Study of Hyperkyphosis, Exercise and Function - SHEAF

Protocol

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PREFACE

Study of Hyperkyphosis, Exercise and Function - SHEAF

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PRÉCIS

Study Title

Study of Hyerkyphosis, Exercise and Function-SHEAF

Objectives

Our long-term goal is to develop interventions to delay functional decline and physical disability in older adults. Exercise interventions targeted at increasing function in older adults often neglect posture and spinal muscle weakness. We propose a paradigm where we can improve physical function in an exercise intervention targeted at reducing hyperkyphosis, which may reduce associated disability.

Design and Outcomes

We propose to conduct a randomized, controlled trial among 100 men and women aged 60 or older with hyperkyphosis to an exercise intervention that includes kyphosis-specific spinal muscle strengthening exercises compared to a non-kyphosis specific stretching exercise control. The study will be conducted in five waves, with 10 participants in the exercise intervention and 10 participants in the control group in each wave.

The experimental and control interventions will be provided in small groups meeting three sessions per week for 6 months. At baseline and 6 months after the intervention, we will measure kyphosis, physical function, spine muscle strength and density, and quality of life.

We will assess the effect of the intervention on the co-primary outcomes of kyphosis, modified PPT (PPT) and gait speed measured as change over 6 months. We will also assess the effect of the intervention on secondary outcomes of physical function and HRQOL, measured as change in Timed Up and Go, Timed Loaded Standing, Six-Minute Timed Walk, the Scoliosis

Research Society SRS-30 (self image domain only) and the PROMIS Physical Function and Global Health Index.

Furthermore, we will investigate whether changes in kyphosis, spinal muscle strength and/or density mediate the effect of the intervention on change in physical function. After the 6-month intervention, both groups will continue their usual activity and we will assess the durability of the effects of the intervention at 1-year follow-up.

Interventions and Duration

Participants assigned to the intervention group will receive a kyphosis-specific spinal strengthening group exercise program for 1 hour three times per week for 6 months, followed by 6 months of usual activity. The participants assigned to the control group will receive a non-kyphosis specific stretching group program for 1 hour three times per week for 6 months, followed by 6 months of usual activity. The intervention and the control group sessions will be conducted in small groups at study intervention sites. A licensed physical therapist will teach the kyphosis-specific strengthening exercise intervention and a different physical therapist will teach the stretching intervention. Physical therapy students and/or research assistants will help ensure the safety of all participants and maintain a ratio of no more than 5 participants to 1 teacher.

Sample Size and Population

One hundred subjects of men and women age 60 years and older and with kyphosis of ≥ 40° will be recruited for this study. In our pilot study, we observed a 2 standard deviation (SD) improvement in kyphosis of 6°.[42] Allowing for improvements in the control group due to regression to the mean, loss to follow-up of 10% of participants, chance under-estimation of the SD of the change in the pilot, and attenuation of the treatment effect due to the imputation procedure, the proposed combined sample size of 100 will provide 80% power in 2-sided tests with a type-I error rate of 5% if the between-group difference in mean kyphosis improvements is at least 50% of the SD of the changes; this calculation accounts for the correlation of the pre- and post-intervention measurements (0.8 for both kyphosis and PTT scores in the pilot study), which will improve efficiency by reducing residual error in the proposed ANCOVA analysis procedure. The pilot study gives strong evidence that these conditions will be met. Similarly, we observed a 1-SD improvement of 2 points in the co-primary PPT endpoint. Thus the study will also be well powered to detect an effect on PTT scores under similarly conservative assumptions about the effect size and retention.

1. STUDY OBJECTIVES

1.1 Primary Objective

We propose 3 specific aims in a randomized controlled trial comparing a 6-month high-intensity kyphosis-specific spinal strengthening exercise intervention to a control stretching intervention in community-dwelling adults 60 years and older with hyperkyphosis.

The exercise intervention will improve hyperkyphosis, as measured by Cobb angle from lateral spine radiographs. The exercise intervention will also improve physical function, as measured by the Modified Physical Performance Test, gait speed, timed loaded standing and spinal extensor muscle strength.

Specific Aim 1: To determine if the exercise intervention improves kyphosis, the Modified Physical Performance Test (PPT) and gait speed in person with kyphosis

Hypothesis 1: We hypothesize that the co-primary outcomes of kyphosis, measured as Cobb angle using lateral spine radiographs, and physical function, measured as the Modified Physical Performance Test and gait speed, will improve after the 6-month intervention.

1.2 Secondary Objectives

Specific Aim 2: Determine if the exercise intervention improves secondary measures of physical function, and health-related quality of life (HRQoL) .

Hypothesis 2: We hypothesize that secondary measures of physical function, including Timed Up and Go, Timed Loaded Standing, and HRQOL, measured as the Scoliosis Research Society SRS-30 (self image domain) and PROMIS Physical Function and Global Health Index, will improve after the 6-month intervention.

Specific Aim 3: Determine if the exercise intervention improves spinal muscle strength and/or spinal muscle density and if changes in spinal extensor muscle strength and/or density mediate the effects of change in kyphosis on physical function.

Hypothesis 3: We hypothesize that spinal muscle strength, measured with a Biodex computerized dynamometer, and spinal muscle density, measured with quantitative computed tomography, will improve after the

6-month intervention. We hypothesize that the intervention will have direct effects on function, as well as indirect effects on function via kyphosis, muscle strength, and density; we also hypothesize an indirect effect of the intervention on kyphosis via strength and density.

2. BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Hyperkyphosis is a highly prevalent condition among elderly persons. While a small amount of anterior curvature of the thoracic spine (kyphosis) is normal due to the shape of the vertebral bodies and intervertebral discs, a thoracic curvature between T4 and T12 that is greater than 40 degrees is defined as hyperkyphosis.[23] Persons with hyperkyphosis have a global misalignment of the spine, measured as a plumb line from C7 to S1 falling in front of the sacral promontory.[7, 25] Several methods quantify kyphosis, including lateral radiographic Cobb angle of kyphosis (the gold standard), and clinical measures including Debrunner kyphometer,[26] supine block method for forward head alignment,[27] occiput to wall distance,[7] electric inclinometer,[28] and flexicurve kyphosis index.[29] There is a strong correlation between radiographic Cobb angle and Debrunner kyphometer measures of kyphosis and these are often used interchangeably.[26, 30] Reports of prevalence of hyperkyphosis in older adults vary from approximately 20% to 40% among men and women.[11, 24] It is estimated that kyphosis angle is 6 - 11% higher per decade of life among women age 55-80 years,[31] and kyphosis increases 7 degrees over 15 years among women in the longitudinal Study of Osteoporotic Fractures.[32]

Hyperkyphosis is not synonymous with spinal osteoporosis. It is often assumed that hyperkyphosis is caused solely by osteoporosis and vertebral fractures, but only a third of individuals with severe hyperkyphosis have radiographic vertebral fractures.[17, 27] In fact, recent evidence suggests that impairments in spinal muscle composition, strength, mobility and alignment are important determinants of the degree of kyphosis.[35-38] Higher multisegmental spinal loads and trunk muscle forces are present in the hyperkyphotic vs. normal spine,[39] and improving the biomechanics of spinal load and muscle force distribution could potentially ameliorate the detrimental effects of kyphosis and slow kyphosis progression. To date, small studies have demonstrated that kyphosis-related impairments can be targeted with exercise, but none have established whether reducing these impairments prevents kyphosis progression, or leads to improvement in physical function.

- ***Spinal muscle weakness.*** Spinal extensor muscle strength is an important independent determinant of degree of kyphosis in older adults.[3, 33] Recent studies demonstrate that spinal extensor muscle strength can be increased with targeted strengthening,[4, 34-37] however the effects on kyphosis have been inconsistent. The only large randomized exercise trial did not improve Cobb angle or Debrunner kyphometer kyphosis.[35] High-intensity strengthening rather than low-intensity or yoga-type exercise may be necessary to reduce the Cobb angle or Debrunner kyphosis.
- ***Spinal muscle fat infiltration.*** We examined fat infiltration in the spinal extensor

muscles on quantitative computed tomography (CT) among healthy community-dwelling older men and women and found lower spinal muscle density (a proxy measure of fat infiltration) among older adults with hyperkyphosis.[38] Furthermore, lower spinal muscle density is a known predictor of impaired physical function in older adults,[39, 40] suggesting that improved muscle quality is a possible mechanism for improving physical function that we will investigate in our study.

- *Spinal mobility.* Decreased spinal mobility interferes with the ability to stand erect and maintain optimal postural alignment.[41] Schenkman, et al. determined that hyperkyphosis results in the loss of combined spinal extension and rotation mobility which is highly correlated with impaired physical performance.[42] Furthermore, short pectoral and hip flexor muscles are linked to severe hyperkyphosis,[7] although it is not known whether the short muscles pull the shoulders and hips anteriorly, increasing kyphosis, or whether the kyphosis results in shorter anterior musculature.
- *Spinal alignment.* Hyperkyphosis may be partially attributed to poor postural habits. Postural taping produced immediate reduction in kyphosis, although it was not sustained without mechanical support from the tape.[43] Specific postural training,[44] combined with strengthening,[5] might be most effective.

Exercise trials to reduce hyperkyphosis are limited. Several randomized studies[40-42, 49] of physical activity interventions have demonstrated improvement in clinical measures of kyphosis, but none has demonstrated a link between improvement in kyphosis and change in physical function. None of these trials used high intensity spinal extensor strengthening to reduce hyperkyphosis while targeting all known musculoskeletal impairments associated with hyperkyphosis[21].

2.2 Study Rationale

2.3 **Exercise trials to improve physical function in the elderly are feasible and effective**. There is strong evidence from 121 randomized controlled trials reviewed in a Cochrane Collaboration meta-analysis that people aged 60 years and older who perform resistance exercises become stronger (standardized mean difference (SMD)=0.84, 95% CI 0.67 to 1.00) and improve their physical function (SMD=0.14, 95% CI 0.05 to 0.22).[50] The majority of these resistance exercise programs target lower extremity muscle groups, and none of these trials targeted the spinal muscles or hyperkyphosis. Lower extremity resistance exercise is effective in improving walking speed (SMD=0.08 m/s, 95% CO 0.04 to 0.12) and rising from a chair (SMD -0.94, 95% CI -1.49 to -0.38.[50] In subgroup analyses, when high intensity resistance exercise was compared to low intensity training, both are effective; however, high-intensity training has a larger effect on strength than low intensity training (SMD=0.48, 95% CI 0.03 to 0.93; test for subgroup differences, p=0.07).[51, 52,53, 54,55, 56,57, 58,59] Even individuals in their 80's benefit from high-intensity resistance exercise and are capable of improving strength and physical

function. Among 100 frail nursing home residents, mean age 87±0.6 years, lower extremity high-intensity resistance exercise 3 times a week for 10 weeks increased lower extremity strength 113±3.8%, gait speed 28±3.8% and stair climbing 28±6.6%.[60] Furthermore, serious adverse effects from high intensity resistance exercise are rare when used appropriately in older adult populations.[50] While musculoskeletal complaints such as joint pain and muscle soreness were reported in many studies, no serious events related to the exercise interventions were reported in the meta-analysis of 121 trials of progressive resistance strength training in older adults.[50]

Unfortunately, these trials did not focus on older adults with hyperkyphosis, and it is not clear if the findings can be generalized to this group. Furthermore, these trials did not target spinal muscle strength that can be amenable to intervention. High-intensity spinal extensor strengthening exercise has not been well investigated in older adults with hyperkyphosis. In contrast, in an uncontrolled trial we demonstrated that a high-intensity spinal extensor strengthening exercise intervention improved spinal extensor muscle strength, reduced kyphosis, and improved physical function for elders with hyperkyphosis.4The benefit of reducing hyperkyphosis on physical function has not been demonstrated in a full-scale randomized controlled trial. Additionally, no clinical trials have investigated whether exercise that improves kyphosis, spinal muscle strength and/or spinal muscle density predicts improved physical function.

In Dr. Katzman's pilot trial, after 12-weeks of training, we observed a 6° decrease in Debrunner kyphosis, an 11% improvement from baseline and exceeding the amount of progression in kyphosis typically observed over a decade in older females.[21] In addition to improvement in kyphosis, physical function improved 2 points ($p<0.001$) on the Modified Physical Performance Test, a 9-item composite test of physical performance, and 1.4 seconds ($p<0.001$) on the jug test ($p<0.001$), a timed lifting test (table1).[21] Improved kyphosis and gains in physical function were maintained 1 year after the participants completed the intervention.[22, 65] Dr. Katzman was responsible for all phases of the study, including conceptualization, design, development of forms, recruitment, implementation, data management, and analysis and presentation of results.

TABLE 1. CHANGE IN KYPHOSIS, STRENGTH, AND PHYSICAL FUNCTION AFTER 12-WEEKS

Kyphosis	change ± sd	p-value
Debrunner kyphosis (degrees)	-6 ± 3	<.001*
Strength		
Biodex spinal extensor strength (% body weight)	21 ± 13	<.001*
Physical function		
Jug test (seconds)	-1.4 ± 1.3	.001*
Modified Physical Performance Test (36-points)	2 ± 2	.001*
Gait speed (meters/second)	0.05 ± 0.10	.06

*p<0.05

Feasibility and retention in the pilot trial: It was feasible to recruit participants for the pilot trial, screen by telephone and a clinic screening visit, and enroll prior to a baseline examination. Our recruitment methods included posting flyers at local clinics, hospitals, and senior community centers. Over 1 year, we screened a total of 189 people by phone, of whom 93 (49%) were eligible to attend the screening visit. Of these eligible participants, 92 (48%) attended the clinic screening visit, which included measurement of kyphosis and a cognitive screening exam. A total of 36 (39%) persons screened at the clinic visit fulfilled study eligibility criteria and were invited to enroll in the study. Eleven (30%) declined participation, and 25 participants were enrolled in the study. Four participants withdrew during the study, 3 due to nonstudy-related injuries and 1 withdrew because of a family emergency. Of the 25 enrolled in the study, 21 (84%) completed the trial.

Adherence in the pilot trial: we measured adherence to the exercise intervention by attendance at the classes and by self-reported frequency of practice of home spinal alignment. We requested that all participants enrolled attend 24 classes over the course of the 12-week pilot trial; we provided four make-up classes to accommodate absences. We requested that participants practice ideal spinal alignment 3 times a day. Each participant was given a log in which to record each practice session.

Adherence to group exercise classes was exceptional. Other than those who withdrew because of unrelated injuries or family emergency, all participants completed 24 sessions and exceeded the required 3-times-per-day home spinal alignment practice. Participants were asked for feedback about the study at the 1-year follow-up visit, and all reported a newfound sense of confidence walking with improved spinal alignment.

3. STUDY DESIGN

Overview. We propose to conduct a randomized, controlled trial among 100 men and women aged 60 or older with hyperkyphosis to an exercise intervention that includes kyphosis-specific spinal muscle strengthening exercises compared to a non-kyphosis specific stretching exercise control. The study will be conducted in five waves, with 10 participants in the exercise intervention and 10 participants in the control group in each wave.

The experimental and control interventions will be provided in small groups meeting three sessions per week for 6 months. At baseline and 6 months after the intervention, we will measure kyphosis, physical function, spine muscle strength and density, and quality of life. We will assess the effect of the intervention on the co-primary outcomes of kyphosis, Modified PPT (PPT) and gait speed measured as change over 6 months. We will also assess the effect of the intervention on secondary outcomes of physical function and HRQOL, measured as change in Timed Up and Go, Timed Loaded Standing, Six-Minute Timed Walk, the Scoliosis Research Society SRS-30 (self image domain) and PROMIS Physical Function and Global Health. Furthermore, we will investigate whether changes in kyphosis, spinal muscle strength and/or density

mediate the effect of the intervention on change in physical function. After the 6-month intervention, both groups will continue their usual activity and we will assess the durability of the effects of the intervention at 1-year follow-up.

4. SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 and 4.2 Inclusion and Exclusion Criteria

Study participants. The study population consists of 100 community-dwelling men and women aged 60 years and older with kyphosis ≥40 degrees measured by Debrunner kyphometer (Proteck AG, Berne, Switzerland), a protractor-like tool placed over the T4 and T12 spinous processes to measure kyphosis externally.[28]

Eligibility criteria: Participant eligibility will be assessed with a telephone interview, a clinical screening visit, and subsequently during a telephone screening with the participant's primary care provider. If the participant's primary care provider does not approve participation, or if they do not have a provider, and is unwilling to see a primary care provider, they will be excluded from the study.

We will exclude for: 1) advanced disability or end-stage disease, 2) no active movement in thoracic spine, 3) unable to execute exercise safety tests, 4) failure to comply with run-in procedures: poor attendance, non-compliant with wearing a pedometer, 5) major psychiatric illness, cognitive impairment, or substance abuse, 6) uncontrolled hypertension, diagnosed vestibular or neurologic disorder, total hip or knee replacement or hip fracture within the previous 12 months, oral glucocorticoid medications for 6 weeks or more the past year, unexplained weight loss (>10 pounds in the past year), gait speed <0.6 m/s, painful vertebral fractures in the past 6 months or 3 or more falls in the past year, and 7) non-English speaking.

4.3 Study Enrollment Procedures

Recruitment: Participants will be recruited by referral from their physician and through posted announcements in the University of California San Francisco (UCSF) Collaborative Research Network (CRN) of local senior clinics and community sites. The CRN will develop a strategy to maximize participant recruitment in each participating network clinic, and design appropriate recruitment flyers. Participants will be recruited from 1) network clinics including Potrero Hill Health Center, Southeast Health Center and the Coleman Clinic, Silver Avenue Clinic, and the primary care clinics at San Francisco General Hospital and Lakeshore Primary Care Clinic, 2) community senior programs at Self-Help for the Elderly, and 3) providers in the UCSF Department of Orthopedics Spine Clinic and the Veterans Affairs Medical Center (VAMC) 4) providers at Kaiser Permanente San Francisco (pending) and 5) UCSF Osher Center for Integrative Medicine (pending).

Obtaining informed consent and enrollment of subjects: After a participant is screened by telephone, they will be invited to attend a group orientation and, an individual screening visit will be scheduled. At this screening visit, Dr. Katzman and a research assistant will explain the study, obtain informed consent, and screen for additional criteria (kyphosis ≥40 degrees, active movement in the thoracic spine, gait speed ≤0.6m/s and unable to execute exercise safety tests). Once they meet initial screening criteria Drs. Long and Shafer will screen for additional medical criteria and contact their primary care provider before enrolling eligible participants in the study.

5. STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

Intervention
Participants assigned to the intervention group will receive a kyphosis-specific spinal strengthening group exercise program for 1 hour three times per week for 6 months, followed by 6 months of usual activity. The participants assigned to the control group will receive a non-kyphosis specific stretching group program for 1 hour three times per week for 6 months, followed by 6 months of usual activity. The intervention and the control group sessions will be conducted in small groups at the study sites. A licensed physical therapist will teach the kyphosis-specific strengthening exercise intervention and a different physical therapist will teach the stretching intervention. Physical therapy students and/or research assistants will help ensure the safety of all participants and maintain a ratio of no more than 5 participants to 1 teacher.

- **Intervention:** Kyphosis-specific spinal strengthening exercises: We developed the intervention protocol of targeted spine exercises during our pilot study based upon the literature and clinical experience[3, 7, 35, 38, 47] We standardized the protocol with a written script and a video. Each exercise session will be preceded by light aerobic activity, ended with cool-down and stretching the neck, chest and all extremities. All participants will be carefully monitored to ensure that all exercises will be performed slowly, with correct body alignment and technique to minimize risk of injury.

Kyphosis-specific exercises include progression to high-intensity spinal extensor muscle strengthening, spinal mobilization, and postural alignment training (Table 3). The exercises target multiple musculoskeletal impairments that are known to be associated with hyperkyphosis, including spinal extensor muscle weakness,[3, 38] decreased spinal mobility,[35, 47] and poor postural alignment.[7]

The strengthening regimen incorporates progression to high-intensity strengthening exercise at a Borg Scale intensity of 15-17, based upon 70-80% of perceived exertion.[76] A 70-80% rating of perceived exertion (RPE) is the stimulus recommended to produce significant strength gains, and often results

in improved endurance, in upper and lower extremity muscles in older adults.[76-79] We will implement a graduated protocol the first 10 weeks beginning without resistance the first month, while participants learn the exercises, and progressing the exercise intensity with theraband or resistance with weights to light (30-40%), moderate (50-60%), then high (70-80%) intensity resistance. We will progress intensity at 3-week intervals allowing time for periodization.[80] When exercising at a Borg Scale intensity of 15-17, within the first 2 repetitions, one typically rates the level of difficulty as "somewhat hard" to "hard".[81, 82] If the participant rates the difficulty less than "somewhat hard", the resistance will be increased, or if the participant rates difficulty as more than "hard", resistance will be reduced. The goal is to perform 2 sets of good quality movement in the range of 70-80% of maximum until momentary muscle fatigue at 8-12 repetitions.[83, 84] Weights will be increased from one pound, in one-pound increments, and theraband resistance will be increased, progressing from yellow to red to green to blue theraband (corresponding to 2 to 10 pounds of force for each percentage of theraband strain).85 Resistance will be increased throughout the trial to maintain a "somewhat hard" to "hard" level of exertion.

The spinal mobilization regimen incorporates foam rollers and end-range exercises to increase spinal extension and rotation, and reduce mobility limitations in the anterior shoulders, chest and spine.[4, 86, 87] Participants will lie supine on foam rollers, and perform sidelying and standing end-range thoracic extension and rotation to mobilize the spine during exercise.[4]

The spinal alignment regimen aims to integrate improvements in spinal extensor strength and spinal mobility into practice.[4] The instructor will train participants to recognize correct spinal alignment and maintain their best spinal alignment during the group exercise program and during activities of daily living.

Table 2. Exercise Intervention

Kyphosis-specific Exercise	*Kyphosis-specific exercise*	Non-kyphosis specific exercise
Spinal strengthening exercises 2 sets of 8-12 repetitions *progressed to 70-80% RPE;* 0 – 5# weights or theraband	Spinal mobility exercises Passive 30 second hold	Warm-up Increase core temperature with aerobic warm-up
Prone trunk lift to neutral	Spine mobilization on roller	
Quadruped arm/leg lift	Standing shoulder flexion/thoracic extension	Stretch/cool-down
Bilateral latissimus pull-down on roller	Quadruped thoracic extension mobilization	Neck and upper extremity Stretches
Sidelying rotation and extension	Spinal alignment	
Transversus abdominus	Training in bilateral and single	Lower extremity

strengthening	leg stance	stretches
Wall push-ups with spine in neutral	Training sit-to stand, squats, lunges	Diaphragmatic breathing

Control: Stretching exercises: To provide both the intervention group and the control group with equal opportunity to experience social support and to receive attention from a teacher, we have designed a control group that gives participants the same frequency and duration of group sessions as the intervention group. The control group exercises include non-kyphosis specific stretching exercise that is also included in the intervention. Sessions begin with aerobic warm-up on the treadmill or the bike at approximately 30-40% of their maximum, at a "fairly light" intensity, followed by stretching of all major muscle groups with a 20-30 second hold repeated 3-5 repetitions each, consistent with guidelines sufficient to increase flexibility.[78, 84] Participants will be instructed to perform static stretching, without ballistic movements.

Maintenance: After the 6-month exercise period, participants from both groups will continue their usual activity during the maintenance phase. They will receive a reminder phone call to wear the actigraph for a week[88] each month to monitor physical activity during the maintenance phase.

5.2 Handling of Study Interventions

Standardization and quality control: Dr. Katzman will provide standardized training to the licensed physical therapists and physical therapy students involved in teaching the exercise sessions. Verbal instructions for the exercise intervention, verbal reinforcement, repetitions and progression in the exercise intervention have been standardized in our previous pilot study, and these procedures will be reviewed periodically to maintain consistency with the protocol. Throughout the study, Dr. Katzman will conduct unannounced drop in visits to the intervention and control group exercise and stretching classes to ensure ongoing consistent standardized implementation. To minimize other co-interventions, all participants will be asked to refrain from beginning any new recreational, exercise, or other treatments for kyphosis until the trial has ended.

5.3 Adherence Assessment

Study adherence will be monitored throughout the study. Attendance at study visits and overall adherence to study protocol will be monitored.

6. STUDY PROCEDURES

The study procedures are detailed in the Appendix.

6.1 Schedule of Evaluations

A participant's eligibility will first be assessed with a telephone screening. If person is still interested and eligible they will be asked to complete the following schedule of events:

- Clinic Screening
- Medical Screening
- Run In
- Testing Visit 1 (Baseline)
- Intervention/Control Visits
- Testing Visit 2 (6 month)
- Maintenance Period
- Testing Visit 3 (1 year)

6.2 Description of Evaluations

Telephone Screening: When potential participants call inquiring about study, the research assistant will explain the study and obtain basic demographic information from the caller. Callers will be screened for age, co-morbidities and if they think they have a curvature in their spine.

Clinic Screening: After a participant is screened by telephone, they will be invited to attend a group orientation and, an individual screening visit will be scheduled. At this screening visit, Dr. Katzman and a research assistant will explain the study, obtain informed consent, and screen for additional criteria (kyphosis ≥40 degrees, active movement in the thoracic spine, gait speed ≥0.6 meters/second and safety assessments).

Medical Screening: Once they meet initial screening criteria a study physician will review their medical criteria and contact their primary care provider before enrolling eligible participants in the study

Run-in: Once enrolled in the study and prior to randomization, participants will be expected to attend a group orientation program at the study site where the exercise sessions will take place. Participants will receive an actigraph with verbal and written instructions to wear it at the waist or hip for 1 week to monitor physical activity. The purpose of this run-in period is to allow us to assess whether participants are committed to full participation in the study by documenting attendance and use of the actigraph.

Test Visit 1 (Baseline and Randomization): After the run-in period, participants will be randomized to the intervention group or control group. Participants will

be randomized in equal proportions to intervention or control using randomly permuted blocks of randomly selected size 4 stratified by age and gender. Treatment assignments will be generated prior to the study, then placed in order in sealed, opaque envelopes with stratum-specific sequential ID numbers. Consenting participants fulfilling study eligibility criteria will be assigned the next available ID number for the appropriate gender and age stratum. The date and time each envelope is opened will be recorded in a log along with participant ID to ensure integrity of randomization. Participants in this study cannot be blinded, but study staff involved in measuring all outcome measures will not be involved in study visits or the study intervention, and will be blinded to group allocation.

Participants will come in to the UCSF Clinical Research Center study site for kyphosis-related impairment, functional performance and health related quality of life measurements. They will receive spinal radiographs and computed tomography scans at the UCSF Department of Radiology.

Intervention/Control Study Visits: Participants assigned to the intervention group will receive a kyphosis-specific spinal strengthening group exercise program for 1 hour three times per week for 6 months, followed by 6 months of usual activity. The participants assigned to the control group will receive a non-specific stretching group program for 1 hour three times per week for 6 months, followed by 6 months of usual activity. The intervention and the control group sessions will be conducted at one of the intervention study sites, including the UCSF PhysFit Physical Therapy Health and Wellness Center at the Mission Bay campus, Kasier Permanente French campus (pending), VA Medical Center (pending) and the Osher Center for Integrative Medicine (pending). A licensed physical therapist will teach the kyphosis-specific strengthening exercise intervention and a different physical therapist will teach the stretching intervention. Physical therapy students and/or research assistants will help ensure the safety of all participants and maintain a ratio of no more than 5 participants to 1 teacher.

Test Visit 2 (6 month): Participants will come in to the UCSF Clinical Research Center study site for kyphosis-related impairment, functional performance and health related quality of life measurements. They will receive spinal radiographs and computed tomography scans at the UCSF Department of Radiology.

Maintenance Period: At the end of 6 months, participants will continue usual activity during the maintenance period. Participants will receive phone calls to wear the step-counter for a week each month to monitor physical activity during the maintenance period.

Test Visit 3 (1 year): At the end of one year, participants will be re-measured at the UCSF Clinical Research Center study site for kyphosis-related impairment, functional performance and health related quality of life measurements. They will receive spinal radiographs only at the UCSF Department of Radiology.

7. SAFETY ASSESSMENTS

7.1 Specification of Safety Parameters

A Data Safety and Monitoring Board has been created to review study safety and any adverse events that may occur. The study research assistants will monitor participants during study visits and teach participants to self-monitor to prevent injury during testing and exercise sessions. Prior to each visit, participants will complete an adverse event log to monitor pain, falls, and any injuries. These will be reviewed daily by the PI and the Data Safety Monitoring Board has been established to review any adverse events.

7.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

The Principal Investigator will review the safety and progress of this study on an ongoing basis. The PI will review the adverse event logs on a daily basis and is responsible for evaluating each AE as it occurs. In addition, results of safety reviews will be summarized in the annual progress reports submitted to the IRB and NIH. The annual report will include a list of all adverse events. The annual report will also address: (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely.

Members of the study team will meet after each wave of the intervention to review the progress of the study and address any human subject issues that occur. These discussions may involve adverse event prevention measures, subject accrual issues, research staff training on protection of human subjects, as well as occurrence of adverse events.

The Data Safety and Monitoring Board will meet two times a year.

7.3 Adverse Events and Serious Adverse Events

Description of Adverse Event Grading and Anticipated Adverse Events: An adverse event (AE) is here defined as any unfavorable and unintended sign, symptom, injury or disease temporarily associated with an intervention or procedure, regardless of whether it is considered related to an intervention or procedure that occurs during the course of the study. An AE may be unrelated to the experimental intervention, but nevertheless related to study participation.

The PI will assess the cause of the AE to determine whether it is definitely related, probably related, possibly related or unrelated to study participation. However, information about AE determined to be unrelated to the study participation must be retained for follow-up, documentation and reference. In this study, we do not anticipate moderate, severe, life-threatening or fatal AEs. AE will be scored as follows:

Grade 1	**Mild**	Transient of mild discomfort; no limitation in activity; no medical intervention or therapy required.
Grade 2	**Moderate**	Mild to moderate limitation in activity – some assistance may be needed; simple therapeutic intervention/therapy may be required.
Grade 3	**Severe**	Results in inability to carry on normal activities and required professional medical attention, hospitalization possible.
Grade 4	**Life-threatening**	Extreme limitation in activity, significant assistance required, results in an immediate risk of death and/or results in persistent or Significant disability.

7.4 Reporting Procedures

Reporting of Adverse Events (AE): The PI will review the adverse event logs on a daily basis and is responsible for evaluating each AE as it occurs. Dr. Katzman will notify the chair of the project's DSMB and the UCSF Committee on Human Research (CHR) Institutional Review Board of the occurrence of any adverse events within 48 hours. Serious adverse events (Death, Grades 3 and 4) that occur during the course of the study will be reported immediately to the CHR Institutional Review Board at the University of California at San Francisco (UCSF) in accordance with current University guidelines for reporting adverse events, and the DSMB and NIH Program Administrator within 48 hours.

7.5 Follow-up for Adverse Events

Participants are informed to tell the study investigator, Wendy Katzman, PT, DPTSc, if they feel they have been injured because of taking part in the study. If they are injured

as a result of being in the study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to the particpant or their insurer just like any other medical costs, or covered by the University of California or the study sponsor the National Institute of Aging, depending on a number of factors. The PI and the study physician will consult to determine if and when an injured participant may return to the study.

7.6 Safety Monitoring

The DSMB will make decisions based on pre-specified guidelines detailed below. Decision-making will explicitly include consideration of both statistical and non-statistical issues.

Subjects will have an opportunity to privately discuss any musculoskeletal or other physical complaints due to study exercise with a member of the research study staff on a weekly basis at the beginning of an exercise session. Participants will also have a contact number to report any potential adverse events that occur in between scheduled study visits. We will monitor participants during the study visits, and teach participants to self-monitor during study visits to prevent injury during the testing or exercise sessions. All participants will complete an adverse event log, including pain scale, falls and any injuries before each study visit. Dr. Katzman will be responsible for monitoring the study for patient safety and adverse events, and reviewing these logs on a daily basis. The DSMB will meet twice a year to review study progress and adverse events.

8. INTERVENTION DISCONTINUATION

Steps Emanating from Data Review

The review of data may result in early termination of the study (see stopping guidelines section below), in protocol amendment, or in changes to the data collection plan or study forms. Should the protocol be amended as a result of data review, the UCSF CHR will be notified and the amendment approved prior to study amendment implementation unless the protocol amendment must be implemented to protect the immediate safety of the study subjects. In such a case, the protocol amendment will be immediately implemented and the UCSF CHR will be notified directly after protocol amendment implementation.

Stopping Guidelines

Stopping Early for Efficacy. Improvements of physical activity are known to be difficult to maintain, so estimates of the durability of the effect, to be obtained at 1 year, will be important. In addition, the sedentary lifestyle this intervention addresses poses little risk of adverse events over the planned duration of the study. Accordingly, the slight delay in publishing results will be outweighed by the value of the information obtained from the longer term follow-up.

Stopping Early for Futility: To avoid wasting resources, it is important to allow for early stopping because the likelihood of finding convincing evidence for a treatment benefit appears too low, in the light of interim results, to justify continuation of the trial. Accordingly, futility analyses will be conducted at the time of each interim efficacy analysis. So-called stochastic curtailment procedures [Lan KKG, Simon R, Halperin M. Stochastically curtailed tests in long-term clinical trials. Comm Statist, Series C (Sequential Analysis). 1982;1:207-219. Halperin M, Lan KKG, Ware JH, Johnson WJ, DeMets DL. An aid to data monitoring in long-term clinical trials. Controlled Clin Trials. 1982;3:311-323] will allow early stopping for futility if the conditional power to detect a beneficial effect is too low, given the data in hand. This lack of power should hold under plausible alternative hypotheses for the effect of treatment, including the effect assumed in determining the original sample size. Note that this procedure involves no inflation of the type-I error rate, in fact inducing slight conservatism. The DSMB would make the complex decision to stop early for futility in the light of the conditional power estimates, informed opinion about the plausibility of the alternatives considered, and other, broader considerations listed below.

Stopping Early for Harm: Because it would be unethical to require the same degree of certainty in repeated testing for a detrimental treatment effect as in repeated testing for benefit, protection of the type-I error rate becomes less important, and maintenance of power more pressing. Moreover, adverse effects on secondary endpoints must be considered, thus involving multiple endpoints as well as multiple looks. In view of these ethical and statistical complexities, stopping for harm will be done at the judgment of the DSMB, taking account of the seriousness and estimated excess risk of any observed adverse effects, the strength of the statistical evidence for them, and the broader guidelines listed below. In addition to considering each adverse event individually, the DSMB will consider all the data together, and any necessary additional analyses to be carried out by the data coordinating center, before making a recommendation that the trial be modified or stopped.

Reporting Temporary or Permanent Suspension of a Funded Clinical Trial

The Principal Investigator will be responsible for immediately reporting to the National Institute of Aging (i.e., the Program Officer responsible for the grant), any temporary or permanent suspension of the project and the reason for the suspension.

9. STATISTICAL CONSIDERATIONS

9.1 General Design Issues

Overview: The primary analyses will be by treatment assignment, without regard to adherence to the intervention. Improvements in kyphosis, the Modified Physical Performance Test (PPT), and gait speed at 6 months will be co-primary endpoints. The Hochberg procedure[108] will be used in testing the effect of treatment on these three endpoints. However, given fiscal and feasibility limitations on this

single-site study, tests of treatment effects on 5 additional physical function and HRQOL measures (Aim 2), as well as muscle strength and density (Aim 3), and all 9 comparisons at 1 year, will be regarded as secondary and analyzed without penalty for multiple comparisons, but with results clearly presented as hypothesis-generating.

In preliminary analysis, we will use t-, Wilcoxon, chi-square, and Fisher exact tests as appropriate to compare the treatment and control groups in terms of baseline age, gender, co-morbidities, vertebral fractures, physical activity and level of kyphosis. If between-group imbalances are found, sensitivity analyses will be conducted adjusting for the imbalanced covariates. However, the primary analysis will be unadjusted, to avoid inflation of type-I error and erosion of confidence due to model selection.

9.2 Sample Size and Randomization

Sample size calculation: We calculated minimal detectable effects (MDE) with 80% power in 2-sided tests with a Bonferroni-corrected type-I error rate of 5%, in a sample of 100, allowing for within-subject correlation of the baseline and 6-month outcomes, and loss to follow-up of 20% of participants. This trial is powered to detect a difference in change in kyphosis over 6 months of 2.2 degrees (or more) between the intervention and control groups. Although the expected improvement in kyphosis is small, the hypothesis underlying this study is that preventing the expected progression of kyphosis,[109] and improving kyphosis even a small amount, in combination with improvements in strength and conditioning, will result in meaningful improvements in physical function. In addition, the MDE for PPT and gait speed are comparable to clinically meaningful changes defined by Perera.[110] Moreover, the MDE for kyphosis, PPT and gait are plausible in view of our uncontrolled pilot study results showing mean improvement of 6 degrees in kyphosis, 2 points in PPT and 0.05 m/s in gait speed over 3 months. Even if regression to the mean and spontaneous improvement account for almost half of the mean improvement in our pilot study, our 6 month intervention is likely to yield benefits larger than the MDE in our trial. Standard methods for ANCOVA, positing reductions in residual variance by a factor of 1-r2 due to adjustment for the baseline value of the outcome, were used to obtain these estimates; here r is the within-subject correlation. We used data from the pilot study to estimate r as 0.8 for kyphosis and PPT, and 0.85 for gait speed; we also used pilot data to obtain residual SD (5, 2.6, and .18 respectively).

9.2.1 Treatment Assignment Procedures

Randomization: After the run-in period, participants will be randomized to the intervention group or control group. Participants will be randomized in equal proportions to intervention or control using randomly permuted blocks of randomly selected size 4 stratified by age and gender. Treatment assignments will be generated prior to the study, then placed in order in sealed, opaque

envelopes with stratum-specific sequential ID numbers. Consenting participants fulfilling study eligibility criteria will be assigned the next available ID number for the appropriate gender and age stratum. The date and time each envelope is opened will be recorded in a log along with participant ID to ensure integrity of randomization

9.3 Interim analyses and Stopping Rules
Monitoring Recruitment and Retention

The adequacy of recruitment and retention will be assessed by the DSMB to ensure that the trial can meet research objectives.

1. The recruitment goal is to enroll 20 eligible participants within a 3-month recruitment period. Enrollment lagging more than 4-weeks behind these goals will be of concern, and may trigger added evaluation, effort and approaches to recruitment. Enrollment lagging more than 8-weeks behind these goals will be of major concern, and may trigger changes in enrollment criteria or other aspects of the trial protocol.

2. Retention of participants in the trial will depend on participant attending study visits and follow-up testing visits. The goal is to have 75% compliance with the 72 study visits and retain at least 75% of enrolled participants for all three testing visits. Loss to follow-up of more than 25% of participants will be reason for concern, and loss of more than 50% may trigger changes in enrollment criteria, changes in the protocol or termination of the trial.

Supplementary Analyses: Interim analyses will also be conducted of the effects of treatment group assignment on outcomes after regression adjustment for any important prognostic baseline characteristics sufficiently maldistributed between study groups to potentially confound the treatment effect estimate. In addition, interim subgroup analyses will be used to help identify individuals more likely to benefit from, or to be harmed by, the treatment. Pre-randomization characteristics will be used to define these subgroups, including ejection fraction, use of percutaneous coronary intervention at the time of the index myocardial infarction, and other factors that might be associated with efficacy. Tests for interactions between treatment and subgroup could be particularly useful in identifying subgroups experiencing differential treatment effects[10]. These exploratory analyses are important for assuring the safety of trial participants, and they will also be used, with appropriate caution, for generating hypotheses for subsequent testing.

Additional Considerations in Interpreting the Data: In addition to the statistical procedures described above, other considerations will be taken into account in interpreting interim results. It is important for these additional considerations to be stated in advance to assure both study participants and investigators, who are masked to the data, that the DSMB will carefully consider many issues related to safety and efficacy and will recommend protocol changes or study termination if warranted. Two important additional considerations will be (1) the consistency of the observed

differences between treatment groups in variables that should be associated with one another, and (2) the importance of these differences to the health and the safety of individuals in the trial. Any differences between treatment groups in either outcome variables or adverse events will be considered for both their statistical significance and clinical importance. These considerations for interpretation of data require the combined expertise of clinical and statistical experts. A number of specific considerations for interpretation of these data can be stated in advance:

- Whether the magnitude or character of an observed difference constitutes a clinically important benefit or risk;
- Whether the risk under consideration is outweighed by assessment of the overall potential benefit of therapy;
- Whether the results could be explained by possible differences in baseline variables between the groups;
- Whether results could be due to ascertainment bias caused by differences in treatment regimens;
- Whether the results are consistent with those for other variables that should be associated with the variable in question;
- Whether the results are consistent among various subgroups of participants and across the various centers involved in the study;
- Whether it is likely that the current trends in the data could be reversed if the trial were to be continued unmodified;
- The degree of additional precision or certainty in the results that could be obtained by continuing the trial; and,
- Whether there would be significant loss in external validity or credibility of the trial by a change in Protocol or discontinuation.

In summary, a recommendation to modify or discontinue the trial would not be based solely on statistical grounds. Rather the DSMB supports the view voiced by Canner, on behalf of the Coronary Drug Project [Coronary Drug Project Research Group. Practical aspects of decision making in clinical trials: The Coronary Drug Project as a case study. *Controlled Clin Trials.* 1981;1(363-76)], that in clinical trial decision-making "No single statistical decision rule or procedure can take the place of the well reasoned consideration of all aspects of the data by a group of concerned, competent and experienced persons with a wide range of scientific backgrounds and points of view."

9.4 Outcomes

Baseline characteristics and outcome measures proposed in this study (Table 3) will be collected at baseline and after the 6-month intervention. All outcome measures except computed tomography will be repeated at 1-year after the intervention.

Table 3. Baseline Characteristics and Outcome Measures at Study Visits

Category Variables: measure	Baseline Testing	6-month Testing	1-year Testing
Demographics – age, gender, ethnicity, education	X		
Aging-related musculoskeletal impairments			
- Bone density: hip BMD (DXA)	X		
- Vertebral fractures: lateral spine radiograph	X		
- Physical activity level: activity counts derived from Actigraph accelerometer	X	X	X
Kyphosis-related impairments			
- Kyphosis: Cobb angle of kyphosis derived from lateral spine radiographs	X	X	X
- Kyphosis: Kyphosis derived from Debrunner kyphometer	X	X	X
- Spinal extensor muscle strength: Biodex computerized dynamometer	X	X	X
- Spinal muscle density: spinal extensor muscle attenuation from CT scans (HU)	X	X	
Functional performance			
- Composite physical function: Modified Physical Performance Test	X	X	X
- Gait speed: 4-meter	X	X	X
- Mobility: Timed Up and Go test	X	X	X
- Spine endurance: Timed Loaded Standing	X	X	X
- Aerobic capacity/endurance: Six Minute Walk Test	X	X	X
Health-Related Quality of Life			
- Spine-specific health-related quality of life: SRS-30	X	X	X
- General health related quality of life: PROMIS Global Health	X	X	X
- Physical function related quality of life: PROMIS Physical function short form	X	X	X

9.4.1 Primary outcome variables

Kyphosis: Kyphosis will be measured using the gold standard Cobb angle of kyphosis derived from standing lateral spine radiographs using a standardized protocol for thoracic kyphosis (T4-T12).[28] The intraclass correlation coefficient (ICC) for repeated observer analysis of Cobb angle from the same radiograph is 0.99 and for single measurements taken from repeated radiographs is 0.82.28 When these estimates are combined, the ICC for radiographic measures of Cobb angle of kyphosis is 0.92, comparable to the ICC for kyphosis measurements using the Debrunner kyphometer 0.95.89

The Modified Physical Performance Test (PPT): This battery was developed as a composite measure of overall physical function in the aging adult.[90, 91] The modified PPT includes 7-item timed standardized tasks: 50-foot floor walk, putting on and removing a lab coat, picking up and penny from the floor, standing up five times from a 16-inch chair, lifting a 7-pound book to a shelf, climbing one flight of stairs, and standing with feet together and two additional untimed tasks: climbing up and down

four flights of stairs and performing a 360º turn. The score for each item ranges between 0 and 4, with 36 representing a perfect total score for the test. Test-retest reliability for the modified PPT score in community-dwelling older adult population is 0.96.90 There is strong correlation with the Berg Balance Scale, r=0.7192 and low scores on the modified PPT predict physical frailty.[92]

Gait speed: A 4-meter walk test will be used to measure gait speed. Slow gait speed has been shown in several different populations to be the single best predictor of functional decline and disability.[74, 93, 94] The object of the 4-meter walk test is to determine the individual's speed while walking at their usual and fast pace. Test-retest reliability is 0.90,95 ICC for measures taken 2-weeks apart is 0.79.[96]

9.4.2 Secondary outcome variables

Timed Up and Go test (TUG): TUG is a widely used clinical tool for detecting mobility impairments in older adults. This test measures the time to rise from a 48 cm height armchair, walk 3 m, turn and return to a fully seated position in the chair.97 This test has excellent reliability (ICC 0.91-0.96) and sensitivity and specificity for identifying elderly individuals at risk for mobility impairments and falls.[98, 99]

Timed Loading Standing: Timed Loading Standing is a test of combined trunk and arm endurance that measures the time a person can stand while standing a two-pound dumbbell in each hand with the arms at 90 degrees of shoulder flexion and the elbows extended.[100] The ICC for same day inter-trial and 6 to10-day test retest reliability is 0.89.[100] Moderately high correlations were found between Timed Loaded Standing and 16 measures of physical impairment and function.[100]

Spinal extension muscle strength: We will use a standardized protocol for spine muscle extensor muscle strength using the Biodex [3] (Biodex Medical Systems Inc.) computerized dynamometer with the spine attachment to measures isometric peak torque to body weight ratio of spinal extension from semi-seated position.[4] The ICC for 1-week test retest reliability is 0.84 (95% CI=0.71, 0.96).[4]

Spinal muscle density: Muscle density of the lumbar paraspinal muscles will be determined from calculations of fat infiltration into the paraspinal muscles at the L4-L5 disc space from axial computed tomography (CT) images using proprietary software (RSI Systems, Boulder, CO). Measurement of fat infiltration from CT images has been validated in muscle biopsy studies.[44] The coefficient of variation for reproducibility of spinal muscle density values among older adults is less than 5%.[46] Dr. Thomas Lang developed the software, he will train our study staff to use the software and oversee quality control of the measurements.

Six-minute Walk Test (SMWT): The SMWT is a widely used test of aerobic capacity; there are gender specific normative data available for community-dwelling older adults.[101, 102] One week test retest reliability is 0.95 and compares with cycle ergometry r=0.58.[101]

Additional outcomes

Health related quality of life (HRQOL): We will use the modified Scoliosis Research Society SRS-30 instrument,[102] (self-image domain only), and the PROMIS Physical Function and Global Health questionnaires. The pain and general self-image domain scores of the SRS-30 have significant correlation with Cobb angle of kyphosis in untreated scoliosis.[104] Internal consistency, Cronbach's alpha, was 0.77 to 0.89 for all domains; validity of the modified SRS-30, determined by Pearson correlation coefficients with comparable SF-36 domains, was 0.70 for 13 of 14 relevant domains.[102]

Other study measures: We will measure height and weight using standard methods, and collect a history of falls and current medications from detailed questionnaires. Bone density of the spine and hip will be measured using Dual X-ray Absorptiometry (DXA) and vertebral fractures will be adjudicated from T4 to L4 with lateral spine radiographs at baseline. Participants will complete a numeric rating pain scale,[105] and adverse event log before participating in each exercise class. Physical activity will be measured with actigraphy.[88, 106, 107]

9.5 Data Analyses

Analysis for Specific Aim 1: Analysis of covariance (ANCOVA) will be used to assess the effects of intervention on changes in measured kyphosis and PTT scores from baseline to the end of the 6 month intervention period, adjusting for the baseline levels of each outcome, as well as for wave of recruitment. Normality and equality of variance of the residuals will be checked.

Analysis for Specific Aim 2: We will also use analysis of covariance (ANCOVA) to assess the effect of intervention on changes from baseline to the end of the 6 month intervention period, in measured HRQoL, as measured by the spinal deformity specific SRS-30 and SF-36 health status instruments, and on secondary measures of physical function including gait speed, spinal extensor muscle strength, Timed Loaded Standing, and the Jug Test. The models will adjust for the baseline level of the outcome.

Analysis for Specific Aim 3: The approach for Aims 1 and 2 will be used to assess intervention effects on muscle strength and density. We will then use structural equation modeling to assess the pathways through which the intervention affects physical function. We hypothesize that changes in kyphosis, strength and density mediate the effect of the intervention on change in physical function. These analyses will also control for mediation by increases in physical activity and aerobic capacity, as well as potential confounders of the changes in kyphosis and strength including age, and baseline kyphosis severity, physical activity level and vertebral fractures. Minimum detectable effects: The sample of 100 will provide 80% power to detect between-group differences of 6.2 points in spinal muscle strength, measured as a percentage of body weight, or 18% of the baseline mean of 35%.

10. DATA COLLECTION AND QUALITY ASSURANCE

10.1 Data Collection Forms

We will use the PROMIS Global Health and Physical Function questionnaires to collect study date. The study instruments are below in the Supplement/ Appendices Section at the end.

10.2 Data Management

Overview of data management: Data will be entered/submitted by clinic staff and participants (where applicable) and tracked by project staff. Authorized project/clinic staff may also update data to correct errors. Data will be managed, queried, and secured by the UCSF Data Management Group (DMG), enabling simple real-time electronic data entry, timely identification and resolution of data discrepancies, and transforming data to SAS for viewing, reporting, and analyses.

Data collection and editing: data will be collected via web forms/surveys with REDCap® software and stored on mySQL/MS SQL databases. Data collected will be viewed via the password-protected study website. Every hour, pre-programmed error-checking programs scan incoming forms for completeness and data ranges. The results of the error-checking procedures are posted to the study web site, where study staff are notified to correct all errors.

Data monitoring reports: Data are monitored on an ongoing basis by the Data Management Group to produce a number of standard reports that are made available on the study website automatically, including recruitment reports comparing goal versus actual recruitment rates; adherence reports comparing the number of expected visits to actual visits; and participant retention reports indicating the number of participants active, completed, and lost.

Computer and data security: The UCSF Data Management Group network is privately maintained and hardware fire-walled, and none of the workstations or database servers can be directly addressed from outside the Local Area Network. All study data will be stored on SQL servers that are backed-up nightly to disk and mirrored to a “failover” site at a co-location facility in San Francisco. In addition, back-up copies of the entire enterprise are archived in Sacramento, CA by Recall, Inc. All servers are housed in a state-of the-art secure server room with controlled access. All servers are protected from viruses by Network Associates Netshield 4.x, Groupshield, and VirusScan Enterprise 7.x (McAfee, Santa Clara, CA.).

10.3 Quality Assurance

10.3.1 Training

Dr. Katzman will provide standardized training to the licensed physical therapists and physical therapy students involved in teaching the exercise sessions. Verbal instructions for the exercise intervention, verbal reinforcement, repetitions and progression in the exercise intervention have been standardized in our previous pilot study, and these procedures will be reviewed periodically to maintain consistency with the protocol.

10.3.2 Monitoring

After each wave of the intervention, the study staff will meet to review protocol compliance, recruitment and retention, adverse events forms, data quality, and review consent forms for completeness.

Throughout the study, Dr. Katzman will conduct unannounced drop in visits to the intervention and control group exercise and stretching classes to ensure ongoing consistent standardized implementation. To minimize other co-interventions, all participants will be asked to refrain from beginning any new recreational, exercise, or other treatments for kyphosis until the trial has ended.

Data quality will be assessed based on time to receipt of data and the proportions of missing, illogical and out of range variables.

Measure	Goal Value	Acceptable Value
• time to receipt of data	<4 working days	<10 working days
• time to resolution of queries	<2 working days	<7 working days
• missing variables	0	< 5%
• variables queried*	5%	<10%

*excluding Adverse Event and Medication Forms that are expected to have pending queries for current or ongoing items

Every hour, pre-programmed error-checking programs scan incoming forms for completeness and data ranges. The results of the error-checking procedures are posted to the study web site, where study staff are notified to correct all errors.

11. PARTICIPANT RIGHTS AND CONFIDENTIALITY

11.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document (Appendix II) and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study. The consent form should be separate from the protocol document.

11.2 Informed Consent Forms

At the beginning of the screening visit, a member of the research staff will review the consent form in detail with the patient and answer all questions before inviting the patient to sign the consent form. A photocopy of the signed consent form with the Experimental Subjects' Bill of Rights is given to the patient. Study personnel will review the content of the informed consent with each participant before they sign it. Participants will be asked to describe the benefits, risks and other options if they choose not to participate with the study personnel.

11.3 Participant Confidentiality

In order to maintain participant confidentiality, the study will ensure that (1) the informed consent process is conducted appropriately and that informed consent is obtained prior to proceeding with any study procedures; (2) data are collected and analyzed per protocol requirements; (3) the privacy and confidentiality of study subjects is maintained. Participation in research can involve loss of privacy; however, the participant's names will not be included on questionnaires or other forms. It will be replaced by an identification number.

The following precautions will be taken to maintain participant confidentiality:

ºData are coded; data key is destroyed at end of study.
ºData are coded; data key is kept separately and securely.
ºData are kept in locked file cabinet.
ºElectronic data are protected with a password.
ºData are kept in locked office or suite.
ºData are stored on a secure network.

11.4 Study Discontinuation

The study may be discontinued at any time by the UCSF Institutional Review

Board (IRB), the National Institute of Aging, or the data safety monitoring board (DSMB) as part of their duties to ensure that research participants are protected.

12. COMMITTEES

Data Safety Monitoring Board - DSMB

13. PUBLICATION OF RESEARCH FINDINGS

All publications of study findings will be reviewed by the NIA publications committee prior to submission.

14. REFERENCES

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3. Mika A, Unnithan VB, Mika P. Differences in thoracic kyphosis and in back muscle strength in women with bone loss due to osteoporosis. *Spine (Phila Pa 1976).* Jan 15 2005;30(2):241-246.
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15. SUPPLEMENTS/APPENDICES

I. PROCEDURES SCHEDULE

Assessment	Phone Screen	Clinic Screen	Medical Screen	Run In	Test Visit 1 (Baseline)	Intervention/ Control Visits (1-72)	Test Visit 2 (6 month)	Maintenance Period	Test Visit 3 (1year)
Informed Consent Form		X							
Group Orientation (explain study)		X		X					
Basic Demographics	X				X				
DXA					X				
Lateral Spine Radiograph					X		X		X
Medical History	X		X						
Screen (gait, kyphosis, safety assessment)		X							
Current Medications	X		X						
Contact primary care providers for OK			X						
Inclusion/ Exclusion Criteria	X	X	X						
Enroll		X							
Randomize					X				
Intervention/ Control Study Visit						X			
Kyphosis: Cobb angle of kyphosis					X		X		X
Kyphosis: Debrunner					X		X		X
Spinal muscle strength: Biodex computerized dynamometer					X		X		X

Assessment	Phone Screen	Clinic Screen	Medical Screen	Run In	Test Visit 1 (Baseline)	Intervention/ Control Visits (1-72)	Test Visit 2 (6 month)	Maintenance Period	Test Visit 3 (1year)
Spinal muscle density: CT scans					X		X		
Functional Performance					X		X		X
Health-Related Quality of Life					X		X		X

II. Informed Consent Form

IRB NUMBER: 12-08917
IRB APPROVAL DATE: 08/03/2012
IRB EXPIRATION DATE: 08/02/2013

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Study of Hyperkyphosis, Exercise and Function-SHEAF is a research study investigating if specific spinal muscle strengthening exercises improve hyperkyphosis, an increased curvature in the upper back, and physical function as compared with a stretching group exercise. The study researchers, Wendy Katzman, PT, DPTSc from the Department of Physical Therapy and Rehabilitation Science, Dr. Nancy Lane, from the Department of Epidemiology and Biostatistics at UCSAF and UC Davis and Dr. Anne Schafer, of the San Francisco VA Medical Center will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study because you are a community dwelling man or woman 60 years or older and have hyperkyphosis.

Why is this study being done?

The purpose of this study is to learn about the effects of specific spine muscle strengthening exercise as compared to a stretching exercise on hyperkyphosis, physical function, spine muscle strength and quality of life. This study is funded by the Institute of Aging of the National Institutes of Health. None of the study investigators have a financial interest.

How many people will take part in this study?

About 100 people will take part in this study in five waves. All participants will be community-dwelling men and women 60 years old and above with hyperkyphosis.

What will happen if I take part in this research study?

If you agree, the following procedures will occur:

First you will need to have the following "screening" tests or procedures to find out if you can participate in the main part of the study: measurement of the curvature in your upper back, a brief test of your cognition to ensure you are able to understand all of the instructions and approval to participate in an exercise program from your primary care physician, nurse practitioner or physician's assistant. We will also ask you to complete a medical questionnaire about your medical history that we will use to screen you adequately for participation in this study. The study will involve two groups, one with kyphosis specific strengthening exercises and the other a stretching exercise.

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If the screening shows that you can be in the main part of the study and you choose to continue this is what will happen next:

Several measurements will be taken of your posture. These include measures of the curvature in the upper and lower back while standing in your usual posture.

We will observe you walking and rising from a seated position.

If the screening exam shows that you can participate in the study and you wish to continue, we will contact your primary care provider for additional medical information.

If you are qualified and wish to continue with the study, the following will happen next:

The concept of randomization, the need to complete the study visits, exercises and measurements will be explained to you.

- Once enrolled, and prior to randomization, you will attend a group orientation program three times for 1 week and be given an step-counter with verbal and written instructions to wear for one week. This is a small step counter that you can wear on your clothing at your waist.
- You will attend a baseline testing visit at the Clinical Research Center at UCSF on Parnassus that will take approximately 2 hours.
- Several timed measures will be taken during tasks of daily living such as walking, balancing, getting out of chair, extending your arms and climbing stairs.
- You will also receive 3 scans: 1) lateral spine x-ray to determine the curvature in your spine, 2) bone density to determine hip and spine bone muscle density 3) computed tomography (CT) to determine the density of your muscles.
- You will attend three one-hour exercise sessions each week for 6 months at the PhysFit Health and Wellness Center at the Mission Bay campus of UCSF at 1675 Owens St. where exercise will occur. Prior to each visit you will complete a log to record pain, falls, and any injuries.
- At the end of 6 months of either strengthening or stretching exercise, all measures will be repeated.
- At the end of 6 months you will continue your usual activity during the maintenance phase. You will receive a reminder phone call to wear the step-counter for a week each month to monitor physical activity during the maintenance phase.
- At the end of one year you will be re-measured, but only have the x-ray scan.

How long will I be in the study?

Participation in the study will take a total of about 76 hours over one year including screening visits, and exercise visits of three times per week for 6 months followed by a screening and a follow-up at one year.

Can I stop being in the study?

Yes. You can decide to stop at any time. Just tell the study researcher or staff person right away if you wish to stop being in the study.

Also, the study researcher may stop you from taking part in this study at any time if he or she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

Participants will be randomized to either a kyphosis-specific strengthening exercise or stretching exercise control group. The risks associated with participation in the study are described below for each group.

Strengthening Group: The most likely risk associated with the strengthening exercise intervention is muscle soreness, joint, or ligament sprain/strain. There is the rare risk of spontaneous vertebral fracture, or an injury from a fall, including a fracture. However, this is highly unlikely given that we have implemented numerous safety measures detailed below. Furthermore, this intervention has been tested in an uncontrolled pilot trial among women 55-80 years old and there were no study-related injuries. The high intensity level of exertion used in this intervention is the level recommended for optimal aging, and prevention and treatment of disease in older adults. The instructors providing instruction for these classes are licensed physical therapists with experience instructing older people with chronic pain conditions and physical disability. We will limit the participant: instructor ratio to no more than 5:1 to ensure proper supervision and enhance safety of all participants. Additionally, we will monitor participants and teach participants to self-monitor during testing and exercise sessions, according to the National Osteoporosis Foundation guidelines for people with osteoporosis.

Stretching Group: The most likely risk associated with the stretching exercise intervention is muscle soreness, joint or ligament sprain/strain. There is the rare risk of spontaneous vertebral fracture, or an injury from a fall, including a fracture. However, this is highly unlikely given that we have implemented numerous safety measures detailed below. The instructors providing instruction for these classes will be licensed physical therapists with experience instructing older people with chronic pain conditions and physical disability. We will limit the participant: instructor ratio to no more than 5:1 to ensure proper supervision and enhance safety of all participants. Additionally, we will monitor participants and teach participants to self-monitor during testing and exercise sessions, according to the National Osteoporosis Foundation guidelines for people with osteoporosis.

Radiation Exposure: This research study involves exposure to radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. The additional amount of radiation that you will receive as a result of participating in this study will be less than the yearly natural background radiation in the US, which is 3 mSv (a mSv, or milliSievert, is a measurement of radiation). This amount of radiation

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involves minimal risk. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the investigator conducting the study.

Loss of confidentiality: Participation in research can involve loss of privacy; however, the participant's names will not be included on questionnaires or other forms. Names will be replaced by an identification number.

Are there benefits to taking part in the study?

There is no guaranteed benefit to subjects who participate in this study. To the extent allowable, results of laboratory tests will be made available to subjects and their medical providers that might prove useful in their clinical management or prevention of future disease. Participants and their doctors will be notified by phone and letter of abnormal test results that require immediate attention. The benefits of participation in this study include the continued monitoring of several important health factors such as weight, physical capacity, and general health. The information gathered in this study will be very important in learning whether targeted exercise can reduce hyperkyphosis, and whether reducing hyperkyphosis improves physical function. These factors might be important in promoting health and improved physical function in older adults.

This innovative study will provide insight into the effectiveness of a high-intensity kyphosis specific spinal strengthening exercise intervention in older adults with hyperkyphosis who are at increased risk for adverse health outcomes. A major advantage of identifying an exercise intervention that reduces hyperkyphosis or improves physical function is that it could potentially be administered to a large number of older adults with hyperkyphosis to reduce risk of adverse health outcomes. Any minor risk of loss of confidentiality or musculoskeletal pain or injury is offset by the potential to help older adults with hyperkyphosis.

What other choices do I have if I do not take part in this study?

Your other choices may include not getting treatment, getting standard treatment for your condition without being in a study, or taking part in another study or participating in a Phys-Fit Health and Wellness Center Stand Tall Class at standard cost. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot guarantee total privacy. Your personal information

may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

A medical record will be created at the Clinical Research Center. Results of the tests for the study will be included in this medical record. This record will not be released and will be used for research purposes only. Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include: the UCSF Clinical Research Center, UCSF's Committee on Human Research.

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. You will be participating in a group class that will make it impossible to maintain full confidentiality, as others will be in your class.

What are the costs of taking part in this study?

You will not be charged for any of the study treatments or procedures.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid $25 for each of three testing visits, and $10 for each exercise visit. You will be issued a debit card and funds will be added at the time of each visit. You will be provided city bus tickets and information about the UCSF shuttle to coordinate your travel to and from the study.

What happens if I am injured because I took part in this study?

It is important that you tell your study investigator, Wendy Katzman PT, DPTSc, if you feel that you have been injured because of taking part in your study. You can tell her in person or call her at 415-353-7238, ext 6.

Treatment and Compensation for injury: If you are injured as a result of being in this study, treatment will be available. The University of California, depending on a number of factors may cover the costs of the treatment. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415-476-1814.

Who can answer my questions about the study?

You can talk to the researcher about any questions, concerns, or complaints you have about this study. Contact the researcher Wendy Katzman, PT, DPTSc. at 415-353-7238, ext. 6.

If you wish to ask questions comments or concerns about taking part in this study, first talk to the researcher (above) for any reason you do not wish to do this, or you still have

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concerns after doing so, you may contact the office of the Committee on Human Research, UCSF's Institutional Review Board (a group of people who review the research to protect your rights).

You can reach the CHR office at **415-476-1814**, 8am to 5pm, Monday through Friday. Or you may write to" Committee on Human Research, Box 0962, University of California, San Francisco (UCSF), San Francisco, CA 94143.

CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.]

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent

Version 1.2

III. Other

1. PROMIS Global Health Questionnaire

PROMIS v.1.0 - GLOBAL

Global Items

Please respond to each item by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02	In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03	In general, how would you rate your physical health?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global09	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.).....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	**Mostly**	**Moderately**	**A little**	**Not at all**
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?.....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Global10	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

		None	Mild	Moderate	Severe	Very severe
Global05	How would you rate your fatigue on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Global07	How would you rate your pain on average?.....	☐ 0 No pain	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 Worst imaginable pain

2. PROMIS Physical Function Questionnaire

PROMIS Item Bank v. 1.0 – Physical Function – Short Form 20a

Physical Function – Short Form 20a

Please respond to each item by marking one box per row.

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA11	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA12	Are you able to push open a heavy door?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA16	Are you able to dress yourself, including tying shoelaces and doing buttons?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA24	Are you able to wash your back?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA28	Are you able to dry your back with a towel?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA51	Are you able to sit on the edge of a bed?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA55	Are you able to wash and dry your body?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA56	Are you able to get in and out of a car?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB19	Are you able to squeeze a new tube of toothpaste?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB22	Are you able to hold a plate full of food?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFB24	Are you able to run a short distance, such as to catch a bus?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

		Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFB26	Are you able to shampoo your hair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC45	Are you able to get on and off the toilet?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC46	Are you able to transfer from a bed to a chair and back?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Not at all	**Very little**	**Somewhat**	**Quite a lot**	**Cannot do**
PFA1	Does your health now limit you in doing vigorous activities, such as running, lifting heavy objects, participating in strenuous sports?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA2	Does your health now limit you in bending, kneeling, or stooping?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA5	Does your health now limit you in lifting or carrying groceries?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC12	Does your health now limit you in doing two hours of physical labor?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC26	Does your health now limit you in walking more than a mile?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFC27	Does your health now limit you in climbing one flight of stairs?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

3. Scoliosis Patient Questionnaire

Scoliosis Patient Questionnaire: **Modified 11/12/03**
Version 30 (Encompasses Versions 22 and 24)

Patient Name:_____ **Age:**_____ **Date:**_____

Medical Record #_____ **SS:**_____

Exam: Pre-treatment 3 mos. 6 mos. 1 year _____ years

Your doctors are carefully evaluating the condition of your back before and after your treatment. Please circle the one best answer to each question unless otherwise indicated. If you already have had surgery, please complete sections 1 and 2. Otherwise, just complete section 1.

All results will be kept confidential.

Section 1: All patients

1. **Which one of the following best describes the amount of pain you have experienced during the past 6 months?**
   - ☐ None
   - ☐ Mild
   - ☐ Moderate
   - ☐ Moderate to severe
   - ☐ Severe

2. **Which one of the following best describes the amount of pain you have experienced over the last month?**
   - ☐ None
   - ☐ Mild
   - ☐ Moderate
   - ☐ Moderate to severe
   - ☐ Severe

3. **During the past 6 months have you been a very nervous person?**
   - ☐ None of the time
   - ☐ A little of the time
   - ☐ Some of the time
   - ☐ Most of the time
   - ☐ All of the time

4. **If you had to spend the rest of your life with your back shape as it is right now, how would you feel about it?**
   - ☐ Very happy
   - ☐ Somewhat happy
   - ☐ Neither happy nor unhappy
   - ☐ Somewhat unhappy
   - ☐ Very unhappy

5. **What is your current level of activity?**
   - ☐ Bedridden/wheelchair
   - ☐ Primarily no activity
   - ☐ Light labor, such as household chores
   - ☐ Moderate manual labor and moderate sports, such as walking and biking
   - ☐ Full activities without restriction

6. **How do you look in clothes?**
   - ☐ Very good
   - ☐ Good
   - ☐ Fair
   - ☐ Bad
   - ☐ Very bad

7. **In the past 6 months have you felt so down in the dumps that nothing could cheer you up?**
   - ☐ Very often
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

8. **Do you experience back pain when at rest?**
   - ☐ Very often
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

9. **What is your current level of work/school activity?**
   - ☐ 100% normal
   - ☐ 75% normal
   - ☐ 50% normal
   - ☐ 25% normal
   - ☐ 0% normal

10. **Which of the following best describes the appearance of your trunk; defined as the human body except for the head and extremities?**
    - ☐ Very good
    - ☐ Good
    - ☐ Fair
    - ☐ Poor
    - ☐ Very poor

11. **Which one of the following best describes your medication usage for your back?**
    - ☐ None
    - ☐ Non-narcotics weekly or less (e.g., Tylenol, Ibuprofen)
    - ☐ Non-narcotics daily
    - ☐ Narcotics weekly or less (e.g., Percocet, Lorcet, Codeine, Darvocet)
    - ☐ Narcotics daily
    - ☐ Other (please specify below)

    Medication:
    _____
    Usage (weekly or less or daily):
    _____

12. **Does your back limit your ability to do things around the house?**
☐ Never ☐ Often
☐ Rarely ☐ Very often
☐ Sometimes

13. **Have you felt calm and peaceful during the past 6 months?**
☐ All of the time ☐ A little of the time
☐ Most of the time ☐ None of the time
☐ Some of the time

14. **Do you feel that your back condition affects your personal relationships?**
☐ None ☐ Moderately
☐ Slightly ☐ Severely
☐ Mildly

15. **Are you and/or your family experiencing financial difficulties because of your back?**
☐ Severely ☐ Slightly
☐ Moderately ☐ None
☐ Mildly

16. **In the past 6 months have you felt down-hearted and blue?**
☐ Never ☐ Often
☐ Rarely ☐ Very often
☐ Sometimes

17. **In the last 3 months have you taken any sick days from work/school due to back pain and, if so, how many?**

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 or more

18. **Do you go out more or less than your friends?**
☐ Much more ☐ Less
☐ More ☐ Much less
☐ Same

19. **Do you feel attractive with your current back condition?**
☐ Yes, very ☐ No, not very much
☐ Yes, somewhat ☐ No, not at all
☐ Neither attractive nor unattractive

20. **Have you been a happy person during the past 6 months?**
☐ None of the time ☐ Most of the time
☐ A little of the time ☐ All of the time
☐ Some of the time

21. **Are you satisfied with the results of your back management?**
☐ Very satisfied ☐ Unsatisfied
☐ Satisfied ☐ Very unsatisfied
☐ Neither satisfied nor unsatisfied

22. **Would you have the same management again if you had the same condition?**
☐ Definitely yes ☐ Probably not
☐ Probably yes ☐ Definitely not
☐ Not sure

23. **On a scale of 1 to 9, with 1 being very low and 9 being extremely high, how would you rate your self-image?**

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9

Section 2: Post-surgery patients only

24. **Compared with before treatment, how do you feel you now look?**
☐ Much better ☐ Worse
☐ Better ☐ Much worse
☐ Same

25. **Has your back treatment changed your function and daily activity?**
☐ Increased ☐ Not changed ☐ Decreased

26. **Has your back treatment changed your ability to enjoy sports/hobbies?**
☐ Increased ☐ Not changed ☐ Decreased

27. **Has your back treatment _____ your back pain?**
☐ Increased ☐ Not changed ☐ Decreased

28. **Has your treatment changed your confidence in personal relationships with others?**
☐ Increased ☐ Not changed ☐ Decreased

29. **Has your treatment changed the way others view you?**
☐ Much better ☐ Worse
☐ Better ☐ Much worse
☐ Same

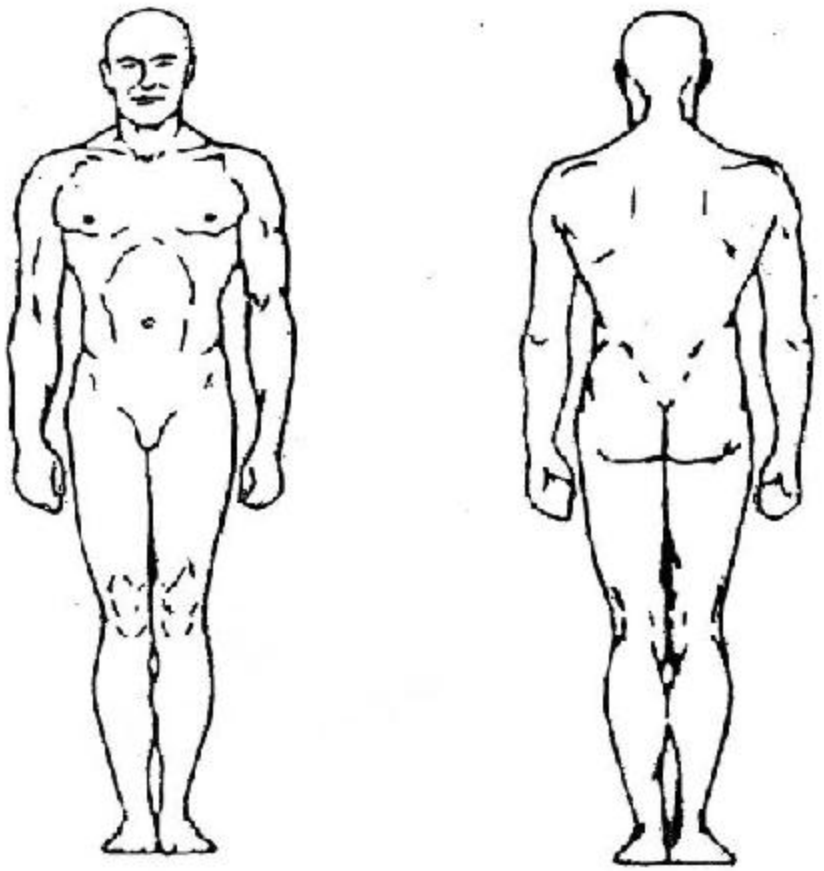
30. **Has your treatment changed your self-image?**
☐ Increased ☐ Not changed ☐ Decreased

Please mark on the drawings any areas where you feel pain. If you are not having any pain, leave blank and initial.

Use the following key to show particular types of pain

KEY:

Pins & needles = 000000
Burning = XXXXXX
Stabbing = //////
Deep ache = ZZZZZZ



4. Adverse Event (AE) Report Form

STUDY NAME:

Site Number: _____

Pt_ID: _____

Has the participant had any Adverse Events during this study? ☐ **Yes** ☐ **No** ***(If yes, please list all Adverse Events below)***

Severity	Study Intervention Relationship	Action Taken Regarding Study Intervention	Outcome of AE	Expected	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely related 2 = Possibly related 3 = Not related	1 = None 2 = Discontinued permanently 3 = Discontinued temporarily 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = Resolved, No Sequel 2 = AE still present- no treatment 3 = AE still present-being treated 4 = Residual effects present-not treated 5 = Residual effects present- treated 6 = Death 7 = Unknown	1 = Yes 2 = No	1 = Yes 2 = No (If yes, complete SAE form)

Adverse Event	Start Date	Stop Date	Severity	Relationship to Study Treatment	Action Taken	Outcome of AE	Expected?	Serious Adverse Event?	Initials
1.									
2.									
3.									

5. Serious Adverse Event (SAE) Report Form

Protocol Title:

Protocol Number: _____	
Site Number: _____	
Pt_ID: _____	

1. SAE Onset Date: _____ (dd/mm/yyyy)

2. SAE Stop Date: _____(dd/mm/yyyy)

3. Location of serious adverse event: _____

4. Was this an unexpected adverse event? Yes ☐ No ☐

5. Brief description of participant(s) with no personal identifiers:
   Sex: F ☐ M ☐ Age: _____

6. Brief description of the nature of the serious adverse event (attach description if more space needed):
   _____
   _____

7. Category of the serious adverse event:

   ☐ death – date __/___/___(dd/mmm/yyyy)
   ☐ life-threatening
   ☐ hospitalization-initial or prolonged
   ☐ disability / incapacity
   ☐ congenital anomaly / birth defect
   ☐ required intervention to prevent permanent impairment
   ☐ other:_____

8. Intervention type:

   ☐ Medication or Nutritional Supplement: specify_____
   ☐ Device: Specify: _____
   ☐ Surgery: Specify: _____
   ☐ Behavioral/Life Style: Specify: _____

9. Relationship of event to intervention:

- ☐ Unrelated (clearly not related to the intervention)
- ☐ Possible (may be related to intervention)
- ☐ Definite (clearly related to intervention)

10. Was study intervention discontinued due to event? ☐ Yes ☐ No

11. What medications or other steps were taken to treat serious adverse event?

_____

_____

12. List any relevant tests, laboratory data, history, including preexisting medical conditions

_____

_____

13. Type of report:

- ☐ Initial
- ☐ Follow-up
- ☐ Final

Signature of Principal Investigator: _____ Date: _____

Hyperkyphosis Telephone Screen

Please complete the survey below.

Thank you!

Participant ID: _____

Acrostic: _____

Interviewer: _____

How was person contacted:
- ☐ Physician referral
- ☐ Previous pilot
- ☐ Recruitment letter
- ☐ Flyer
- ☐ Personal referral

Physician name: _____

Where did you see the flyer? _____

Subject Name: _____
((Please spell))

Telephone: home _____

cell phone number: _____

Are you 60 years of age or older?
- ☐ Yes
- ☐ No

Can you comfortably communicate in English with verbal and written communication?
- ☐ Yes
- ☐ No

Have you or a family member or friend noticed that you do not stand as straight and tall as you used to?
- ☐ Yes
- ☐ No

Are you able to walk inside without a cane or walker?
- ☐ Yes
- ☐ No

Are you able to walk Â¼ block without using a cane or a walker?
- ☐ Yes
- ☐ No

Are you able to climb one flight of stairs independently - without assistance from another person?
- ☐ Yes
- ☐ No

Are you able to rise from a chair with your arms crossed at your chest?
- ☐ Yes
- ☐ No

Are you able to straighten your upper back?
- ☐ Yes
- ☐ No

Do you have any chronic medical conditions such as:

A painful fracture of your vertebra (spine) in the past 3 months?
- ☐ Yes
- ☐ No

Total hip or knee replacement, or hip fracture in past 6 mos.
- ☐ Yes
- ☐ No

Oral glucocorticoid medications (steroids) >=3 months in the past year
- ☐ Yes
- ☐ No

Uncontrolled hypertension, chest pain, myocardial infarct within past 6 months)
- ☐ Yes
- ☐ No

Peripheral neuropathy in your arms or legs
- ☐ Yes
- ☐ No

Diagnosed vestibular or neurologic disorder
- ☐ Yes
- ☐ No

Unexplained weight loss (>10 pounds in the past year)
- ☐ Yes
- ☐ No

Have you fallen 3 or more times in the past year?
- ☐ Yes
- ☐ No

Do you have any chronic medical conditions that could prevent you from participating in an exercise program?
- ☐ Yes
- ☐ No

Have you been advised by a physician not to exercise?
- ☐ Yes
- ☐ No

Do you already engage in regular (at least 3 days/week) vigorous (at least 30 continuous minutes) exercise that includes spine strengthening exercise?
- ☐ Yes
- ☐ No

Do you have a current major uncontrolled psychiatric illness, cognitive impairment or substance abuse?
- ☐ Yes
- ☐ No

Do you have plans to move out of the area within the next 6 months?
- ☐ Yes
- ☐ No

Are you interested in participating in a study that meets three times a week for 6 months for one hour of group exercise?
- ☐ Yes
- ☐ No

Are you interested in participating in a study that meets twice a week for 3 months for one hour of group exercise?
- ☐ Yes
- ☐ No

Which location would you prefer to attend the exercise classes (check all that apply):
- ☐ Osher Center on Divisadero and Post Street?
- ☐ UCSF Department of Physical Therapy and Rehabilitation Health and Wellness Center at Mission Bay?
- ☐ Kaiser Permanente - French Campus on Geary and 4th Ave.
- ☐ SF VA Medical Center on Clement and 25th Ave.

Do you have a friend or partner you want to be in the study with?
- ☐ Yes
- ☐ No

Who is this person? _____

What is your address? _____

City: _____

State:

- ☐ AL
- ☐ AK
- ☐ AZ
- ☐ AR
- ☐ CA
- ☐ CO
- ☐ CT
- ☐ DE
- ☐ FL
- ☐ GA
- ☐ HI
- ☐ ID
- ☐ IL
- ☐ IN
- ☐ IA
- ☐ KS
- ☐ KY
- ☐ LA
- ☐ ME
- ☐ MD
- ☐ MA
- ☐ MI
- ☐ MN
- ☐ MS
- ☐ MO
- ☐ MT
- ☐ NE
- ☐ NV
- ☐ NH
- ☐ NJ
- ☐ NM
- ☐ NY
- ☐ NC
- ☐ ND
- ☐ OH
- ☐ OK
- ☐ OR
- ☐ PA
- ☐ RI
- ☐ SC
- ☐ SD
- ☐ TN
- ☐ TX
- ☐ UT
- ☐ VT
- ☐ VA
- ☐ WA
- ☐ WV
- ☐ WI
- ☐ WY

Zip code _____

What is the best phone number to reach you at? _____

What is your date of birth? _____

What is the name of an emergency contact for you? _____

What is the phone number of an emergency contact for you? _____

Do we have permission to contact your provider about your participation in the study? if no, advise this is required for study participation

- ☐ Yes
- ☐ No

Name of primary physician, nurse practitioner or physician's assistant: _____

Address: _____

City: _____

State:

- ☐ AL
- ☐ AK
- ☐ AZ
- ☐ AR
- ☐ CA
- ☐ CO
- ☐ CT
- ☐ DE
- ☐ FL
- ☐ GA
- ☐ HI
- ☐ ID
- ☐ IL
- ☐ IN
- ☐ IA
- ☐ KS
- ☐ KY
- ☐ LA
- ☐ ME
- ☐ MD
- ☐ MA
- ☐ MI
- ☐ MN
- ☐ MS
- ☐ MO
- ☐ MT
- ☐ NE
- ☐ NV
- ☐ NH
- ☐ NJ
- ☐ NM
- ☐ NY
- ☐ NC
- ☐ ND
- ☐ OH
- ☐ OK
- ☐ OR
- ☐ PA
- ☐ RI
- ☐ SC
- ☐ SD
- ☐ TN
- ☐ TX
- ☐ UT
- ☐ VT
- ☐ VA
- ☐ WA
- ☐ WV
- ☐ WI
- ☐ WY

Zip code: _____

Phone number: _____

Are you available to come into UCSF Parnassus for a clinical screening exam?

- ☐ Yes
- ☐ No

Provide them with a screening appointment

Why not?

- ☐ Not interested in study
- ☐ Other

Would you like to be contacted about future studies?

☐ Yes
☐ No

What is the best phone number to reach you at in the future?

_____

Hyperkyphosis Clinic Screening Exam

Please complete the survey below.

Thank you!

Participant ID

_____

Acrostic

_____

Interviewer

_____

Was blood pressure measured?

☐ Yes
☐ No

Enter value: Systolic:

_____

Diastolic:

_____

Was Resting heart rate measured?

☐ Yes
☐ No

Enter value: Resting heart rate:

_____

Gender

☐ Male
☐ Female

Age of menopause:

_____

Current or prior hormone replacement

☐ Yes
☐ No

Prior chronic glucocorticoid use (> 3 months in a row in the past year)

☐ Yes
☐ No

Have you ever smoked cigarettes?

☐ Never
☐ Yes

Current smoker

☐ Yes
☐ No

Past smoker

☐ Yes
☐ No

Do you currently drink alcohol (more than 1 drink a month)?

☐ Yes
☐ No

Average number of drinks/week

_____

History of fracture

☐ Yes
☐ No

Where:

☐ spine
☐ hip
☐ arm
☐ leg
☐ other

Biological parent fractured a hip?

☐ Yes
☐ No
☐ Don't know

Biological parent had stooped posture?

☐ Yes
☐ No
☐ Don't know

Which parent?

☐ mother
☐ father

Current or past osteoporosis medication use

☐ Yes
☐ No
☐ Don't know

current or prior use?

☐ current
☐ prior

Do you have chest pain on exertion?

☐ Yes
☐ No
☐ I don't know

Shortness of breath on exertion

- ☐ Yes
- ☐ No
- ☐ I don't know

Joint pain or arthritis

- ☐ Yes
- ☐ No

what joint?

- ☐ shoulder
- ☐ elbow
- ☐ wrist/hand
- ☐ neck
- ☐ back
- ☐ hip
- ☐ knee
- ☐ ankle
- ☐ jaw

Hyperkyphosis Medical History

Please complete the survey below.

Thank you!

Participant ID

_____

Acrostic

_____

Interviewer

_____

Have you ever been diagnosed with any of the following conditions?

Heart attack

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Transient ischemic attack

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Stroke

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

High blood pressure

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Peripheral vascular disease

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Diabetes

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Kidney disease

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Neuropathies (problems with sensation)

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Respiratory disease including asthma

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Parkinson's disease

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Multiple sclerosis

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Polio/post-polio syndrome

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Epilepsy/seizures

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Cancer

☐ Yes
☐ No
☐ Don't know

what kind?

☐ breast ☐ prostate ☐ bladder ☐ colon/rectal ☐ endometrial ☐ kidney (renal cell)
☐ leukemia ☐ lung ☐ melanoma ☐ non-Hodgkin lymphoma ☐ pancreatic ☐ thyroid
☐ other

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Osteoporosis

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Rheumatoid arthritis

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Osteoarthritis/joint pain

☐ Yes
☐ No
☐ Don't know

where?

☐ neck
☐ back
☐ shoulder
☐ elbow
☐ wrist/hand
☐ hip
☐ knee
☐ foot/ankle
☐ other

Osteoarthritis: neck:
what is average level of pain

☐ 0 (none)
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 (worst imaginable pain)

Osteoarthritis: neck:
does it interfere with basic activities of daily living (including dressing, eating, walking, toileting, hygiene)

☐ Yes
☐ No

Osteoarthritis: neck:
does in interfere with instrumental activities of daily living (including shopping, housekeeping, accounting, food preparation, telephone/transportation)

☐ Yes
☐ No

Osteoarthritis: back:
what is average level of pain

☐ 0 (none)
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 (worst imaginable pain)

Osteoarthritis: back:
does it interfere with basic activities of daily living (including dressing, eating, walking, toileting, hygiene)

☐ Yes
☐ No

Osteoarthritis: back:
does in interfere with instrumental activities of daily living (including shopping, housekeeping, accounting, food preparation, telephone/transportation)

☐ Yes
☐ No

Osteoarthritis: shoulder:
what is average level of pain

☐ 0 (none)
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 (worst imaginable pain)

Osteoarthritis: shoulder:
does it interfere with basic activities of daily living (including dressing, eating, walking, toileting, hygiene)

☐ Yes
☐ No

Osteoarthritis: shoulder:
does in interfere with instrumental activities of daily living (including shopping, housekeeping, accounting, food preparation, telephone/transportation)

☐ Yes
☐ No

Osteoarthritis: elbow:
what is average level of pain

☐ 0 (none)
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 (worst imaginable pain)

Osteoarthritis: elbow:
does it interfere with basic activities of daily living (including dressing, eating, walking, toileting, hygiene)

☐ Yes
☐ No

Osteoarthritis: elbow:
does in interfere with instrumental activities of daily living (including shopping, housekeeping, accounting, food preparation, telephone/transportation)

☐ Yes
☐ No

Osteoarthritis: wrist/hand:
what is average level of pain

☐ 0 (none)
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 (worst imaginable pain)

Osteoarthritis: wrist/hand:
does it interfere with basic activities of daily living (including dressing, eating, walking, toileting, hygiene)

☐ Yes
☐ No

Osteoarthritis: wrist/hand:
does in interfere with instrumental activities of daily living (including shopping, housekeeping, accounting, food preparation, telephone/transportation)

☐ Yes
☐ No

Osteoarthritis: hip:
what is average level of pain

☐ 0 (none)
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 (worst imaginable pain)

Osteoarthritis: hip:
does it interfere with basic activities of daily living (including dressing, eating, walking, toileting, hygiene)

☐ Yes
☐ No

Osteoarthritis: hip:
does in interfere with instrumental activities of daily living (including shopping, housekeeping, accounting, food preparation, telephone/transportation)

☐ Yes
☐ No

Osteoarthritis: knee:
what is average level of pain

☐ 0 (none)
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 (worst imaginable pain)

Osteoarthritis: knee:
does it interfere with basic activities of daily living (including dressing, eating, walking, toileting, hygiene)

☐ Yes
☐ No

Osteoarthritis: knee:
does in interfere with instrumental activities of daily living (including shopping, housekeeping, accounting, food preparation, telephone/transportation)

☐ Yes
☐ No

Osteoarthritis: foot/ankle:
what is average level of pain

☐ 0 (none)
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 (worst imaginable pain)

Osteoarthritis: foot/ankle:
does it interfere with basic activities of daily living (including dressing, eating, walking, toileting, hygiene)

☐ Yes
☐ No

Osteoarthritis: foot/ankle:
does in interfere with instrumental activities of daily living (including shopping, housekeeping, accounting, food preparation, telephone/transportation)

☐ Yes
☐ No

Osteoarthritis: other:
what is average level of pain

☐ 0 (none)
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 (worst imaginable pain)

Osteoarthritis: other:
does it interfere with basic activities of daily living (including dressing, eating, walking, toileting, hygiene)

☐ Yes
☐ No

Osteoarthritis: other:
does in interfere with instrumental activities of daily living (including shopping, housekeeping, accounting, food preparation, telephone/transportation)

☐ Yes
☐ No

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Degenerative disc disease

☐ Yes
☐ No
☐ Don't know

where?

☐ neck
☐ back

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Joint replacement surgery

☐ Yes
☐ No
☐ Don't know

which joint?

☐ shoulder
☐ hip
☐ knee
☐ other

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Prior spine surgery

☐ Yes
☐ No
☐ Don't know

what type?

☐ spinal fusion
☐ laminectomy
☐ foramenotomy
☐ other

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Scoliosis

☐ Yes
☐ No

Year of diagnosis

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Cerebellar problems (ataxia)

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Chemical dependency (alcohol or drugs)

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Depression

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Post traumatic stress disorder (PTSD)

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Latex allergy

☐ Yes
☐ No
☐ Don't know

Year of diagnosis:

_____

Are you currently under a physician's care for this?

☐ Yes
☐ No

Was time to walk over 4 m course collected?

☐ Yes
☐ No

Time to walk over a 4 meter course:

_____
(seconds)

why not?

☐ Participant refused
☐ Participant unable

Was usual Kyphosis measured?

☐ Yes
☐ No

record :

_____
(degrees)

why not?

☐ Participant refused
☐ Participant unable

was Best kyphosis measured?

☐ Yes
☐ No

record:

_____

why not?

☐ Participant refused
☐ Participant unable

Difference between Best and usual kyphosis:

_____

Sit to stand from 16" high chair (Able to perform with arms crossed over chest)

☐ Yes
☐ No

Safety tests:

Able to transition from standing to recumbent on the floor and rise from the floor to standing

☐ Yes
☐ No

Able to lift both arms to shoulder level

☐ Yes
☐ No

Able to stand with feet side by side for 30 seconds

☐ Yes
☐ No

Able to stand with feet hip-width apart for 60 seconds.

☐ Yes
☐ No

Hyperkyphosis Medications Inventory

Please complete the survey below.

Thank you!

Do you take medications, vitamins and supplements?

☐ Yes
☐ No

Medication allergy?

☐ Yes
☐ No

How many do you take?

☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10

Name:

_____

Prescription:

☐ Yes
☐ No

Duration of use:

☐ < 1 month
☐ 1 month - 1 year
☐ 1 - 3 years
☐ 3 - 5 years
☐ > 5 years
☐ Don't know

Frequency:

☐ As needed
☐ Regular

Hyperkyphosis Demographics

Please complete the survey below.

Thank you!

Participant ID

_____

Acrostic

_____

Interviewer

_____

Date of birth

_____

Sex

☐ male
☐ female

Ethnicity

☐ Hispanic or Latino
☐ Not Hispanic or Latino

Race (mark all that apply)

☐ American Indian/Alaska Native
☐ Asian
☐ Native Hawaiian/Other Pacific Islander
☐ Black or African American
☐ White

Highest level of education

☐ Some high school or less
☐ High school graduate or GED or equivalent
☐ Some college, vocational school (or junior college)
☐ College graduate (BA, BS)
☐ Professional or graduate degree (MA, MS, MBA, PhD, MD, JD, etc.)

Hyperkyphosis Kyphosis and Strength Characteristics

Please complete the survey below.

Thank you!

Participant ID

_____

Acrostic

_____

Interviewer

_____

Height

_____
(cms)

Weight

_____
(kgs)

Cobb angle of kyphosis from kyphometer - usual1

_____
(degrees)

Cobb angle of kyphosis from kyphometer - usual2

_____
(degrees)

Difference between Usual 1 and Usual 2

_____
(degrees)

Cobb angle of kyphosis from kyphometer - usual3

_____
(degrees)

Lumbar lordosis from kyphometer - usual1

_____
(degrees)

Lumbar lordosis from kyphometer - usual2

_____
(degrees)

Difference between Usual 1 and Usual 2

_____
(degrees)

Lumbar lordosis from kyphometer - usual3

_____
(degrees)

Mean lumbar lordosis from kyphometer

_____

Spinal extension total work from biodex at 60 deg/s

_____
(newtons)

Spinal extension peak torque/body weight from biodex at 60 deg/s

_____
(%)

Spinal extension coefficient of variation at 60 deg/s

_____
(%)

Spinal flexion total work from biodex at 60 deg/s

_____
(newtons)

Spinal flexion peak torque/body weight from biodex at 60 deg/s

_____
(%)

Spinal flexion coefficient of variation at 60 deg/s

_____
(%)

Spinal extension total work from biodex at 90 deg/s

_____
(newtons)

Spinal extension peak torque/body weight from biodex at 90 deg/s

_____
(%)

Spinal extension coefficient of variation at 90 deg/s

_____
(%)

Spinal flexion total work from biodex at 90 deg/s

_____
(newtons)

Spinal flexion peak torque/body weight from biodex at 90 deg/s

_____
(%)

Spinal flexion coefficient of variation at 90 deg/s

_____
(%)

Hyperkyphosis Physical performance testing

Please complete the survey below.

Thank you!

Participant ID

_____

Acrostic

_____

Interviewer

_____

Standing Static Balance

Were the balance tests completed?

☐ Yes
☐ No

Side-by-side stand

Was participant able to hold side-by-side stand for 10 seconds?

☐ Yes
☐ No

Did the participant hold the side-by-side stand for more than 0 seconds?

☐ Yes
☐ No

Enter time:

_____
(seconds)

Why wasn't the side-by-side test completed?

☐ participant unable to hold side-by-side stand for any time
☐ participant refused side-by-side test
☐ side-by side test not attempted or data missing

Semi-tandem stand

Was participant able to hold semi-tandem stand for 10 seconds?

☐ Yes
☐ No

Did the participant hold the semi-tandem stand for more than 0 seconds?

☐ Yes
☐ No

Enter time:

_____
(seconds)

Why wasn't the semi-tandem test completed?

☐ participant unable to hold semi-tandem stand for any time
☐ participant refused semi-tandem test
☐ semi-tandem test not attempted or data missing

Tandem stand

Was participant able to hold tandem stand for 10 seconds?

☐ Yes
☐ No

Did the participant hold the tandem stand for more than 0 seconds?

☐ Yes
☐ No

Enter time:

_____
(seconds)

Why wasn't the tandem test completed?

☐ participant unable to hold tandem stand for any time
☐ participant refused tandem test
☐ tandem test not attempted or data missing

Chair Rise

Were the chair tests completed?

☐ Yes
☐ No

Was participant able to rise once without using arms?

☐ Yes, did not use arms
☐ No

Why wasn't participant able to rise once without arms?

☐ Used arms to stand
☐ Unable to rise once from chair even with arm use
☐ Participant refused to rise from chair once
☐ Rise from chair once not attempted or data missing

Was participant able to rise five times without using arms?

☐ Yes
☐ No

enter time to complete

_____
(seconds)

Why wasn't participant able to rise five times without arms?

☐ participant used arms to stand but completed 5 stands
☐ unable to complete all 5 stands (regardless of arm use)
☐ participant refused to rise from chair five times
☐ rise from chair five times not attempted or data missing

Book lift

Was participant able to complete the book lift task?

☐ Yes
☐ No

Enter time:

_____
(seconds)

Why wasn't the book lift task completed?

☐ Participant unable to do this task
☐ Participant refused test
☐ Test not attempted or data missing

Jacket task

Was participant able to complete the jacket on/off task?

☐ Yes
☐ No

Enter time:

_____
(seconds)

Why wasn't the jacket on/off task completed?

☐ Participant unable to do this task
☐ Participant refused test
☐ Test not attempted or data missing

Pick up penny task

Was the participant able to complete the pick up a penny from floor task?

☐ Yes
☐ No

Enter time:

_____
(seconds)

Why wasn't the pick up penny task completed?

☐ Participant unable to do this task
☐ Participant refused test
☐ Test not attempted or data missing

Turn 360 degrees task

Was the participant able to complete the turn 360 degrees task?

☐ Yes
☐ No

Why wasn't the turn 360 degrees task completed?

☐ Participant unable to do this task
☐ Participant refused test
☐ Test not attempted or data missing

Was number of steps taken in 360 degree task collected?

☐ Yes
☐ No

How many steps were taken in the turn 360 degree task?

_____
(steps)

Were the steps taken in the turn 360 degrees task discontinuous or continuous?

☐ Discontinuous steps
☐ Continuous steps
☐ Unable to assess steps

Was the gait in the turn 360 degrees task steady or unsteady?

☐ Unsteady (grabs, staggers)
☐ Steady
☐ Unable to assess gait

50-foot walk

Was the participant able to complete the50-foot walk from floor task?

☐ Yes
☐ No

Enter time:

_____
(seconds)

Why wasn't the 50-foot walk completed?

☐ Participant unable to do this task
☐ Participant refused test
☐ Test not attempted or data missing

4 meter walk

Was the 4 meter (13.1234 feet) task completed?

☐ Yes
☐ No

enter time to complete

_____
(seconds)

Why wasn't the 4 meter task completed?

☐ Participant unable to do this task
☐ Participant refused test
☐ Test not attempted or data missing

Stairs

Was the stairs task completed?

☐ Yes
☐ No

Why wasn't the stairs completed?

☐ Participant unable to do this task
☐ Participant refused test
☐ Test not attempted or data missing

Were number of flights climbed recorded:

☐ Yes
☐ No

How many flights of stairs were climbed?

_____
(flights)

Was blood pressure measured after the stairs task?

☐ Yes
☐ No

Enter diastolic:

_____

Enter systolic:

_____

Was heart rate measured after stairs task?

☐ Yes
☐ No

Enter heart rate:

_____
(beats per 15 seconds)

Timed up and go

Was the timed up and go test completed?

☐ Yes
☐ No

enter time to complete

_____
(seconds)

Why wasn't the timed up and go test completed?

☐ Participant unable to do this task
☐ Participant refused test
☐ Test not attempted or data missing

Timed loaded standing

Was the timed loaded standing test completed?

☐ Yes
☐ No

enter time to complete

_____
(seconds)

Why wasn't the timed loaded standing test completed?

☐ Participant unable to do this task
☐ Participant refused test
☐ Test not attempted or data missing

Six minute walk test

Was the six minute walk test completed?

☐ Yes
☐ No

enter total lengths completed

_____

Feet in final lap

_____
(ft.)

Total distance covered (total lengths completed x 60) + feet in final lap) =

_____
(ft.)

Total distance covered in meters:

note: I can round this down to a certain number of decimal places

_____
(meters)

Why wasn't the six minute walk test completed?

☐ Participant started unable to complete this task (could not walk for 6 minutes)
☐ Participant unable to walk at all
☐ Participant refused test
☐ Test not attempted or data missing

Was the time that the participant walked recorded?

☐ Yes
☐ No

enter time:

_____
(minutes)

enter distance walked in that time:

_____
(feet)

Hyperkyphosis Physical Activity Survey

Please complete the survey below.

Thank you!

Participant ID:

_____

Acrostic:

_____

Interviewer:

_____

The next few questions ask about your physical activity during the last 7 days. If the last 7 days have not been typical because of illness or bad weather, please estimate based on two or three weeks ago.

Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?

☐ Never
☐ Seldom (1-2 days)
☐ Sometimes (3-4 days)
☐ Often (5-7 days)

What were these activities?

On average, how many hours per day did you engage in these sitting activities?

☐ Less than 1 hour
☐ Between 1 and 2 hours
☐ 2-4 hours
☐ More than 4 hours

Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

☐ Never
☐ Seldom (1-2 days)
☐ Sometimes (3-4 days)
☐ Often (5-7 days)

What were these activities?

On average, how many hours per day did you spend walking?

☐ Less than 1 hour
☐ Between 1 and 2 hours
☐ 2-4 hours
☐ More than 4 hours

Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier, or other similar activities?

☐ Never
☐ Seldom (1-2 days)
☐ Sometimes (3-4 days)
☐ Often (5-7 days)

What were these activities?

On average, how many hours per day did you engage in these light sport or recreational activities?

☐ Less than 1 hour
☐ Between 1 and 2 hours
☐ 2-4 hours
☐ More than 4 hours

Over the past 7 days, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

☐ Never
☐ Seldom (1-2 days)
☐ Sometimes (3-4 days)
☐ Often (5-7 days)

What were these activities?

On average, how many hours per day did you engage in these moderate sport or recreational activities?

☐ Less than 1 hour
☐ Between 1 and 2 hours
☐ 2-4 hours
☐ More than 4 hours

Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic exercise, skiing (downhill or cross country) or other similar activities?

☐ Never
☐ Seldom (1-2 days)
☐ Sometimes (3-4 days)
☐ Often (5-7 days)

What were these activities?

On average, how many hours per day did you engage in these strenuous sport or recreational activities?

☐ Less than 1 hour
☐ Between 1 and 2 hours
☐ 2-4 hours
☐ More than 4 hours

Over the past 7 days, how often did you do any exercise specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

☐ Never
☐ Seldom (1-2 days)
☐ Sometimes (3-4 days)
☐ Often (5-7 days)

What were these activities?

On average, how many hours per day did you engage in exercises to increase muscle strength and endurance?

☐ Less than 1 hour
☐ Between 1 and 2 hours
☐ 2-4 hours
☐ More than 4 hours

During the past 7 days, have you done any light housework, such as dusting or washing dishes?

☐ Yes
☐ No

During the past 7 days, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows or carrying wood?

☐ Yes
☐ No

During the past 7 days, did you engage in any of the following activities? (Please answer yes or no for each item.)

Home repairs, like painting, wallpapering, electrical work, etc.?

☐ Yes
☐ No

Lawn work or yard care, including snow or leaf removal, wood chopping, etc.?

☐ Yes
☐ No

Outdoor gardening?

☐ Yes
☐ No

Caring for another person, such as children, dependent spouse, or another adult?

☐ Yes
☐ No

During the past 7 days did you work, either for pay or as a volunteer?

☐ Yes
☐ No

How many hours in the past week did you work for pay and/or as a volunteer?

_____

Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

☐ Mainly sitting with slight arm movements - Examples: office worker, watchmaker, seated assembly line worker, bus driver, etc.
☐ Sitting or standing with some walking - Examples: cashier, general office worker, light tool and machinery worker
☐ Walking, with some handling of materials generally weighing less than 50 pounds - Examples: mailman, waiter/waitress, construction worker, heavy tool and machinery worker
☐ Walking and heavy manual work often requiring handling materials weighing more than 50 pounds - Examples: lumberjack, stone mason, farm or general laborer.

Hyperkyphosis Weekly Log

Please complete the survey below.

Thank you!

Participant ID

_____

Acrostic

_____

Interviewer

_____

Class number:

_____

Wave number:

_____

Have you fallen since the last group exercise class?

☐ Yes
☐ No

how many times:

☐ 1
☐ 2
☐ 3 OR MORE

was it an injurious fall?

☐ Yes
☐ No

check all that apply

☐ Muscle strain
☐ Joint sprain
☐ bruise
☐ fracture
☐ Other

Have you had any injuries not related to a fall since the last group exercise class?

☐ Yes
☐ No

please check all that apply

☐ Muscle strain
☐ Joint sprain
☐ bruise
☐ fracture
☐ OTHER

Has your usual level of pain changed since the last class?

☐ Yes
☐ No

Overall average pain level in the 48hours prior to assessment at rest

☐ 0 - No pain
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 - Worst pain imaginable

Describe location: (Mark all that apply):

☐ arms R
☐ arms L
☐ legsR
☐ legs L
☐ shoulders R
☐ shoulders L
☐ backR
☐ back L
☐ neckR
☐ neck L
☐ head
☐ other

other:

_____

Overall average pain level in the 48hours prior to assessment during movement

☐ 0 - No pain
☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☐ 8
☐ 9
☐ 10 - Worst pain imaginable

Describe location: (Mark all that apply):

- ☐ arms R
- ☐ arms L
- ☐ legsR
- ☐ legs L
- ☐ shoulders R
- ☐ shoulders L
- ☐ backR
- ☐ back L
- ☐ neckR
- ☐ neck L
- ☐ head
- ☐ other

other:

_____