core (BCC) chaired by Dr. Kerry Stewart, who has decades of experience with these measures (35, 36). Measurements are taken with the subject in a supine position. Scans will be analyzed using the adult medium mode for all subjects. Phantom calibration will be performed before each scan. For densitometry, bone mineral content (BMC, g) and bone area (BA, cm^2) are measured for the total body, lumbar spine (L1–L4), and total hip (sum of the average femur neck, trochanteric region and proximal femoral shaft from dual-sided measurements). BMD ($g\ m^2$) is calculated from the BMC and BA. Total body soft tissues in terms of muscle (lean) mass and fat mass are also measured for total and regional body composition (35, 36). A major effort of the BCC will be to assure data comparability by site and to quickly create the reports for PCPs.

Sociodemographics and Medical History: We will measure age, gender, race and ethnicity, smoking status, education and the prevalence of common chronic conditions (i.e., osteoarthritis, osteoporosis) using questions from the Behavioral Risk Factor Surveillance System (BRFSS)(46-49).

Blood Pressure and Heart Rate: Blood pressure and heart rate will be measured by the study research coordinator.

Height and weight:

For Group leaders we will collect self-reported height and weight. These will be collected during baseline and at 36 months assessments.

For participants we will use height and weight to calculate Body Mass Index (BMI) using standardized procedures. We will use a portable, calibrated stadiometer and scale with high reliability (r =0.96) (50) as in Dr. Sciamanna's ongoing study.

Fear of Falling: We hypothesize that the intervention will reduce fear of falling as a mediator to increasing physical activity. We will use the 7-item version of the Falls Efficacy Scale International (FES-I), which has high test-retest (r=0.80) reliability and is strongly associated with future falls and depression (p<.001)(51).

Osteoporosis and Other Medications: At baseline, past osteoporosis medication use will be obtained and, at the 36 month assessments, patients will be asked for their current list of medications.

30 Second Chair Stand Test: At baseline and the 36 month follow-up the participants will perform the 30 second chair stand test. This will be used as a measure of functional lower extremity strength.

30 Second Arm Curl Test: At baseline and the 36 month follow-up the participants will perform the 30 second arm curl test. This will be used as a measure of functional upper extremity strength.

Cognition Screener: Six-item Callahan screener

Physical Activity Survey: We will use the NHIS physical activity questions (6 questions) at baseline and 12, 24, and 36 month follow-ups to measure participants' activity level. The survey identifies patients that are sedentary, moderately active, or very active.

Social domain – caregiver: We will use two questions from the AARP Caregiver Identification Study, February 2001 at baseline and 36-month follow-up. We will be able to identify whether the patient is a caregiver or not.

Additional self-reported questions: We will have participants answer the following 16 questions on chronic conditions, recent healthcare utilization, medical devices, hospital admissions, transportation, health insurance, home care, and nursing home/rehab facility stay.

Virtual Short Physical Performance Battery (VSPPB): The vSPPB is a novel self-report measure that uses computer animation to present the physical tasks in the SPPB. We will send 12 questions via email at the Month 36 Visit to all participants with an email address.

2.0 Background

2.1 Scientific Background and Gaps

Fall-related fractures due to osteoporosis are a leading cause of death and disability. Fragility fracture (FF), typically fractures due to falls of standing height or less in adults with osteoporosis, are a devastating consequence of aging. Scientific advances have greatly increased lifespan and reduced the need for physical activity, producing seniors with less bone and muscle than ever before. Nearly half of women suffer a FF over their lifetime and there are approximately 1.8 million FF each year, including 300,000 hip fractures (1). Hip fractures increase the risk of death 6-fold over 3 months (2), lead to

140,000 nursing home admissions per year (3) and leave 60% unable to ever walk 10 feet without assistance (4). This matters because seniors are far more fearful of losing their independence even than dying (5).

The declining use of bisphosphonates, a key treatment for preventing FF, suggests that new options are needed. Between 2007 and 2012, the number of prescriptions filled for bisphosphonates fell by 50% (6), despite the 2008 expiration of the patent for Fosamax (alendronate). A key reason for decreasing use of these medications is their common (e.g., GI upset) and rare (e.g., osteonecrosis of the jaw) adverse effects (7). Though newer treatments exist, most are expensive and, in the case of Forteo (teriparatide), carry a black box warning about osteosarcoma risk (8). In all, this suggests that patients and providers need new treatment options to reduce the risk of FF.

Exercise programs with coaching appear to reduce FF, however, no large-scale effectiveness studies exist (RQ-1). This type of coaching support is not reimbursed by insurance today, even in programs like Silver Sneakers (11-15). Only a large-scale pragmatic trial, such as proposed, can answer the key question to inform coverage decisions: "If a doctor recommended a coach-supported exercise program, would it reduce fractures and fall-related injuries?"

Coaching interventions are effective and growing, but have not been tested to reduce fractures. Due to the ACA, the market for care management is expected to grow from $8.3 to $26.4 billion by 2018 (117). While care management companies offer telephone lifestyle counseling, none offer what is proposed here. Interviews with FF patients for this proposal, however, suggest that patients and their caregivers: "It would be nice to have that person once a week come over, make a little report and tell her her progress. It was such a help at that time…" and "I would want help explaining the exercises to me, because I'm afraid of falling." If this study proves effective, Health Dialog (Project Partner) has agreed to consider offering it as a new service, and we have activities planned to encourage other care management companies to do the same.

2.2 Previous Data

A 2012 Cochrane review identified six efficacy trials (n=804) and observed a pooled 64% reduction in fracture risk from these exercise programs (9). Each of the six interventions included a combination of strength, aerobic, and balance exercises plus an individual who played a coaching roll (10), working closely with subjects to encourage adherence and help overcome barriers to participation. A great number of clinical trials for exercise promotion (e.g., LIFE Trial) have included "coaching," typically from a research assistant (16) being integrated into medical care, due to financial incentives for population health management in the Affordable Care Act (ACA)(18). Health Dialog is one of the largest US companies doing this coaching, also called "care management." In 2010, Health Dialog completed a randomized trial of 174,120 subjects, published in the *New England Journal of Medicine*, showing that telephone care management reduced hospitalizations (19).

2.3 Study Rationale

Physicians and patients need options for preventing the consequences of osteoporosis. The most feared complication of osteoporosis is a fragility fracture (FF), which often precipitates disability, nursing home admission and death (2, 3). The need for treatment options is exacerbated by the striking reduction in use of bisphosphonates, due to fear of adverse events, leaving many patients untreated. In addition, two of the top 100 Priority Topics for Comparative Effectiveness Research from the Institute of Medicine are relevant to this question: "*Compare the long-term effectiveness of weight-bearing exercise and bisphosphonates in preventing hip and vertebral fractures in older women with osteopenia and/or*

osteoporosis" and "*Compare the effectiveness of primary prevention methods, such as exercise and balance training, versus clinical treatments in preventing falls in older adults at varying degrees of risk.*"

The $30 Million PCORI-funded falls prevention trial tests a different, yet complementary, intervention. PCORI is now conducting a 6000-person study of a falls care manager to reduce fall-related injuries, by focusing on using therapy services (e.g., vision, PT/OT). This is very different – yet complementary – to the 450 hours of exercise programming supported by 90 exercise coaching contacts in the study proposed here. Another difference is that exercise coaching has the potential to improve a key patient-centered outcome – loneliness – through the use of group-based exercise. The difference between the interventions can be seen in the proposed effect size. The PCORI falls care manager trial requires 6000 seniors to detect an effect on fall-related injury, though the study we propose needs only 2000 seniors, as the studies show that exercise interventions supported by a coach reduce fractures by 2/3 (9). If both studies prove effective, it will provide seniors with two complementary choices. Patients may benefit from such therapy services before or during exercise coaching, to overcome barriers to exercise.

Policy changes are best informed by large-scale effectiveness trials. Medicare currently pays for cardiac rehabilitation, which took years and numerous large-scale studies to provide sufficient evidence to allow its approval. There is no other common disease complication that appears to be more preventable with physical activity than FF, yet the evidence is based solely on six small studies (total N=810) (9). This study has been designed, from the beginning, to inform policy decisions by 1) being large enough to impact a key clinical outcome (FF) that patients care deeply about, 2) adhering to pragmatic trial design principles (31) and 3) involving a care management provider (Health Dialog), so that the findings can be rapidly disseminated as a service offered to health plans and Accountable Care Organizations (ACOs).

There will be three organizations (Penn State Hershey, University of Pittsburgh, and Temple University) that will carry out identical intervention procedures, including participant recruitment, DXA scans, stakeholder engagement, recruiting community sites, training group leaders, implementation planning with the PCPs, intervention delivery, outcomes assessment, and provision of feedback to the referring physicians. Each site is recruiting a different number of subjects, based on the difference in the populations seen at those centers (e.g., Temple is the lowest, UPMC is the highest). No patients will be enrolled at Johns Hopkins.

Johns Hopkins University will contribute two Co-Investigators, Dr. Kerry Stewart, Dr. Suzanne Jan De Beur. They will be involved in various leadership committees and managing the DXA data. They will not see subjects though will have access to *Protected Health Information* (PHI).

Additional coordination and oversight by Penn State Hershey:
The Penn State research staff include a "Core" group, including the study's Principal Investigator, Project Manager, and Exercise Physiologist. Each research site (Penn State Hershey, Pittsburgh, Temple) has a Site Principal Investigator, Site Project Manager, and one or more Exercise Coaches. The Core Project Manager is responsible for overseeing all Site Project Managers. The Core Exercise Physiologist is responsible for overseeing all Exercise Coaches.

The lead investigative team (which includes the core Principal Investigator (PI), core project manager, core exercise physiologist, all site PIs – from Penn State, Pittsburgh, Temple, and Johns Hopkins – and all site project managers, meet on a weekly basis. Site PIs will review and update the core PI on the study's progress at their site. Each quarter, the core project manager will visit or remotely monitor each of the research sites (Pittsburgh and Temple) to audit a set number of research files, for completion and accuracy. The core project manager will also audit a number of phone interviews and a number of face

to face meetings between research staff and participants to assure that protocols are being followed equally across sites.

In addition to the core project manager, the core exercise physiologist will perform travel visits at all three locations (Pittsburgh, Temple, and Penn State) to oversee the exercise intervention, and will work closely to the coaches at each research institution. Table 1 clarifies the group leaders and coaches' responsibilities.

Table 1. Group leaders vs coaches responsibilities.

Person	Responsibilities
Group Leader	Lead exercise class
Exercise Coach	Phone calls to participants Exercise prescription/modification Data entry/tracking Supervise/observe group leaders

To prevent any confusion during this review, we have decided to define our study subjects (Table 2).

Table 2. WISE Study Subjects

Subjects	Description
Participants	Individual 65 years or older who have had a fragility fracture in the past 10 years
Group leader	Members of the community who are willing to lead exercises at least once a week.
Community members	Members of the community who would like to participate in the exercise program but will not have access to exercise coaching.
Spanish Speaking Interview Group	Members of the community who are willing to participate in an individual interview and provide feedback to study staff regarding the Spanish version of the program

The recruitment for the exercise site locations are already approved under the quality improvement project, "Peer-led Strength Training Program for Older Adults", IRB# 40418NR.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

Group Leaders

- ≥ 21 years old
- Fluently read and speak English
- Willing to lead sessions three times a week for most weeks for the next 36 months or to the end of the study, whichever comes first

Participants

- ≥ 65 years old
- Previous Fragility Fracture (FF) in past 10 years.
- Able to speak and understand English.
- Patients will need to be willing to try exercising and agree to annual follow-up measurements

Community Members

- Able to speak and understand English.
- ≥ 18 years old

Spanish Speaking Interview Group

- Fluently read and speak Spanish
- ≥65 years old

3.2 Exclusion Criteria

Group Peer Leaders

- If the group leader's blood pressure reading is ≥180 systolic or ≥110 diastolic OR heart rate is ≥ 120 bpm
- If the answer to the following questions are "yes", we will exclude the participant from the study
  - Have you ever been told by a health professional that you should not exercise OR exercise only when supervised by a professional?
- Unable to walk 100 feet without using any special equipment, such as a walker, or a wheelchair
- Unable to obtain PCP's consent
- If they answer "NO" to the following question
  - Is it OK if we contact your PCP?
- Plans to move in the next 36 months
- Pregnant or planning to become pregnant in next 36 months
- Currently enrolled in the WISE Study as a participant as defined in section 3.1 of this protocol

Participants

- If the participant's blood pressure reading is ≥180 systolic or ≥110 diastolic OR heart rate is ≥ 120 bpm
- If the answer to the following questions are "yes", we will exclude the participant from the study
  - Have you ever been told by a health professional that you should not exercise OR exercise only when supervised by a professional?
- Unable to walk 100 feet without using any special equipment, such as a walker, or a wheelchair
- Unable to obtain PCP's consent
- If they answer "NO" to the following question
  - Is it OK if we contact your PCP?
- Planning on moving out of the area in the next 36 months
- Has ever participated in the Band Together exercise program
- Positive Callahan cognition screener: If participant fails 2 questions, research coordinator will explain study in detail and ask read-back questions. Exclude participant if failed read-back.
- Participating in research involving strength, balance, or aerobic exercise
- No more than one person per household can participate
- If participant lives in Lebanon County (except Palmyra – zip code 17078)

Community Members

- If the answer to the following questions are "yes", we will exclude the participant from the study
  - Have you ever been told by a health professional that you should not exercise OR exercise only when supervised by a professional?
  - Are you currently enrolled in the WISE study as a participant?
- Unable to walk 100 feet without using any special equipment, such as a walker, or a wheelchair

- Unable to obtain PCP's consent
- If they answer "NO" to the following question
  - Is it OK if we contact your PCP?

Spanish Speaking Interview Group

- Unable to speak or read Spanish
- Currently enrolled in the WISE Study as a control participant as defined in section 3.1 of this protocol
-

Ineligible participants will be asked if they would be interested in being group leaders for the study.

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

It is possible we will withdrawal participants from the study if they become injured and cannot exercise or if they are asked by their Primary Care Provider to suspend exercise. The Principal Investigator reserves the right to remove a participant from the study for any reason, based on their discretion.

3.3.2 Follow-up for withdrawn subjects

If the participant contacts us that they want to withdraw from the study, we will do so at that time. For the Spanish Speaking Interview Group, we will replace subjects who are withdrawn.

4.0 Recruitment Methods

4.1 Identification of subjects

<u>Group leaders</u>

We will be sending letters to churches, community centers, and senior centers to see if they would be willing to serve as an exercise site location for the intervention.
Group leaders will be members of the community; they will be identified by the community sites using personal contacts or an advertisement that can be placed in a common area or newsletter (e.g., church bulletin).

We will work with marketing companies (eg. infoUSA, Lorton Data) to identify potential volunteers that meet our eligibility criteria in the specified zip codes surrounding our community locations to mail recruitment letters. Marketing companies have – on average – more than a thousand points of data about each US citizen (How Your Data Are Being Deeply Mined, AE. Marwick, 2014). We will use them to send letters based on AGE and Zip codes. Marketing companies provide these bulk mailing services for companies across the US. Our goal with using these companies is to identify additional potentially eligible group leaders who might not hear of the study through other means (posting flyers in community locations). We are uncertain about the number of potentially eligible individuals this type of mailing will reach, but it is a cost-effective way to reach a large number of people.

The Penn State Research team will mail a recruitment letter asking potential volunteers to contact us if they are interested in learning more or participating in the research as a Group Leader.

We will work with RSVP (Retired and Senior Volunteer Program) of the Capital Region, Inc. to identify potential group leaders. This volunteer-based organization serves the Central PA region by engaging volunteers 55+ in volunteer positions that have positive impact on the community. Potential Group leaders will be identified by RSVP using flyers or advertisement. For more information about RSVP, please see the following link: http://rsvpcapreg.org/.

Participants

We will use the PaTH Network (one of PCORI's Clinical Data Research Networks) to identify potential subjects within a 25 mile radius of the exercise site locations by conducting queries of electronic health records of each institution for patients with fragility fractures. The PaTH data managers will send a list of patients who meet our eligibility criteria and the research staff will mail the recruitment letters out to the patients.

Matt Bolton, an IT specialist from the Clinical and Translational Science Institute (CTSI), will go into the Penn State Hershey Medical Center's Electronic Health Records (EHR) to pull patients who have had fractures from the year 2005 to present (using ICD codes) and are 65 years old or older. He will also pull patients who have a diagnosis of osteoporosis or osteopenia (using IDC codes) and are 65 years old. He will provide us with the patients' names, mailing address, and phone numbers in order for us to send the recruitment letters. We will do opt-out recruitment; patients can be called unless they let us know not to contact them. In addition, we will ask for the date they were seen by doctor and the doctor's name who saw the patient and assigned the ICD code.

Highmark and other insurers (eg. Cigna, Capital Blue Cross, UPMC) will be engaged to recruit patients from their insured based on similar criteria from claims data as outlined above.

We will be using an osteoporosis database from Dr. Edward Fox, a Penn State orthopedic surgeon, to send letters to patients who were evaluated from the year 2005 to present for a fragility fracture.
We will work with any groups/source willing to help us recruit for our study. (e.g., the Orthopedic Institute of Pennsylvania and other physician groups, physical therapy clinics, and other hospitals in the central PA area).

We will do opt-out recruitment; patients can be called unless they let us know not to contact them.

We will work with marketing companies (eg. infoUSA, Lorton Data) to identify patients that meet our eligibility criteria in the specified zip codes to mail recruitment letters. Marketing companies have – on average – more than a thousand points of data about each US citizen (How Your Data Are Being Deeply Mined, AE. Marwick, 2014). We will use them to send letters based on AGE and Zip codes. Marketing companies provide these bulk mailing services for companies across the US. Our goal with using these companies is to identify additional potentially eligible participants who might not receive a recruitment letter through other means (through their hospital system or insurance company). We are uncertain about the number of potentially eligible individuals this type of mailing will reach, but it is a cost-effective way to reach a large number of people.

Lorton Data will provide us a list containing adults 65 and older with osteoporosis in Dauphin, York, Lancaster, and Cumberland counties. The Penn State Research team will mail them a recruitment letter asking them to contact us if they had a fracture in the last 10 years. Lorton will also provide us with a list

of adults age 65 or older in Dauphin, York, Lancaster, Cumberland, and Berks counties.

We will use the Penn State College of Medicine StudyFinder website (studyfinder.psu.edu) to post information about the study.

We will work with the Physicians' Alliance Limited (PAL) primary care clinics to identify and recruit participants from their electronic health records (EHR) using the same identification method described above used for Hershey Medical Center's EHR, including mailing to all patients with fracture/osteoporosis, history of falls, and/or bisphosphonate use (potentially indicative of osteoporosis or osteopenia diagnosis).

Community Members

Community members will be people living around our exercise sites. They will be identified by our exercise sites and our participants. They may be, but not limited to, parishioners of a church that hosts our program, members of the senior center hosting our program, control and intervention participants who have completed the WISE study, or a family member or friend of a current participant.

Spanish Speaking Interview Group

Individuals who were previously screened for a study within our department; who have previously stated that they spoke and read Spanish and who have previously given us permission to contact them for future studies, may also be called by phone to seek their participation. We will also mail to potential subjects using a third-party list from a marketing company, such as Lorton. When possible we will partner with community organizations that can assist in identifying potential subjects, these community organizations include local church organizations and recreation centers. Lastly, we will use our Partnership with Penn State community health workers to identify Spanish speaking members.

4.2 Recruitment process

Group leaders:

They will be recruited by the community sites (e.g. churches, senior residential facilities, community centers) using personal contacts or an advertisement (provided by us) that can be placed in a common area or newsletter (e.g., church bulletin). Interested individuals will either provide their name and contact information on a sign-in sheet for research staff to call or call research staff to get more information about the study. Research staff will complete the screening over the phone or in person. If the individual is eligible, staff will schedule the baseline and training visit appointment with the patient.

The RSVP of the Capital Region, Inc. will help recruiting group leaders, especially for those community sites without interested individuals, using study flyers. Interested RSVP volunteers will call research staff to get more information about the study. Research staff will complete the screening over the phone or during community events. If the individual is eligible, staff will schedule the baseline and training visit appointment with the patient.

Participants

The PaTH Network will send a list of patients who meet our eligibility criteria and the research staff will mail the recruitment letters out to the patients.

Highmark and other insurers will mail recruitment letters to the potential subjects based on our eligibility criteria.

Matt Bolton, from the CTSI, will provide us with the patients' names, phone numbers, and mailing address from Penn State HMC's EHR in order for us to send the recruitment letters. We will do opt-out recruitment; patients can be called unless they let us know not to contact them.

Using the preparatory to research provision, Physicians' Alliance Limited (PAL) staff will disclose potentially eligible patient names and addresses to research staff to aid in recruitment. Research staff will prepare recruitment mailings at the PAL central office, and letters will be mailed from this office. The recruitment letter is similar to the letter sent to Hershey Medical Center patients. Subjects will be directed to call the same study phone number used for HMC patients.

We will post study flyers at Penn State Hershey Medical Center, the exercise site locations and other community locations (eg. YMCA).

The Orthopedic Institute of Pennsylvania and other groups/sources (e.g., Drayer and other PT clinics), will provide us a list of patients meeting our eligibility criteria, recommend the study to their patients, and/or post flyers.

We will post an advertisement in the local newspapers and online social media sites. We will also advertise on local radio stations, and through the Penn State Hershey Medical Center telephone on-hold system.

The letters, flyers and newspaper advertisements will instruct interested patients to call the study line to learn more information. Research staff will complete the screening over the phone or in person during community events. If the patient is eligible, staff will schedule the baseline visit appointment with the patient.

Recruitment letter mail to participants from the EHR will either instruct individuals to call the study line if they do not want to be contacted further about the study. If the individual doesn't opt-out, research staff will be calling them to provide more information about the study and complete the screening over the phone. If the patient is eligible, staff will schedule the baseline visit appointment with the patient.

We would like to record conversations between the research staff and possible participants during the phone screener for training and quality assurance purposes. We will ask the individual the following question during the phone screener:

> Is it okay if we record this conversation for quality and training purposes?
> (If YES) record
> (If NO) continue with phone screener without recording

These recordings will be kept in a secure location. Once we're done with recruitment, they will be destroyed.

Churches are not responsible for recruiting study participants; only group leaders. It is possible that there may be church members who are eligible and could participate in the study, and we can work with churches to recruit those individuals, but this will not be a primary ask of the churches.

We will screen interested individuals during community events. Ineligible participants will be asked if they are interested in being group leaders for the study.

Community Members

Community health workers that work with the Hispanic and Latino communities in Central Pennsylvania will hand out recruitment letters during their visits to community centers and the events that they attend. Interested individuals will contact research staff to get more information about the study. Research staff will complete the screening over the phone. If the individual is eligible, staff will notify the exercise site's group leaders that the community member is allowed to exercise.

Spanish Speaking Interview Group Interested individuals will contact research staff to get more information about the study. Research staff will complete the screening over the phone. If the individual is eligible, staff will reach out for availability to schedule individual phone interviews.

4.3 Recruitment materials

Group Leaders:

Flyers – posted at exercise sites community locations (e.g. churches, senior residential facilities, community centers)

Sign-in sheet – interested individuals can provide their name and contact information for research staff to call

Recruitment letter – to areas surrounding the community locations from marketing companies such as, but not limited to, Lorton Data.

Participants:

Recruitment letter – from PaTH network, Highmark and other insurers, marketing companies, and letters promoting our presentations and outreach at community events.

Recruitment letter - Opt-out post card, and rack card providing information about the study.

Flyers – posted at exercise site locations and community locations

Newspaper ads – posted in local newspapers

Online ads – posted on social media websites (eg. Facebook)

Radio ads – to advertise the study on local radio stations

On-hold ads (same Radio ad) – to be used on the Penn State Hershey Medical Center telephone on-hold system

Study website – to host information on the study and advertise our study on wisestudy.org

Recruitment video – to be used on the study website (wisestudy.org) and on social media websites.

Community members:

Flyers – posted at exercise sites community locations (e.g. churches, senior residential facilities, community centers)

Spanish Speaking Interview Group Recruitment letter – to areas surrounding the community locations from marketing companies such as, but not limited to, Lorton Data or local community organizations such as but not limited to, churches and recreation centers.

Recruitment flyers – given out by our Community Health Workers

4.4 Eligibility/screening of subjects

Participants and Group Leaders
Interested subjects will either provide their name or contact information on a sign-in sheet for research staff to call or call our research study team to learn more, they will be read the phone screening document which will ensure eligibility and will inform them of study procedures. We will also do opt-out recruitment; research staff will call participants unless they let us know not to contact them. If eligible and interested in participating, they will be asked to attend the baseline visit to learn more about the program, sign consent, and collect measurements.

Community Members
Interested subjects will call our research study team to learn more, they will be read the phone screening document which will ensure eligibility and will inform them of study procedures. If eligible and interested in participating, they will be scheduled to give consent in-person or over the phone with research staff.

Spanish Speaking Interview Interested subjects will be screened by phone by research staff who will read the phone screening document which will ensure eligibility and will inform them of study procedures. If eligible and interested in participating, they will be scheduled to for an individual phone interview.

5.0 Consent Process and Documentation

5.1 Consent Process

5.1.1 Obtaining Informed Consent

5.1.1.1 Timing and Location of Consent

Group leaders:
Participants will individually review the consent form with one of the research coordinators at the beginning of the baseline visit. The baseline visit will be conducted at Penn State Hershey Medical Center.

Participants:
Patients will individually review the consent form with one of the research coordinators at the beginning of the baseline visit. The baseline visit will be conducted at Penn State Hershey Medical Center or at recruited/signed exercise community locations (e.g.; senior centers, churches).

Community Members
Community members will be consented in 1 of 2 ways. 1) The community member and exercise coach will schedule a date and time to review the consent

form at a WISE exercise site. 2) If community members are unable to visit a WISE exercise site, they will be consented over phone. For the phone consent, 2 copies of the consent form will be sent community member prior to the phone call. A staff member and a witness will call the community member and review consent form over the phone. If the community member agrees to participate in the study, he/she will sign a copy of the consent form and mail it back to research team. A consent for research phone signature page will be completed by the research staff member and the witness. No study procedures will take place until the signed copy of the consent has been received by the study team.

Spanish Speaking Interview Group Members will be sent a summary explanation by mail or email for review depending on their preference. The summary explanation will be reviewed with study staff at the beginning of the individual phone interview. Participants will be given the opportunity to ask questions.

5.1.1.2 Coercion or Undue Influence during Consent

Participants will be mailed/emailed a copy of the consent form before the baseline visit so they will have ample time to review the consent document. They will be encouraged to ask questions during the consent process on a one-on-one basis with the study staff. They can withdraw from the study at any time.

5.1.2 Waiver or alteration of the informed consent requirement

Participants, group leaders, community members, and Spanish Speaking Interview Members will give verbal consent during the screener to allow the research team to collect personal health information. We will contact the participant's and group leader's Primary Care Provider to ask for PCP permission to participate. If the community member has not been active in the WISE exercise intervention for the past 6 weeks they will be asked to contact their PCP to sign a PCP permission form and return it to study staff. Spanish Speaking Interview Members members will not be required to obtain PCP permission prior to participating.

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

For participants and group leaders, consent will take place at the beginning of the baseline visit. Research coordinator will individually review the consent form with participants, answer any questions, and obtain written consent. A copy of the consent form will be provided to participants to keep for their records.

For community members
Consent will take place before the community member starts their first exercise session. Staff will review the consent form with the community member, answer any questions, and obtain written consent. A copy of the consent form will be provided to community members to keep for their records.

Spanish Speaking Interview Group Staff will review a summary explanation of research at the beginning of the individual interview. The participants will be given the opportunity to ask questions prior to the individual interview beginning.

5.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)
Due to the minimal risk nature of the planned individual interviews, which does not involve physical activity and minimal personal health information is obtained (i.e name, telephone number and address), we will use a Summary Explanation of Research document to consent Spanish Speaking Interview Members

5.3 Consent – Other Considerations

5.3.1 Non-English Speaking Subjects
NOT APPLICABLE

5.3.2 Cognitively Impaired Adults
NOT APPLICABLE

5.3.3 Subjects who are not yet adults (infants, children, teenagers)
NOT APPLICABLE

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☐ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☒ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☒ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☒ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Identifiers will be kept until all data is analyzed.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Group Leaders

We need to collect personal health information from the group leaders during the phone screening to determine eligibility for the study.

Participants

The PATH data managers or Matt Bolton, from the CTSI, will go into Penn State HMC's EHR to pull patients who have fractures (using ICD codes) and are 65 years old or older. They will provide us with the patients' names and mailing address so research staff can send recruitment letters. We need to collect personal health information from the participants during the phone screening to determine eligibility for the study.

Community Members

We need to collect personal health information from the community members during the phone screening to determine eligibility for the study.

Speaking Interview Members We will not have access or use PHI for the Spanish Interviews, only PII (i.e name, telephone, address and email address) will be collected for contact purposes.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Group Leaders

Since this is an exercise study we want approval from the group leader's primary care provider to minimize any health risks. We will contact their Primary Care Provider to provide permission to participate.

Participants

Since this is an exercise study we want approval from the participant's primary care provider to minimize any health risks. We will ask their Primary Care Provider to provide permission to participate.

Community Members

Since this is an exercise study we want approval from the community member's primary care provider to minimize any health risks. The community member will contact their Primary Care Provider to obtain permission to participate. If the community member has completed enrollment in the WISE study, has been active in the Band Together program within the past 6 weeks, and has had no change in health status since they last exercised, PCP permission will be carried over from the WISE study and not reobtained.

Focus Groups Spanish Speaking Interview Members
Since limited PII will be collected (name, address, and telephone number) from the interviewparticipants and the participants will not be partaking in any exercises, we will be requesting a waiver of documentation of consent for this group.

6.3 Waiver or alteration of authorization statements of agreement

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

7.1 Study Design

We propose a 36-month multi-center randomized effectiveness trial to compare the impact of an Enhanced Usual Care (Control) intervention, with Exercise Coaching (Exercise), on FF/SFRI in patients with a previous fragility fracture (FF). We will also examine the impact of the intervention on several secondary outcomes like: loneliness, physical function, and bone strength. We will do this by following a Pragmatic trial design: 1) limiting exclusions to increase representativeness, 2) limiting research contacts and 3) limiting measures to those practicable for use in usual care.

The intervention will be held in churches, community centers, and senior residential facilities. We will work with the exercise sites and RSVP and send mailings to recruit up to 125 individuals to serve as the Group leaders at each site location. They will be trained on the exercises and leadership roles to help lead the group. We will ask them to come at least once per week, so the time commitment is minimal.

We will be recruiting approximately 500 patients who have suffered a FF and will randomly assign them to one of two conditions: (A) Control Group – Enhanced Usual Care and (B) Intervention Group – Enhanced usual care plus Exercise coaching that includes in-person and phone coach contacts to encourage and support strength, balance and walking activities.

We will be recruiting up to 250 people that are members of the community that would like to participate in our exercise program. These eligible community members will have access to our exercise program up to 3 times a week and can attend whenever best fits their schedule. The recruitment of community members is to supplement the loss of intervention group participants over the 4 year period of the study. It will also provide a way for participants that have completed the study a way to continue exercising with their group if they so choose.

During the conduction of the randomized control trial, we will conduct individual interviews with Spanish Speaking members within the Spanish community, via phone. The phone interviews will be with Spanish speaking adults who will identify changes to the Band Together intervention that will be needed to adapt to the Spanish population. During these interviews, we will present the intervention materials in Spanish and request feedback from Spanish speaking individual. The interviews will be in Spanish and led by a Spanish speaking team member. Sessions will be recorded and translated to English for analysis.

7.2 Study Procedures

7.2.1. Study Procedures Flowchart

Group Leaders

MEASURES	Burden (questions or time)	M0 (In-person)	M36 (phone)
Blood Pressure and Heart Rate	5 minutes	X	
Demographics, past medical history	15 questions	X	
Self-reported Height and Weight	2 question	X	X
Self-reported health	1 question	X	X
PROMIS: Depression, Anxiety, Physical Function	12 questions	X	X
Brief Loneliness Questionnaire	3 questions	X	X
Physical Activity – NHIS	6 questions	X	X
Satisfaction Survey	3 questions		X

Participants:

MEASURES	Burden (questions or time)	M0 (In-person)	M12 (Phone)	M24 (Phone)	M36 (In-person)
Height and Weight	2 minutes	X			X
Blood Pressure and Heart Rate	8 minutes	X			X
DXA: Bone Mineral Density, Muscle Mass	30 minutes test	X			X
Demographics, past medical history	15 questions	X			
Fear of Falling	7 questions	X	X	X	X*
Falls history (BRFSS at baseline, STRIDE at 12, 24, 36)	2 questions	X			
Self-reported health	1 question	X	X	X	X*
Fall Calendar questionnaire	10 questions		X	X	X*
PROMIS: Depression, Pain, Fatigue, Anxiety, Physical Function, Sleep Disturbances, Social Roles and Activities	29 questions	X	X	X	X*
Brief Loneliness Questionnaire	3 questions	X	X	X	X*
Callahan Cognition Six-item Screener	6 questions	X			X*
30 Second Chair Stand Test	3 minutes	X			X
30 Second Arm Curl Test	2 minutes	X			X
Physical Activity – NHIS	6 questions	X	X	X	X*
Caregiver questions	2 questions	X			X*

Medication List Review	3 minutes	X			X*
Fractures, Serious Fall-Related Injuries and Healthcare Utilization	5 minute interview		X	X	X*
Healthcare Utilization from PaTH Network	No patient time		X	X	X*
Virtual SPPB Questions	12 questions				X**

*****Measures may be collected over the phone if the participant is unable to attend the 36 month in-person visit. (See 7.2.9)

**Measure will be emailed to all participants that have an email address

7.2.2. Establish up to 15 exercise site locations – This is already approved under the quality improvement project, "Peer-led Strength Training Program for Older Adults", IRB# 40418NR.

To enhance the disseminability of the program, sessions will be held in community locations. The exercise program is built on a model that efficiently uses resources by engaging Group leaders, donated spaces and simple equipment (resistance bands, pedometer, etc). Having sessions in community settings also reduces travel barriers.

Once the study is completed, the program will remain in the site along with the resistance bands, which is highly attractive to the sites and allows for program sustainability. Many churches and senior centers are looking for free or low-cost programming for their members.

7.2.3. Group leader training (8 hours)

Group leaders are members of the community, recruited by the research coordinator or the coaches with the help of the exercise sites using personal contacts or an advertisement that can be placed in a common area or newsletter (e.g., church bulletin).

Group leaders will be trained by the coaches using the Group leader training manual. This training manual is consistent with other state sponsored and evidence based volunteer led exercise programs for seniors (Pennsylvania's Healthy Steps in Motion– http://www.aging.pa.gov/aging-services/health-wellness/Pages/Healthy-Steps-in-Motion.aspx#.Vv0_jZwrK9I, and RSVP's Bone Builder's program– http://www.volunteersinvt.org/bonebuilders.php). The training includes:

- 30 minutes community partner research ethics training designed by the University of Pittsburgh
- 30 minutes American Heart Association (AHA) Family & Friends CPR Anytime training, and an Emergency plan training
- 1 hour training on exercise basics and instructions to lead the exercise classes. The exercise basics will go over the rules of when to and when not to perform an exercise as well as explain the difference between soreness and pain as described by APTA (American Physical Therapy Association).
- 1 hour Band Together class demonstration
- 45 minutes presentation on the WISE Study background and Band Together history and principles
- 2 hours training and practice on core and balance exercises (43, 58, 59)
- 1 hour Group leader exercise session practice, and questions and answers session.

The coaches will meet regularly with group leaders and will supervise sessions on a rotating basis. The coach will provide support and review exercise cues and proper form with the group leader. If the group

leader would like to review exercises outside of class they will be given links to videos of the exercises on youtube.

In addition to the initial training at the beginning of the study, the group leaders will be invited to an optional annual group leader meeting. This half-day meeting will include retention activities, study updates and a training review. Those not in attendance will receive all of the information during their quarterly check-in. The activities include:

- Importance of volunteer leaders talk
- Training for emergency plan review, study updates, and exercise testing review
- Retention activity (physical activity and trivia game)
- Review of best practices
- Question and answer session
- Closing and survey

7.2.4. Recruitment

Group leaders:

Group leaders will be recruited by the exercise sites using an advertisement that can be placed in a common area or newsletter (e.g., church bulletin). Interested group leaders, will contact our research coordinator for screening and eligibility.

The RSVP of the Capital Region, Inc. will help recruiting group leaders, especially for those community sites without interested individuals, using study flyers. Interested RSVP volunteers will call research staff to get more information about the study. Research staff will complete the screening over the phone or during community events. If the individual is eligible, staff will schedule the baseline and training visit appointment with the patient.

Additionally, group leaders may be recruited by other methods including word-of-mouth advertising, flyers hung in community locations, mailings, and participants who have completed the exercise intervention and who wish to be trained as a group leader. Any interested individual will be instructed to contact research staff to be screened for eligibility.

Up to 125 group leaders will be recruited to lead at our exercise sites. Group leaders are not being randomized, because they are all part of the intervention group. We ask them to come at least once per week, so the time commitment is minimal.

Participants:

We will send letters to people ≥ 65 who have had a fragility fracture (FF) and/or have a diagnosis of osteoporosis or osteopenia (using IDC codes). We will work with PaTH data managers and Matt Bolton, from the CTSI, to export a list of patients who meet inclusion criteria based on age and FF history and/or have a diagnosis of osteoporosis or osteopenia. The list will include, phone numbers, date they were seen by doctor and the name of the doctor who seen the patient and assigned the ICD code. We will do opt-out recruitment; research staff will contact patients, unless patients let us know not to contact them.

We will work with insurers (eg. Highmark Blue Shield, Capital Blue Cross, Aetna), to send letters to FF patients in Pennsylvania.

We will be using an osteoporosis database from Dr. Fox, to send letters to patients who were evaluated between 2008 and 2015 for a fragility fracture.

We will work with any groups/source willing to help us recruit for our study. (e.g., the Orthopedic Institute of Pennsylvania and other physician groups, physical therapy clinics, and other hospitals in the central PA area). We will do opt-out recruitment; patients can be called unless they let us know not to contact them.

We will post an advertisement in the local newspapers, and online social media sites.

We will work with marketing companies (eg. infoUSA) to identify patients that meet our eligibility criteria in the specified zip codes to mail recruitment letters. While we will NOT ask marketing companies to use any medical information to decide who to send letters to, we will use them to send letters based on AGE and PROXIMITY to an exercise site. Marketing companies provide these bulk mailing services for companies across the US. The marketing company will not be providing us with any information; they will simply be mailing a letter. Our goal with using these companies is to identify additional potentially eligible participants who might not receive a recruitment letter through other means (through their hospital system or insurance company). We are uncertain about the number of potentially eligible individuals this type of mailing will reach, but it is a cost-effective way to reach a large number of people.

We will work with the Hershey Medical Center Marketing Department to do media outreach and generate free publicity through stories in newspapers, on radio, and on television.

WISE Marketing Plan – May-December, 2018
GOAL: To enhance recruitment, to finish by 12/31, by adding methods other than letters and opt-out calls. Our recruitment rate at Penn State has fallen to about half of what is required. We need ~5 per week and have been averaging 3 in the past few months. At that pace we will miss our 12/31 drop dead goal and risk doing an underpowered study and/or violating the terms of our contract with PCORI and jeopardizing future funding.

APPRROACH: We propose the following action steps to increase awareness of the WISE study:

1) Create a short video. While we have a video that describes the intervention, we never made one to assist in recruitment. This video would summarize the information in the consent process and that includes video from participants who have enrolled, to tell their story about why they decided to participate, assuming they all sign media release forms as we have done during the Philadelphia Inquirer story. The IRB would review this video before posted to a URL (most likely www.wisestudyPA.org). The talking points will be:

--After a fragility fracture, there's a gap in care – few patients get a DXA or intervention
--Medications for osteoporosis have worrisome side effects which have made people stop taking them.
--Without treatments the rate of hip fractures is no longer falling.
--It's also not clear what the best exercise program is for reducing falls and keeping bones strong.
--Before Medicare or insurers approve a treatment, it needs to be proven effective in a research study.
--Most all of the treatments people use have been proven effective in research studies with volunteers.
--Exercise is not yet proven to be effective for preventing injuries from falls.
--About 1/3 seniors (those with Medicare Advantage) have access to Silver Sneakers though 90% don't go.
--Healthy Steps is a free statewide program for reducing falls, call your local Area Agency on Aging for

information.
--How to know if you're at risk for falls and fractures?
--The goal of WISE - prove that exercise can prevent injuries from falls.
--Disclose Dr. Sciamanna's Conflict of Interest.
--If you're over 65 and broke a bone with very little force, such as just from falling, you are probably eligible.
--If you decide to participate, what happens? (phone calls, visits)
--If WISE works, what might happen (pursue insurance coverage, business development).
--We're thankful to our volunteers in helping us do this important work that may benefit many people.

2) Conduct a series of Bone Health/Falls Reduction presentations. We could conduct these informational sessions in the counties that we are recruiting in. These talks would discuss the problems more generally along with all of the methods that can be used to treat falls and osteoporosis, many of which are outside of the WISE study. These will be completed in partnership with the ADRC (Aging and Disabilities Resource Center), which exists in each county and which serves to inform the public about important issues that pertain to older adults. Dr. Sciamanna will conduct these talks. If needed we can provide a slide deck. We would plan to send letters to patients with fragility fracture (who we already have permission to mail letters to), an include a notice about this talk in their community. The talk is tentatively called "the Great Bone Debate" as the problem of medication side effects and the right exercises for bones have been widely covered in the NY Times and Wall Street Journal in 2018. The same talking points would be as above.

3. Participate on Radio Smart Talk with Dr. Neal Thomas and Scott Lamar. Dr. Sciamanna is planned to be participating on 5/23 with Dr. Thomas about clinical research and the WISE study in particular. The hour will focus more on how clinical trials are done but some information will be shared about several studies, WISE in particular.

4. Create a Facebook page. We propose creating a facebook page to post video, audio and comments from community members and group leaders. It will not be private, as the goal will be to share it with people and create more awareness of the WISE study to drive recruitment.

5. Create a study website. We propose creating a study website to post information about the study, host the recruitment video, host interviews and articles about the study, and provide study contact information.

<u>Community Members:</u>
Community members will be recruited by personal contacts of current participants or the exercise sites using an advertisement that can be placed in a common area or newsletter (e.g., church bulletin). Community members may also be recruited by participants who completed the WISE study showing interest in continuing the exercise program. Interested community members will contact our research staff for screening and eligibility.

Spanish Speaking Interview Members Spanish Speaking Interview Members will be recruited from previously screened participants who have indicated that they fluently speak and read Spanish and have consented to allow us to contact them in the future. We will allow current intervention participants to participate within the individual interviews, as they have a deep understanding of the intervention materials and can provide insightful feedback on how to adapt the materials. We will also use third-party lists from marketing companies such as Lorton to send out recruitment letters to potentially eligible participants. Finally, we hope to connect with community organizations within the Spanish

population who would be willing to send IRB-approved recruitment letters to their communities.

7.2.5. Screening for eligibility

Group leaders:
The screening will be completed over the phone. People who call will be screened by a research assistant based on the eligibility criteria. Research coordinator will ask interested participants for authorization to contact PCP during this time. If the person is eligible, we will schedule their baseline/training session.

Before enrollment (signing inform consent and liability waiver), we will need to screen individuals for blood pressure and heart rate.

Participants:
The screening will be completed over the phone or during community events. Patients who call will be screened by a research assistant based on the eligibility criteria. Research coordinator will ask interested participants for authorization to contact PCP during this time. If the patient is eligible, we will schedule their baseline visits. Patients of the Hershey Medical Center will be asked if the researchers may contact their doctor to confirm if they have had a fragility fracture.

If there is a delay of 6 or more weeks between the time that the patient's PCP gives permission to participate in the study, and the scheduling of the baseline visit, research staff will ask whether the patient has had any hospitalizations, major changes in health, and still meets the eligibility criterion for walking 100 feet without the use of a walker or wheelchair. If the patient reports a hospitalization or major change in health, research staff will consult with the Site PI, who will determine whether research staff needs to obtain permission from the patient's PCP again before the patient can participate in the study. Patients who can no longer walk 100 feet without use of a walker or wheelchair will be considered ineligible at that time.

Before enrollment (signing inform consent and liability waiver), we will need to screen individuals for blood pressure and heart rate.

Community Members:
The screening will be completed over the phone. People who call will be screened by a research staff based on the eligibility criteria. Research staff will ask interested community members for authorization to contact PCP during this time. If the person is eligible, we will ask the community member to obtain PCP permission in order for them to participate. If the community member has completed enrollment in the WISE study, has been active in the Band Together program within the past 6 weeks and has had no change in health status since they last exercised, PCP permission will be carried over from the WISE study and not be reobtained.

Spanish Speaking Interview Members

Interested subjects will be screened by phone by a Spanish speaking, Community Health Worker who will read the phone screening document which will ensure eligibility and will inform them of study procedures. If eligible and interested in participating, they will be scheduled to attend an individual phone interview.

7.2.6. Visit 1 – Baseline Visit

Group Leaders:

During the baseline visit the Group leaders will complete an 8 hour training session, which includes: (1) review consent and liability waiver, (2) obtain blood pressure and heart rate for screening eligibility, (3) obtain signatures for the informed consent and liability document, (4) conduct the baseline assessment (e.g. questionnaires, blood pressure and heart rate, self-reported height and weight, (5) complete community partner research ethics training designed by the University of Pittsburgh, (6) hands only CPR using the AHA Family & Friends CPR Anytime training, and (7) go over the comprehensive group leader training manual and exercises with the exercise coaches.

A research staff will review the informed consent document and the liability waiver with them. Before enrolling the individual (signing the inform consent and liability waiver), a research staff will take the group leader's blood pressure and heart rate to screen for eligibility.

- If blood pressure is $\geq$ 180 systolic OR $\geq$110 diastolic OR heart rate is $\geq$ 120 bpm, research staff will suggest the individual to see a PCP to control their blood pressure or heart rate, and if they would like to still participate in our study they would have to receive PCP permission before re-screening for eligibility.
- If blood pressure is between 160 to 179 systolic OR 100 to 109 diastolic AND heart rate is <120 bpm, research staff will provide critical value letter to individual and suggest him/her to see a PCP about their high blood pressure, but they will still be enrolled into the study.

If the individual is eligible, based on their blood pressure or heart rate results (above), a research staff will ask if they have any questions about the consent and liability waiver, and if they agree, both the research staff and participant will sign. The group leader will be provided with a copy of the signed consent liability waiver for their records.

Group Leaders will then be asked to record self-reported height and weight, emergency contact information, weekly availability, and will complete the following questionnaires: sociodemographic and past medical history, self-reported health, PROMIS 12, brief loneliness questionnaire, and physical activity. Research staff will remind participants that they may skip any questions that they prefer not to answer. To assure that the participant can safely be part of the study, critical clinical information (e.g., high blood pressure, depression screen) will be communicated to the PCP and group leader.

The coaches will train the Group leader on each of the exercises in the coached exercise program. Group leaders will learn how to lead the exercise groups. They will lead 50 minute group sessions using resistance bands and balance exercises, 1 to 3 times a week for 36 months or until the end of the study, whichever comes first. The sessions will be held at exercise site locations (eg. Churches, community centers or senior centers) across Central PA.

To increase the safety of the study, we are having the group leaders take the community partner research ethics training designed by the University of Pittsburgh, the AHA Family & Friends CPR Anytime training, and Emergency plan training

The coaches will meet regularly with group leaders and will supervise sessions on a rotating basis. Coaches will provide ongoing support and monitor the safety of the program for all participants.

Group Leader's will receive $50 or completing the visit.

If blood pressure is $\geq$ 180 systolic OR $\geq$110 diastolic OR heart rate is $\geq$ 120 bpm at the baseline assessment (post-consent), research staff will suggest the individual to see a PCP to control their blood

pressure or heart rate, and if they would like to still participate in our study, they would have to receive PCP permission before completing the baseline visit and training session, and continuing with the study.

Participants

Participants will complete their first visit with research staff at Penn State Hershey or signed exercise sites (60 minutes baseline visit plus 30 minute DXA scan, if applicable).

Prior to the baseline visit, research staff will send participants the following questionnaires, to be completed at home and brought with them to the baseline assessment: sociodemographic and past medical history, fear of falling, falls history (BRFSS), self-reported health, PROMIS 29: depression, anxiety and physical function, fatigue, pain, sleep disturbance, ability to participate in social roles and activities, brief loneliness questionnaire, physical activity, social domain (caregiver), and assistive devices. These surveys should take approximately 20 minutes to complete.

Research staff will review the informed consent document and the liability waiver with individual. Before enrolling the individual (signing the inform consent and liability waiver), a research staff will take the individual's blood pressure and heart rate to screen for eligibility.

- If blood pressure is $\geq$ 180 systolic OR $\geq$110 diastolic OR heart rate is $\geq$ 120 bpm, research staff will suggest the individual to see a PCP to control their blood pressure or heart rate, and if they would like to still participate in our study they would have to receive PCP permission before re-screening for eligibility.
- If blood pressure is between 160 to 179 systolic OR 100 to 109 diastolic AND heart rate is <120 bpm, research staff will provide critical value letter to individual and suggest him/her to see a PCP about their high blood pressure, but they will still be enrolled into the study.

If the individual is eligible, based on their blood pressure or heart rate results (above), a research staff will ask if they have any questions about the consent and liability waiver, and if they agree, both the research staff and participant will sign. The participant will be provided with a copy of the signed consent liability waiver for their records.

Research staff will take the participant's baseline measurements: (1) height and weight, (2) blood pressure and heart rate, (3)30 second chair stand test, 30 second bicep curl test. Research staff will also review participant's medications.
Research staff will remind participants that they may skip any questions that they prefer not to answer. To assure that the participant can safely be part of the study, critical clinical information (e.g., high blood pressure, depression screen) will be communicated to the PCP and participant.

Research staff will recommend participants review the fall risk brochures from Centers for Disease Control and Prevention (CDC) on preventing falls, checking for safety and staying independent.

If PCP authorized a DXA scan, a research staff will take the participant to the DXA center for a Dual-energy X-ray absorptiometry (DXA) scan.

After completing the baseline visit, each participant will receive $25.

If blood pressure is $\geq$ 180 systolic OR $\geq$110 diastolic OR heart rate is $\geq$ 120 bpm at the baseline assessment (post-consent), research staff will suggest the individual to see a PCP to control their blood

pressure or heart rate, and if they would like to still participate in our study, they would have to receive PCP permission before completing the baseline visit and continuing with the study.

Spanish Speaking Interview Members

60 minute individual interview will be conducted over the phone. A Spanish speaking member of our team will facilitate the interviews and we will audio record the sessions for translation and data analysis purposes. The facilitator will use the interview guide to lead the discussion/interview. The interview guide will include the following: (1) How best to design the Band Together intervention for the Spanish population? (2) How best to interest potential participants? (3) What concerns exist about participating? (4) How to design a recruitment within the Spanish population and (5) How would you change/update the current Band Together intervention material to be better suited the Spanish population. Participants will be given a $50 stipend.

7.2.6.1. Baseline Dual-energy X-ray absorptiometry (DXA)

Participants

The National Osteoporosis Foundation Guidelines suggest a DXA in postmenopausal women and men over 50 who have a fragility fracture. As part of standard of care, patients in the study are asked to have an AXIAL (Central) DXA scan, if their PCP thinks it is clinically indicated. Patients, WILL be billed as they normally would in a clinical setting.

In addition, as part of research, we will be asking the participants to do a total body DXA scan to measure body composition. For this scan, Dr. Timothy J. Mosher, chair for the Department of Radiology, had agreed to do it at no cost to the research. Results from the total body scan will be placed in the participants' EHR. This optional scan will be performed the same way at all institutions (Penn State Hershey, University of Pittsburgh, and Temple University). Patients will NOT be billed for this DXA scan. Radiation exposure is reported in the consent form.

We will ask that the patient have the DXA done at Penn State Hershey Medical Center. We are currently working with Dr. Mosher and his team, which use the same DXA machine (Hologic) as our other study sites. The participant's PCP will receive a faxed report with the test results, as they would usually.

If PCP authorized a DXA scan, a research staff person, during the baseline visit, will take the participant to have their DXA scan. We will remind the patient 2 days before of their DXA appointment. The DXA scan will take about 30 minutes.

If the participant has received a DXA scan within 2 years of their baseline visit date and the research staff has obtained the records either through the participant or the participant's PCP, the DXA scan results are able to be analyzed. If the DXA results are received via the participant's PCP prior to the participant's baseline visit, the research staff person will obtain consent from the participant to analyze the DXA report.

7.2.6.2. Communicating Baseline Measurements

We will communicate the results of any critical values of a baseline measure (e.g., Blood pressure, Depression screener) and fracture risk and treatment recommendations to both the patient/group

leader and primary care provider. These are considered enhancements to usual care, as most patients who suffer a FF are never tested or treated, and to maximize patient safety (29, 30).

7.2.6.3. Randomization

Once eligible participants who sign the informed consent and completed the baseline questions, research staff at each site will randomize the participant into one of two groups (control, enhanced usual care; or intervention groups, enhanced usual care plus coached exercise program) in a one-to-one ratio. Stratification factors for randomization will be study site location (1=Penn State, 2=University of Pittsburgh, 3=Temple University), gender (0=female, 1=male), and bisphosphonate and other potent medication use (0=never, 1=ever). The research staff will conduct the randomization during the baseline visit through REDCap.

Participants randomized to the intervention group will also receive an introductory letter from their exercise coach with picture/name and details on a forthcoming phone call.

Group leaders, community members, and Spanish Speaking Interview members will not be randomized.

Group A: Control Group- *Enhanced Usual Care Intervention*

Research staff will review the three printed pamphlets on fall risks and exercising during baseline. We will recommend the control group to exercise. However, they will NOT be able to participate in our exercise program intervention. Control group participants will receive information about exercise from the Centers for Disease Control and newsletters about fall prevention that include exercise. They are encouraged to exercise, though they are not invited to Band Together, nor will they receive one-on-one support from our coaches. We will not ask people to abstain from any form of exercise.

In addition, to enhance the usual care intervention and maximize patient safety, the baseline bone density results (measured by Dual-energy X-ray absorptiometry, DXA) will be communicated to their PCP, and any *critical* values of a baseline measure (e.g., Blood pressure, Depression screen) to both the patient and primary care provider.

Group B: Exercise intervention Group - *Enhanced Usual Care plus Exercise Coaching Intervention*

At baseline, the exercise group will receive the three printed pamphlets on fall risks and exercising in groups (same as the controls) plus:

- An *exercise program* that includes strength, balance, and aerobic exercises
- An *exercise coach* that provides in-person, email, and/or telephone support/feedbacks to enhance participation in the exercise program
- *Regular progress reports* sent by coaches by fax/EHR every 6 months, to communicate the patient's progress**.**
- *Paper-based Exercise Trackers* will be given to help exercise coaches review the participant's progression with strength exercises

If any Group Leader or Participant is hospitalized and/or absent for 6 consecutive weeks or more and wants to return to the exercise sessions, Research Coaches will complete a return to exercise protocol with the individual. The Coach will ask if the Group Leader or Participant has had a hospitalization or a major change in their health since their last exercise session. If the Group leader or Participant answers yes, Research Coaches will ask about the event, hospitalization, and current health status and report the event as an Adverse Event in REDCap. A Principal Investigator will review the case and may request that the Group Leader or Participant obtain PCP permission before returning to the exercise program. In all cases, Group Leaders and Participants will be

instructed to “Start Low and Go Slow” upon resuming exercise: starting at a lower resistance band, and slowly working their way back to the level at which they were exercising before their absence or hospitalization.

Exercise program

For the first month of the exercise intervention we will conduct only *strength* and a few *balance* exercises to rehabilitate our participants. After the first month, and once our participants feel comfortable, we will incorporate *aerobic and additional balance exercises*. We will personalize participant programs based on baseline levels and increase them gradually. The exercise session will be conducted 50 minutes 3 times a week. Between sets there is a 60-second break.

- ***Warmup and Activity*** *(5 minutes)* The warmup consists of marching in place followed by a brief group aerobic activity.
- ***Strength exercises*** *(30 minutes 3 days a week):* The strength exercises will focus on the major muscle groups (chest, shoulders, arms, back, abdomen, and legs) and will use resistance bands for each exercise. The participant will progress to a harder band when the exercise becomes easy, or are able to complete both sets without strain.
- ***Balance Exercises*** *(10 minutes 3 days a week):* We will incorporate common balance exercises, including those proven in a randomized trial, developed by Dr. Edward McAuley, to improve physical performance in seniors. (RP 46, 47) Some of these exercises include: Woodchop, Superman Pose and Straight-line walking.
- ***Cool Down Activity*** *(3-5 minutes):* Participants will complete a brief cool down activity that includes flexibility exercises and stretching following each exercise session.
- ***Aerobic exercises:*** After the first month of intervention, the coaches and Group leaders will help participants work towards 150 minutes a week of aerobic exercise. Participants will be educated on different aerobic activities (e.g. walking, dancing, games) they can do within their home and community.

Starting a new exercise site

For the first week the coaches will:

a. Attend each exercise session and observe the group leaders leading the class. The exercise coach will observe each group leader and provide continuous support, as needed.

For weeks 2-6 of the new site, the coaches will attend the exercise sites weekly. During this visit the coaches will:

a. Make sure the site has all of the required materials.
b. Meet with the group leader and answer questions.
c. Work with the participants on progression and form.
d. Perform chair stand test, arm curl test, single leg stance test, and make pedometers available to participants (monthly)
e. Collect participant data.

For weeks 7-12 of a new site, items a through e will be done bi-weekly. After the 12th week of a new site, items a through e will be done monthly. Coaches will continue site visits to ensure program fidelity and to provide feedback to Group Leaders.

Exercise coaching

For the first 4 weeks of the intervention the coaches will:

a. After randomization occurs, the coach will call participants in the intervention group for introduction and to learn more about the participant and any medical conditions that may be important for the exercise coach to know. If the coach learns of any serious medical events or hospitalizations since baseline they will follow the return to exercise protocol and present the case to a PI through adverse event reporting in REDCap.
b. Contact the patients by weekly phone calls or during site visits(duration of call: approximately 5 minutes) to give exercise tips, discuss goals and progress toward goals, injuries, soreness, and enjoyment.
c. Conduct site visits to assure program fidelity, provide quality control feedback to volunteer Group Leaders.

For weeks 4-8 of the intervention coaches will follow item b, but instead of every week they will perform them bi-weekly.

After the 8th week of intervention coaches will follow items b & c, performing these items every month

The coaches will meet regularly with group leaders and will supervise sessions on a rotating basis. If the participant misses 3 consecutive classes without notifying exercise coach, or the group leader expresses concerns for a participant, the coach will perform a check-up call between the regularly scheduled calls. Coaches will provide ongoing support and monitor the safety of the program for all participants.

Fitness Testing

In order to capture the participant's progress, the participant will perform fitness tests once a month that will be shared with their PCP via regular progress reports. Each fitness test is based off of exercises already performed in the program. The 3 fitness tests are:

a. 30 second chair stand test
b. 30 second arm curl test
c. Single leg stance test

Regular Progress Reports

Every month the coach will record steps from the pedometer, patient adherence to exercise sessions, and measure functional fitness and strength (30 second chair stand test, 30 second arm curl test, and single leg stance test). The purpose of these activities is to provide feedback (via fax or electronic health record) to PCPs, considered key for integrating exercise coaching into primary care and the standard of care after referral to a specialist (e.g., cardiologist) (53).

Exercise program at home and/or community sites

Our study design is to be "pragmatic", therefore, the intervention is designed to be something that the vast majority of people would be interested in, and we know that some people are shy and avoid group programs or do not like to travel. For that reason we have created an "at home" option, which will include the same exercises at the same times, but via DVD. Participants who regularly attend class, but may miss a session due to vacation or other obligations and insist on doing the exercises remotely, may be given the home exercise manual if they don't have access to a DVD player. The home exercise manual can be used as a reminder for the proper way to perform the exercises that they have already learned and reviewed with their

exercise coach. The manual is not intended to replace the Band Together sessions or Band Together DVD. This allows "choice" to be part of the study, though it will be a limitation as well. Giving people options is important and is part of standard clinical care, which this study – a pragmatic clinical trial – is designed to approximate. Patients will have the ***choice*** to participate at home and/or at community sites and can modify that ratio as they choose. As a key secondary outcome is loneliness, the coach will encourage participation at community sites, but patients will choose.

The "at home" option for the exercise session will also be heavily utilized during times that our in-person community exercise sessions may be canceled due to circumstances outside of the study's control. These circumstances may include weather related cancelations, disease outbreaks and/or recommendations from Penn State University or Milton S. Hershey Medical Center to stop in-person visits. When these circumstances arise, we will contact intervention participants and encourage them to participate in the DVD portion of the program. Exercise Coaches will continue to make contact with the research participants during these cancelations to ensure exercise are being done properly and to collect adverse events, as needed.

For the individuals who want to exercise at home, we will distribute the exercise DVDs every 9 months and the coach will continue to contact them, just as if they were joining the group. Coaches, over the phone and in-person at community sites, will encourage group participation, based on the belief that the social opportunities in groups reduce loneliness and depression. The main goal, however, is to encourage exercise, where people do it matters less.

If a participant wants to do the exercises at home, but does not have a DVD player, we will provide him/her a DVD player for the duration of their participation in our study. Upon completion of the study, the participant will return the DVD player during his/her 36 month follow-up visit. If the participant chooses to withdraw from the study, he/she will be asked to return the DVD player by mail or by dropping it off at one of our active exercise sites.

In the event of exercise sessions being canceled at our sites, we will offer optional Zoom exercise sessions to our participants to complete their exercises at home. The Zoom exercise session will be hosted and led by our trained exercise coaches. If a participant is interested in joining our Zoom exercise sessions they will be provided with instructions on how to connect to our HIPAA compliant Zoom session. The exercise coach will lead the exercise session with the same instructions and exercises that are on the DVDs.

At any time during the study at home participants are welcome to join any exercise site to continue the program.

If a participant does not have a computer or access to the internet, we will provide tablets and data plans for those who want to exercise virtually, for the duration of the study. Upon completion of the study, we will attempt to collect the tablets back by calling the participant over the phone and sending a prepaid mailer or collecting them in-person if applicable. If participant continues as a community member, they will be allowed to use the tablet until the study end date.

Community Members – *Nonrandomized exercise participants*

Once the community members consents to the research study, and obtain PCP permission to participate, they will have access to:

- The same group leader led exercise program as the intervention participants with the exception of access to an exercise coach.
- Zoom exercise sessions
- *Paper-based Exercise Trackers* that list the rules for progression and help track the community member's progression over time. These trackers are for optional use and will not be collected by the research staff.
- A set of resistance bands if they do not their own.
- If a community members does not have a computer or access to the internet, we will provide tablets and data plans for those who want to exercise virtually, for the duration of the study. Upon completion of the study, or withdrawal from the study, we will attempt to collect the tablets back by calling the community members over the phone and sending a prepaid mailer.

7.2.6.4 Strategies for Promoting Adherence in the Physical Activity Group

To keep participants engaged and adherent in the Physical Activity Group, the following strategies will be implemented at each site

1. **Rotation of balance exercises** – The balance exercises will be cycled through at a frequency determined by each exercise site, so that it adds variety to each exercise session.
2. **Monthly themes** – Each month the exercise coach will introduce a theme to each exercise site. The theme can include educational materials, a monthly challenge, and/or a monthly activity. An example of these monthly challenges could include encouraging participants to take advantage of the nice weather and go for a walk in their community or participating in outdoor activities that could not be done during winter months.
3. **A WISE Study Facebook Group-** A Facebook group will be created for intervention participants to join, if they would like. This group will be used to communicate with other participants across exercise sites. All posts in the group will be voluntarily made by participants, and they do not need to join if they wish not too. Additionally, pictures of research participants may be added by staff for functions such as holiday parties. Only participants with a signed media release form will appear in the photos.
4. **WISE Study Cookbook-** A cookbook was created with recipes submitted by intervention participants. This cookbook will be compiled by research staff and provided to intervention participants who would like a copy. The idea for this cookbook is for intervention participants to share recipes and to help build a broader sense of community within the study. Recipes were submitted on a voluntary basis.

7.2.7. Phone Follow-ups

Group leaders

Every 3 months the Exercise Coach will call, talk to in person, or email the Group leaders to complete a survey to ask about how they feel status of the group they are leading.

Participants

Every 4 months we will call the participants asking questions about the main outcome (SFRI), hospitalization or emergency department visit. A fall calendar will be given to the participant to record all fall events (e.g., date, location). This will help participants to recall falls during the 4 month period. In addition, this will allow medical records to be requested, using a signed authorization form (part of the

consent form). We will review all relevant Electronic Health Records (EHR) information, such as hospital and emergency department discharge summaries, outpatient visit notes, consultation notes, physical exam notes, dictated radiologist notes and plain film radiography.

We will ask questions related to adverse events using the adverse event form.

Community members

Every 3 months the community members will be emailed a REDCap survey, 'Community Member AE and Satisfaction Survey' asking a few satisfaction survey questions and if they have had an adverse event in the last three months. If the community member does not respond to the survey, an exercise coach will call in an attempt to complete the survey. If the participant does report an adverse event, an adverse event form will be completed and reviewed by a study physician within 15 business days of staff being made aware of the adverse event.

7.2.8. Visit 2 and 3 – 12- and 24- Month Phone Follow-up

At years 1 and 2, a telephone follow-up call will be done by a research assistant to collect a brief set of questions and to identify patients who have had a FF/SFRI, hospitalization or emergency department visit. This call will take about 15 minutes. For any subjects with a FF/SFRI or hospitalization/ED use, details about the event (e.g., date, location) will be asked. This will allow medical records to be requested, using a signed authorization form (part of the consent form). We will review all relevant EHR information, such as hospital and emergency department discharge summaries, outpatient visit notes, consultation notes, physical exam notes, dictated radiologist notes and plain film radiography. In addition, staff will notify participants and their PCPs of any critical values from the PROMIS questionnaire sections for anxiety and depression at the 12 and 24 assessment calls, and for PROMIS anxiety and depression scores.

Research staff will mail an answer guide for the 12 and 24 month assessments with each participant's falls calendar, starting with the 2019 calendar mailed in December, 2018. Having a visual guide to the questions and response choices will aid both the participant and study staff in responding to questions and collecting data.

We will ask questions related to adverse events using the adverse event form.

After completing the phone follow-ups, participants will receive $25 each time.

7.2.9. Visit 4 – 36-Month Follow-Up Visit

Group leaders

At 36-month, Group leaders will receive a telephone follow-up by the research coordinator to collect a brief set of measurements (same questions as baseline) and the net promoter score. This call should not take more than 20 minutes.

Group leaders will receive $100 for completing the 36-months follow-up.

Participants

Participants will complete their 60 minute follow up visit with research staff at Penn State Hershey.

Prior to the 36-month visit, research staff will send participants the following questionnaires, to be completed at home and brought with them to the 36-month assessment: fear of falling, self-reported health, PROMIS 29: depression, anxiety and physical function, fatigue, pain, sleep disturbance, ability to participate in social roles and activities, brief loneliness questionnaire, physical activity, social domain (caregiver), VSPPB and assistive devices. The participant will also be asked to bring along a list of their current medications. These surveys should take approximately 20 minutes to complete.

Research staff will take the participant's blood pressure, height and weight. Research staff will then have the participant complete the 30 second chair stand test, 30 second bicep curl test to measure strength and review medications. Research staff will notify participants and their Primary Care Providers of a critical value for the PROMIS depression and anxiety measures, and of high blood pressure at the 36-month visit.

Research participants who are unable to attend an in-person visit due to extreme circumstances will be given the opportunity to complete a portion of the visit remotely via a telephone call with research coordinators. These circumstances include but are not limited to, travel burden, severe weather, disease outbreak and any recommendations by Penn State University or Penn State Milton S. Hershey Medical Center to stop in-person visits. These remote visits will not include the collection of the participant's blood pressure, height and weight or fitness testing.

Participants will receive $75 for their participation.

7.2.9.1. 36-Month Follow-Up Dual-energy X-ray absorptiometry (DXA)

If PCP thinks it is clinically relevant for the participant to have a DXA scan after the 36-months, the Research staff will take the participant to have the DXA scan at the Penn State Hershey Breast Center. The DXA scan should not take more than 30 minutes.

If the participant has received a DXA scan within 1 years of their 36-month visit date, the research staff person will request a copy of the DXA report either from the participant or the participant's PCP.

7.2.10 Quarterly Newsletters

As a part of our retention strategy, all of the participants will be mailed a newsletter every 3 months. These newsletters will be used to promote ongoing support and participation and to provide ongoing information related to the research study. The content of the newsletter may include study updates, information about study staff, healthy living tips, a crossword puzzle or similar game, or recipes. In addition to the previously mentioned content, the intervention arm's newsletter may contain updates specific to active exercise sites, DVD updates, or exercise updates.

7.3 Duration of Participation

All participants will be in the study for 36 months. Group leaders will be in the study for 36 months or until the last participant is enrolled, whichever date comes first. Community members will be in the study until the last participant is enrolled and the study ends. Spanish Speaking Interview Members will be in the study for a one-time phone interview.

8.0 Subject Numbers and Statistical Plan

8.1 Number of Subjects

Participants

For the study-wide enrollment (across all 3 institutions) we will aim to enroll 1130 participants. We anticipate about 15% of participants will drop or be lost to follow up or die. We will need a total of 960 to complete the study.

At Penn State, we will aim to enroll 501 participants to the study. We anticipate that about 15% of participants will drop out or be lost to follow up or die. We will need a total of 425 participants to complete the study.

Group Leaders

We will enroll about350 Group leaders into the study across all 3 institutions. At Penn State, we will enroll approximately 125 Group Leaders.

Community Members

We will enroll up to 250 community members.

Spanish Speaking Interview Members We will enroll up to 75 subjects.

8.2 Sample size determination

In order to have 95% statistical power to detect a 6% difference in the composite outcome measure of SFRI (including FF) between groups at 36 months follow-up, we will enroll 500 subjects at baseline. We assume a Type 1 error rate (alpha) of 5% (.05), statistical power of 95% (.95), and a two-tailed log-rank test for the time until SFRI (including FF), which allows us to detect significant differences in either direction. We estimate that 10% of subjects will be lost to follow-up at 36 months, as losses to follow-up in studies of older adults tend to be lower (37). Also, for subjects lost to follow-up, we will conduct an electronic health record, to measure the incidence of FF/SFRI. The study is over-powered for the main outcome measure (SFRI, including FF), in order to (1) provide the possibility of seeing an impact on FF, the most clinically meaningful measure and (2) insuring, given the amount of money spent on the study, that it is powered to observe a clinically meaningful difference even if several of our assumptions are not met.

8.3 Statistical methods

We will conduct the primary analyses on the main outcome measure, SFRI, including FF. Initially, the two randomized groups will be compared qualitatively on important demographic and other baseline variables to ensure successful randomization. For the primary outcome (SFRI, including FF), we will apply intention to treat (ITT) principles with all available data and the covariates of medical center, age, gender, race and ethnicity, smoking status, education included in the primary set of analyses (112, 113). If it is determined that the groups, by chance, are significantly different on other covariates, then we will include those covariates in secondary analyses. Of note, while the original proposed study of 2100 subjects was powered to detect a difference in fragility fractures, the modified sample size of 1130 will be powered only to detect a difference in serious fall-related injuries, of which fragility fracture is only one type. As the rate of fragility fracture is lower than the rate of serious fall-related injury, the study is no longer powered to detect a difference in fragility fracture, yet is powered to detect a difference in serious fall-related injury.

Power Estimates (assuming 15% lost to follow-up, 960 remaining at 3 years).

	Control rate	Intervention Rate	Relative Risk Reduction	Number Needed To Treat	Power
Serious Fall-related injury (BASE)	13%	7%	46%	17	87%
● Scenario 2 (smaller effect)	13%	8%	38%	20	71%
● Scenario 3 (lower rate of FF/SFRI)	12%	6%	50%	17	90%
● Scenario 4 (smaller effect + lower rate of FF/SFRI)	12%	8%	33%	25	54%
Fragility Fracture alone	7%	4%	43%	33	53%

Sample Size Calculations. In order to have 95% statistical power to detect a 6% difference in the composite outcome measure of FF/SFRI between groups at 36 months follow-up, we had planned to enroll 2100 subjects at baseline. Since the original application and after extensive discussions with PCORI in response to a lower-than-expected enrollment rate, we have lowered the recruitment projections to 1130. We assume a Type 1 error rate (alpha) of 5% (.05), statistical power of 87% (.95), and a two-tailed log-rank test for the time until FF/SFRI, which allows us to detect significant differences in either direction. We estimate that 15% of subjects will be lost to follow-up at 36 months (170), as losses to follow-up in studies of older adults tend to be lower. For example, the LIFE study was 2.6 years and had a 97% follow-up rate, with less than 1% dying (4/1635) despite a baseline of 78 (37). Also, for subjects lost to follow-up, we will conduct an electronic health record, to measure the incidence of FF/SFRI. The study is over-powered for the main outcome measure (SFRI, including FF), in order to 1) provide the possibility of seeing an impact on FF, the most clinically meaningful measure and 2) insuring, given the amount of money spent on the study, that it is powered to observe a clinically meaningful difference even if several of our assumptions are not met (see table above).

9.0 Confidentiality, Privacy and Data Management

See the research data plan review form

10.0 Data and Safety Monitoring Plan

The intervention and measurement protocols pose greater than minimal risk to participants.

The Data and Safety Monitoring Team includes at least one faculty member from Penn State Hershey, one statistician from Penn State Hershey, one faculty member from Temple University, and one faculty member from University of Pittsburgh. They will conduct bi-annual meetings to evaluate the progress of the study, including consent and regulatory procedures, recruitment goals, response assessment, participant follow-up, intervention administration, reporting of adverse events, data quality/completeness, protocol adherence, accrual and retention of participants, confidentiality and other factors that may affect safety and study outcome. Data and safety monitoring activities will continue until all participants have completed the intervention and follow-up phase and are beyond the time point at which study-related adverse events would presumably be encountered.

All adverse events will be documented on study specific case report forms and entered into REDCap. The potential adverse effects associated with the study are few and we believe are primarily related to participants exercising and uncovering a dormant orthopedic problem (e.g., rotator cuff tendinitis). We will ask subjects at all follow-ups whether they believe that the program harmed them in some way. If the subject believes that this is the case, details about the circumstance will be obtained. At Penn State, Dr. Noel Ballentine will examine the information for any subjects that report a potential adverse event. Each case of a potential inaccuracy will be reviewed by the Data and Safety Monitoring Team, who will then make recommendations to prevent future events. Penn State Hershey Medical Center (PSHMC) has an established formal mechanism for promptly reporting adverse events. We will follow this mechanism in identifying and reporting adverse events. Moreover, bi-annual meetings will be scheduled to track, report and assess participant data and reporting of adverse reactions to the intervention. In addition to monitoring adverse events by randomized arm, the monitoring team will monitor for individual adverse events, regardless of arm, to identify adverse events and then deliver corrective actions.

All deaths on study, not related to progression of underlying disease and probably related to the study, will be reported to the IRB (FDA, sponsor, etc) immediately. All unanticipated AEs related or possibly related to the study will be reported by Dr. Rovniak to the IRB according to HSPO policies and procedures.

The PI and study Statistician will review cumulative adverse events, early termination of study participation, and report any issues requiring modification of the study or alteration of the risk: benefit ratio to the IRB immediately. A summary of adverse events, study progress and protocol modifications will be included for IRB review in the continuing review report.

11.0 Risks

The risks to subjects in this study are judged to be minor. Foreseeable risks to participating include possible injury from exercising. We aim to decrease this risk by instructing participants to exercise at a level that is somewhat hard, but not very hard. Also, we will individualize the exercises depending on the capabilities of each person. Every participant will start at the lightest resistance band and once exercises become easy, they may progress to a higher resistance band.

Exercise is recommended as a standard of care for all adults with fragility fractures, as per the National Osteoporosis Foundation Guidelines (2014). We have modeled our program based on Silver Sneakers, the nation's largest senior exercise program, available in over 7000 locations in the US today. This point alone, we believe, categorizes the study as minimal risk because it is similar to what would be "*ordinarily encountered in daily life*" in a Silver Sneakers (or other standard) programs available across the country.

For participants, there is the risk of ionizing radiation due to the optional whole body DXA scan.

To reduce risk, we are performing pre-participation screening that is above and beyond what Silver Sneakers or other programs typically do. We made this modification as an update to the pre-participation screening guidelines were released late in 2015.

In addition, the balances and cardiovascular exercises will be personalized depending on the individual's needs. Coaches will train Group leaders to make sure they can instruct participants to do the exercises correctly and prevent injuries. Group leaders will make sure bands and equipment are in good condition to use (to prevent an injury do to breaking equipment).

Group leaders will be instructed to what to do in case of an injury or emergency during the BT session. The following trainings will be included: the Community Partner Research Ethics Training (CPRET) designed by the

University of Pittsburgh, and the AHA Family & Friends CPR Anytime training. In addition, each site has a written emergency plan and kit that includes materials such as Band-Aids, ice packs and glucose tables, for a patient with diabetes whose glucose falls (we have experienced this in Band Together in the past).

It is possible that personal information (including, but not limited to health) will be disclosed during the exercise sessions, as part of normal conversation that happens each time. We will encourage Group leaders to regularly mention that "Like any other social interaction, personal information will be shared – so we ask that everyone do their best to respect the confidentiality of everyone's personal information".

Loss of confidentiality is a risk but precautions will be taken to prevent this from happening. All PHI (in both paper and electronic form) will be separated from data collected from subjects. Paper documents and electronic information containing data will have only the subject's code/ID number. Research staff will use REDCcap (a password-protected and encrypted electronic research data program) to both collect and store data. Staff will have some paper copies of research documents and data (eg. Surveys), that will be stored in a locked cabinet in Dr. Sciamanna's research office Critical data collected on paper will then be inputted in the REDCap data base. Data not labelled as critical may be left only on the paper source document.. PHI will be located in Redcap.

12.0 Potential Benefits to Subjects and Others

12.1 Potential Benefits to Subjects

Participant, Group Leaders & Community Members

There is no guaranteed benefit from participating in the studies. A participant may benefit by becoming stronger, more flexible and fit due to the strength, balance and aerobic exercises.

Spanish Speaking Interview Members There is no benefit from participating in the research study

12.2 Potential Benefits to Others

We hope that by demonstrating the effectiveness that a 36-month, exercise-coached intervention in older adults who have had a fall-related fracture, insurance companies and Medicare could determine whether such a service should be covered for health insurance purposes.

13.0 Sharing Results with Subjects

1. We will communicate any *critical* values of a baseline measure to the both the patient/group leader and their primary care provider (e.g., Blood pressure and Depression screen). In addition, staff will notify participants and their PCPs of any critical values from the PROMIS questionnaire sections for anxiety and depression at the 12 and 24 assessment calls, and for PROMIS anxiety and depression scores and high blood pressure at the 36-month visit. This is in addition to notifying participants and PCPs about critical values at the baseline visit.

14.0 Subject Stipend (Compensation) and/or Travel Reimbursements

Group leaders:

Group leaders will receive a total of $150 on a GreenPhire Clincard, or in Target or Walmart gift cards, depending on their preference, throughout the 3 years study:

- $50 for the baseline visit/training
- $100 for the 36 month phone follow up

Participant

Patients in the intervention and control groups will receive a total of $150 on a GreenPhire Clincard, or in Target or Walmart gift cards, depending on their preference, throughout the 3 years study:

- $25 for the baseline visit
- $25 for the 12-month follow up
- $25 for the 24-month follow up
- $75 for the 36-month follow up

Community Member

There is no monetary stipend for community members. They will be given access to the free exercise program at our exercise sites.

Spanish Speaking Interview Members Spanish Speaking Interview Members will receive a either a $50 Target or Walmart gift card depending on their preference.

15.0 Economic Burden to Subjects

15.1 Costs

Patients and their medical insurance will be billed for the Axial DXA scan that is part of standard of care.

15.2 Compensation for research-related injury

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

16.0 Resources Available

16.1 Facilities and locations

Group Leaders:

Baseline and Training session will be held at Penn State Hershey Medical Center or at signed exercise community locations (e.g., senior centers, churches).

Participants.

Baseline and 36 month follow-up

We will reserve a meeting room at Penn State Hershey Medical Center to be used for our baseline and 36 month follow up measurements.

We will use the DXA center facilities to perform Axial scan and total body scan.

Weekly Exercise Sessions Location

The exercise session will be held at the community sites (e.g. churches, senior residential facilities, community centers).

Spanish Speaking Interview Members Individual interviews will be conducted with the Spanish speaking members over the phone. .

16.2 Feasibility of recruiting the required number of subjects

The feasibility of our study will depend on the ability to recruit, maintain participant adherence, and deliver a consistent intervention across sites, among other factors. The Lead group team will review and provides feedback respect with goals for recruitment, adherence, and retention.

We will use electronic health records of ICD-codes for FF. We anticipate sending letters to about 10,000 patients ≥ 65 who have had a FF (about 5,000 from Penn State and 5,000 from Highmark). At Penn State, we will work with Matt Bolton, CTSI IT, to export a list of patients who meet inclusion criteria based on age and FF history. In addition, we have partnered with several health insurance companies, including, Highmark Blue Shield, which insures 3.5M Pennsylvanians, to send letters to FF patients around the main 3 study institutions (Penn State, University of Pittsburgh, and Temple University).

16.3 PI Time devoted to conducting the research

Dr. Sciamanna will monitor the progress of participant recruitment and enrollment and will hold weekly meetings with research staff and co-investigators. He will notify the PCORI Program Director of any important issues.

16.4 Availability of medical or psychological resources

Not applicable.

16.5 Process for informing Study Team

The overall research project manager is responsible for creating and updating a working protocol of study procedures. In addition, the project manager is responsible for training the research staff on the protocol.

17.0 Other Approvals

17.1 Other Approvals from External Entities

We will get approvals from the 15exercise site locations that we can hold the exercise programs at their location for the duration of the 3 years. The site locations will include churches, community locations or senior residential facilities.

17.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – Hershey only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of the Use of Human Tissue For Research Form on the "Supporting Documents" page in CATS IRB. This form is available on the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/forms

☐ Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – All campuses – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.

☒ Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload the Radiation Review Form on the "Supporting Documents" page in CATS IRB. This form is available on the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/forms

☐ IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – Hershey only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external Group-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/investigator

18.0 Multi-Site Research

18.1 Communication Plans

The lead investigative team (Core PI, all site PIs, core project manager and core exercise physiologist) meet on a weekly basis to create and modify the protocol and well as address any issues that arise from any of the sites. The core project manager and core Principal Investigator will work together to create a standard protocol and disseminate it among the sites to submit to each institution's IRB. The core project manager will also coordinate and review any modifications to the protocol with both the lead team and with all the site project managers (there is a project manager for each site) to submit the appropriate changes to their IRB.

18.2 Data Submission and Security Plan

The core Principal Investigator will discuss with the lead investigative team when data should be submitted to the main site (Hershey). During the regularly scheduled site visits (core project manager and core exercise physiologist), they will ensure that all sites are safeguarding the research data per security policies.

Critical data will be entered into REDCap (https://redcap.vanderbilt.edu/) on the servers of each study site separately. As this is a multi-site study, research data will need to be moved from research site to research site (e.g., University of Pittsburgh to Penn State) as well as from the bone densitometry machines to the research site. To move the data, a Friends of Penn State ID will be created to share data between sites through REDcap. In addition, we will use the Penn State Hershey Secure File Transfer (SFT).

18.3 Subject Enrollment

The lead investigative team meets on a weekly basis and one of the topics discussed will be recruitment. The core project manager and Site PIs will provide updates to the group on each site's recruitment

status. The core project manager will also check in weekly with the site project managers. In addition, we will have an Engagement committee who will be meeting regularly to discuss recruitment and retention milestones and barriers.

Randomization will be conducted through REDCap. The randomization scheme is stratified by site (Penn State/ University of Pittsburgh/ Temple University), gender (male/female), and bisphosphonate use (ever/never). Dr. Chinchilli will work with the study statistician to create the randomization list, based on expected rates of recruitment of each strata from each study site.

18.4 Reporting of Adverse Events (AE) and New Information

All potential AEs that are brought to the attention of the research staff will be passed on to the site PIs. At each research institution, the site PI will determine the likelihood that the AE is due to the study. AEs will be reported to the IRB if the harm was unexpected AND likely/probably related to the research

Site project managers will be responsible for communicating all site adverse events to the core project manager. The core project manager will review all adverse events and place them into categories to be reviewed by the data and safety monitoring team during the bi-annual meeting (described in section 10).

18.5 Audit and Monitoring Plans

The lead investigative team meets on a weekly basis. During this time the Site Principal Investigators will review and update the Core Principal Investigator on the study's progress at their site.

Each quarter, the overall project managers will visit each of the research sites to audit a set number of research files, for completion and accuracy. The overall project manager will also audit a number of phone interviews and a number of face to face meetings between research staff and participants to assure that protocols are being followed equally across sites.
In addition to the project manager, a clinical trial monitoring group from Penn State's department of Public Health Sciences will be conducting data quality control process for determining whether the study activities are being implemented according to the protocol (e.g., adverse events are reported as defined in the protocol; data quality, completeness, and timeliness evaluated).
Based on these audits, the frequency of future audits will be determined. If, for example, problems with procedures are observed, the core project manager will return sooner than later, to assure that a plan to fix any errors has been put in place and is being used successfully.

19.0 Adverse Event Reporting

19.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

20.0 Study Monitoring, Auditing and Inspecting

20.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

21.0 Future Undetermined Research: Data and Specimen Banking

Not applicable.

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