Title: Effect of Vibration Exercise on Upper Limb Strength, Function and Pain

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Background

Strong upper limb musculature is essential for people who have paraplegia with spinal cord injury (SCI) to operate manual wheeled mobility devices in order to live independently and perform activities of daily living such as wheelchair propulsion, wheelchair transfer activities, and weight relieving maneuvers. These activities, however, place high demands on the upper extremities and practicing them over time negatively impacts upper extremity health. The shoulders, elbows and wrists are all highly susceptible to degeneration, overuse injuries, and pain. The shoulder is the most common site of upper extremity pain in manual wheelchair users, with reported pain ranging from 32% to 78%. A range of pathological conditions at the shoulder have also been documented including impingement syndrome, adhesive capsulitis, recurrent dislocations, rotator cuff tears, and tendinitis. Shoulder pain has been most closely associated with transfers, weight relieving activities, and ramp propulsion indicating that these activities may be the most demanding ones performed.

The benefits of upper limb resistance training for wheelchair users with paraplegia have been well documented and include moderate to large gains in muscle strength, endurance, and performance of activities of daily living. Studies among various populations ranging from children to older adults, untrained to elite athletes, and persons with and without disabilities have shown that when resistance training is paired with high-frequency whole body vibration there is greater potential to increase and coordinate muscle recruitment and build muscle strength and power more quickly. More recently vibrating dumbbells have been developed so that training can be localized to the upper extremities. This form of training could greatly benefit persons with paraplegia who need an effective and efficient solution to building muscle work capacity for weight bearing tasks and for protecting the joints from overuse and aging effects.

Numerous studies have examined the effects of varying forms of structured resistance and endurance training among individuals with SCI. These studies have demonstrated that engaging in structured fitness training, including resistance training 2-3 times/week, of the upper limbs following SCI leads to improvements in muscle strength, increased performance during activities of daily living and improved quality of life. While a combination of endurance and resistance training is recommended for overall increased fitness, resistance training targets and leads to greater gains in upper extremity work capacity, muscle strength, and power over endurance training. Resistance training is also recommended for combating muscle imbalances associated with overuse and for treating shoulder pain. In one study wheelchair users with SCI who concentrated on strengthening the muscles of the posterior shoulder and upper back while stretching the muscles of the anterior shoulder and chest reported greater pain relief and an easier time performing propulsion and weight relief activities when compared to an attention control group who received video instruction on pain relief. The amount of strength gain achieved through resistance training reportedly varies from study to study (10-60%) with larger gains found in studies that involve weight lifting universal systems or equipment and frequent, progressive increases in training loads. Most of the studies evaluating effects of training report outcomes of muscle strength, anerobic power, endurance, pain, and general improvement in the performance of daily tasks (e.g. Functional Independence Measure). Few studies have examined the effects of resistance training on propulsion performance and skills. We are not aware of any studies that have assessed the impact of resistance training on transfer ability specifically. Therefore the present study will determine the effectiveness of the proposed resistance training programs (vibration and non-vibration) in improving forces generated during wheelchair mobility tasks and the ability to transfer to higher and lower surfaces.

Vibration exercise has gained recent popularity and adoption among recreational to elite athletes. This is because vibration training has been shown in numerous studies to increase muscle strength, power and performance when integrated into a resistance training program or when used as a supplement to alternative modes of training. Vibration exercise is mostly practiced in the form of whole body vibration

(WBV), where one stands or sits on an oscillating platform. Vibrating dumbbells have also been developed more recently for upper-body exercise. Despite controversy surrounding possible training effects with vibration, multiple studies have shown that both WBV and vibrating dumbbell use elicits greater muscle activation not only in the muscles targeted but also in the surrounding and supporting muscle groups (e.g. antagonists). Using vibration above a certain threshold frequency (12 Hz for plates, and 16 Hz for dumbbells) elicits a stretch reflex (contraction) in the muscle. The number of contractions is equivalent to the vibration frequency (e.g. 20 Hz = 20 contractions per second). When frequencies exceed 20 Hz for plates (28 Hz for dumbbells), the muscle fibers activated do not have enough time to complete a full contraction and relaxation cycle and are therefore in constant co-contraction which results in increased muscle force and power post-vibration. Moreover, muscle electromyographic patterns observed with upper limb vibration at high frequencies (44 Hz) have indicated a more efficient and effective recruitment of high threshold motor units during fatiguing contractions. The effects of vibration on the body have been extensively studied and guidelines have been developed to regulate exposure to such stimuli. The frequency, amplitudes and exposures used in previous vibration studies and the proposed study are considered acceptable and safe. Results from all of these studies combined suggest that vibration may be an effective and safe tool for enhancing resistance training among wheelchair users with SCI.

Objective

The primary purpose of this study is to explore the benefits of vibration dumbbell resistance improving upper limb strength, function and pain among manual wheelchair users with paraplegia.

Specific Aim 1) Explore the effects of vibration dumbbell training on improving strength, function and pain

Hypothesis 1): Subjects will demonstrate the following changes overtime:
Primary outcomes: Increased peak isokinetic muscle torque output as measured using a Biodex machine of the shoulder internal rotators, external rotators, shoulder abductor/adductors, and shoulder flexion/extension, elbow flexion/extension, forearm pronation/supination, wrist flexion/extension, and hand grip measured using a handheld dynomometer at 6 weeks (mid-way into training) and 12 weeks (end of training) when compared to baseline.

Secondary outcomes:
o Propulsion testing: Increased maximum speed and acceleration attained, peak force, and mechanical effective force measured using the SmartWheel during start-up propulsion over level and inclined surfaces at 12 weeks when compared to baseline
o Transfer testing: Higher maximum and minimum attainable transfer heights to a height-adjustable transfer station at 12 weeks when compared to baseline;
o Reduced upper limb pain across all joints (as recorded on the Numerical Rating Scale (NRS) and shoulder pain reported during activities (Wheelchair Users Shoulder Pain Index (WUSPI)) at 6 weeks and 12 weeks when compared to baseline;
o Increased self-perceived aspects of health and function as measured using the Short Form SF-36 Walk Wheel scale at 6 weeks and 12 weeks and when compared to baseline.
o Increased peak power and average power output at 12 weeks compared to baseline.
Specific Aim 2) Assess subjects' perceptions of the effectiveness of the vibration dumbbell training program

Hypothesis 2) Subjects will report a high level of satisfaction with the training on factors of efficiency, tolerance, perceived strength and functional benefits.

Study Design and Methods

Each subject will be asked to come to HERL three times over a 12-week study period. During these visits the following activities will take place a) Pain and Health Surveys (Baseline and Weeks 6, and 12), b) Muscle Strength Testing (Baseline and Weeks 6 and 12), c) Functional Testing (Baseline and Week 12), and Pre-Training Assessment and Instructions (Baseline). The 12-week Training Phase will start after Visit 1

Data will be collected electronically using redcap, or on paper as needed.

Visit 1 (Initial Visit)

After signing informed consent, all subjects will complete a basic information questionnaire. The questionnaire will survey the frequency of wheelchair usage, transfers, percentage of non-level transfers, basic demographics (age, gender, years since SCI, etc.), work history, history of medical problems, current medications, and alcohol and smoking usage.

Pain and Health Measures

Numerical rating scale (NRS): Subjects will complete this scale once for each upper limb joint (wrist, elbow, and shoulder). The subjects will be asked to rate their average, most severe, and least severe wrist, elbow or shoulder pain during the past 24 hours using an 11-point scale (i.e. 0-10) anchored at the ends by "no pain" and "worst pain ever experienced." An 11-point NRS measure of pain intensity allows for comparison across clinical trials of pain treatment and is recommended as a core outcome measure for chronic pain clinical trials. NRS pain measures are widely used and have been shown to be valid and reliable assessments of pain.

WUSPI – Wheelchair User's Shoulder Pain Index: The WUSPI is a 15-item, self-report instrument that measures shoulder pain intensity, within the last week, in wheelchair users during various functional activities of daily living, such as transfers, loading a wheelchair into a car, wheelchair mobility, dressing, bathing, overhead lifting, driving, performing household chores, and sleeping. The WUSPI is a valid and reliable measure of shoulder pain. This survey asses the previous tasks over the time span of the week leading up when the survey was being answered. Test-retest reliability of the total index score was 0.99 and Cronbach's alpha (internal consistency) was 0.98.

Carpal Tunnel Syndrome Self-Report Questionnaire: This self-report instrument includes two scales: a Symptom Severity Scale consisting of 11 questions and a Functional Status Scale evaluating 8 different activities. This instrument is reproducible, internally consistent, and responsive to clinical changes in symptoms.

Vibration Tolerance: Participants will be screened for their tolerance to the feeling of the vibration prior to collecting the biomechanics outcome measures. Participants will hold the dumbbell at 25Hz for 30 seconds with their arm at a forty-five-degree angle away from their bodies (position similar to a bicep curl). If they are unable to complete the assessment they will not be permitted to continue the study.

If subjects successfully complete the vibration screening they will continue with the following assessments during Visit 1:

General Health and Function: The 36-Item Short Form Health Survey Walk Wheel (SF-36 WW) is a slightly modified version of the original SF-36 that has been validated for persons with SCI. The SF-36 is a brief, multi-dimensional, self-report health questionnaire that measures eight concepts - Physical Functioning,

Role limitation due to Physical problems, Bodily Pain, General Perception of Health, Vitality, Social Function, Role limitation due to Emotional problems, and Mental Health. The domain scales ranges from 0 (worst possible health state measured by the questionnaire) to 100 (best possible health state).

Power output: the Lode Arm Ergometer will be used to measure the maximum power output for each participant. This test will be done with the participant seated in their wheelchair. The arm ergometer height will be adjusted such that participants are able to comfortably reach and crank both pedals. Additionally, we will want subjects to be in a stable participation. If they are able to, participants should brace their feet on their foot plate. If a participant does not feel enough stability in their wheelchair we will have a stable chair for them to transfer to in order to perform the evaluation. Participants will start out by cycling on the arm ergometer at a comfortable pace as a warm up. Once the participant feels as though they are sufficiently warmed up the test will begin. Participants will begin cycling against maximum resistance. Once that happens participants will be instructed to cycle as hard and as fast as they can for as long as they are able to. Once they are no longer able to crank against the resistance the test will stop and the maximum resistance will be recorded. We will complete this process three separate times, with a minimum of 30 seconds of rest in between. After the test is completed, the resistance will return to zero and the participants will cycle at a comfortable pace to cool down. They will cycle as long as they need to in both the warm up and cool down phases.

Muscle Strength Testing

Isokinetic strength measurements will be recorded at a torque arm speed of 60 deg/sec using an instrumented dynamometer (Biodex Medical System, New York, USA). The torque measurements will be recorded in a randomized fashion for both arms for the following test maneuvers: shoulder flexion/extension in the sagittal plane (-30 to 50 degrees), shoulder abduction/adduction in the frontal plane (10 to 70 degrees), shoulder internal/external rotation in the transverse plane (0 to 45 degrees), elbow flexion/extension (0 to 90 degrees), forearm supination/pronation (-80 to 80 degrees) and wrist flexion/extension (-45 to 45 degrees) and grip strength. One trial of 5 practice repetitions for each movement tested will be completed prior to data collection. In order to ensure the maximal force production of the tested upper extremity subjects will be secured into the chair with three padded belts: two diagonally across their chest and one across their lap. After the practice trial, one trial of five repetitions will be recorded for each muscle group. In between the practice trial and data collection trial, participants will rest a minimum of 60 seconds and in between each muscle groups participants will rest a minimum of 2 minutes. Participants may request additional time as needed. After completing all the strength testing subjects may rest before performing the functional tests.

Functional Testing

Wheelchair Propulsion Assessment: If a subject's wheelchair is equipped with quick release wheels, it will be fit with a SmartWheel (Three Rivers Holdings, Mesa, AZ), an instrumented wheel that measures forces and moments applied to the pushrim on the non-dominant side of the subject's wheelchair. A dummy wheel with matching inertial properties to the SmartWheel will be placed on the dominant side. Subjects will propel down a level hallway that is 5 feet wide by 250 feet long. Subjects will be asked to start from a dead stop with their front castors at the beginning of the runway and propel their wheelchairs up to a maximum velocity until they reach the end of the runway. Subjects will also propel up three different ramp grades (3, 5 and 8 degrees) at a comfortable pace. The ramps are 4 feet wide by 10 feet long with a 4 by 4 foot landing platform at the top. Three propulsion trials on the level surface and for each ramp slope will be collected. Subjects may rest in between trials as needed. Each trial will be timed using a stop watch and their level of exertion recorded for each trial. If a person does not have quick release wheels or uses manual power assist wheels, they will complete the propulsion trials with their

standard wheels instead of the Smartwheel. All propulsion trials will still be timed and the exertion recorded.

Transfer Assessment: Subjects will be asked to transfer to a custom height adjustable transfer station. The platform on the station contains a 24 inch wide by 16 inch deep cushioned seat and has an adjustable height range from 10 inches to 43 inches above the floor in 1 inch increments. The subject will first transfer to and from the platform set at level height with their wheelchair seat using their habitual methods. Afterwards the platform will be raised to a level that the subject feels would be the maximum height that they could transfer and then the subject will perform a transfer to and from the elevated platform. Subjects will be spotted by study personnel throughout the process. If a subject has difficulty making the transfer or requires any help from the spotters, the platform will be lowered and the subject will be offered a second attempt. If they feel they can go higher, the platform will be raised and they will be given another attempt. Subjects will be instructed to only perform transfers in this protocol that they feel comfortable and safe in performing. The subject will repeat the attempts until their maximum transfer height has been found with success (e.g. defined by requiring no spotting assistance and by landing safely and securely on the target surface). The same procedure will be used to determine how low the subject can transfer. The maximum transfer heights high/low that were attainable will be recorded. In addition to recording the height attained, participants will be asked about their perceived exertion using the Borg scale. Participants will be shown a visual analog scale ranging from 6 to 20, where 6 is no exertion and 20 is maximum exertion. From the scale, participants will select their level of exertion after each transfer. In addition to the perceived level of exertion, measurements about the wheelchairs location next to the transfer station will be recorded. Participants will initially set up in front of the station as they would normally transfer. To insure they transfer in the same place at the follow up visit, their position will be recorded. This protocol has been used successfully in our previous work to measure transfer ability and generally involves performing fewer than 10 transfers.

All subjects' one rep maximum (1RM) for each of the exercises to be performed in the training phase will be determined at their baseline visit with a non-vibrating dumbbell in accordance with standard procedures. The following exercises will be tested for a one rep max as well as will be performed during the study: butterflies, serratus punches, side flies, straight arm rows, bicep curls, internal and external rotation, front raises, triceps extension, and bent over rows. Pictures of each exercise can be found in other attachments. Dumbbell weight will be increased accordingly until the subject reaches their 1 RM. If a subject is not able to perform a 1RM with the dumbbell for a given exercise, they will start their training protocol using a lower weight dumbbell for that exercise until they can hold the vibrating dumbbell for 30 seconds.

After the standard 1RM test, subjects will receive education and instructions on the use of the vibrating dumbbell. They will start with holding the dumbbell at a moderate frequency (25 Hz) and experience how the effects of the vibration on the arm and body can change with differing arm positions and grips. They will be instructed to grip the dumbbell as hard/tightly as possible throughout the course of training in order to concentrate the vibrations to the arm muscles and surrounding structures. Subjects will receive a pair of gloves to aid in maintaining a strong, firm grip during the exercises. These gloves will be for the personal use of each participant during the testing and will be theirs to keep at the conclusion of the study. Starting with the biceps curl exercise to demonstrate what higher vibrations feel like, subjects will hold the bicep curl in the static training posture (90 degrees of elbow flexion, 60% 1 RM) while the frequency is progressively increased to 40 Hz. They will be asked to hold the position for as long as they can until they reach a pain-free level of muscle exhaustion. This same process will be repeated for all the exercises to ensure they can tolerate each position at 40 Hz. If they can hold the position for an exercise for longer than 60 seconds at 40 Hz, weight will be added to the dumbbell (see below Training Intensity Assessment and Adjustments). If a subject is unable to tolerate 40 Hz for any one of the exercises, they will start that exercise in their first training session at 30 Hz, the minimum frequency for

training upper limb muscle force and power. For any subject who begins training at 30 Hz, the frequency will be reassessed at each training session to progressively increase him/her (in increments of 5 Hz) to 40 Hz.

The vibrating dumbbell, without added weights, weighs 6 pounds. It is possible that early in the exercise program a subject in the vibration intervention group may not be able to properly perform a specific exercise with that weight. In this case the subject will perform the exercise with a lighter weight standard dumbbell until they increase sufficiently in strength.

Visit 1 will take up to 5 hours to complete.

Optimally, each subject will be scheduled for three training sessions per week in their home for 12 consecutive weeks. Although the home was chosen for the training setting to make it easier on subjects to comply with the protocol, training can take place in another location based on subject convenience. The training equipment is portable and can be easily setup and broken down after each session. All the training for both the control and vibration groups will be supervised by a trainer with appropriate knowledge of proper exercise form and safety. The trainer will travel to the agreed upon location and guide the subject through each training session. The training sessions will be monitored by a physical therapist (PT). Both the trainer and PT will be masked to subjects' performance on outcome measurements.

Prior to beginning each exercise session, female subjects will be reminded that they should not participate in vibration exercise activities if they are pregnant and should notify the study team if they think they could be. Female subjects will be asked weekly if they are or could be pregnant and this will be documented. If pregnancy is a possibility, the subject will be offered an over the counter pregnancy test. Subjects will be given the test to perform themselves, unless they are physically unable to because of disability related functional limitations. In these circumstances, a female staff member will assist as needed. Any subject reporting or testing positive for pregnancy will be withdrawn from the study.

Sessions will ideally be scheduled on a Monday, Wednesday and Friday to allow time for muscles to rest and rebuild in between training sessions. Prior to starting the weight training, subjects will go through a warm-up phase (approximately 5-10 minutes) and stretching phase (approximately 5 minutes). The warm-up phase will consist of non-resisted arm movements that parallel motions of the resistance exercises and forward and backward arms circles. The stretching phase will consist of stretching exercises for the arms, chest and upper back.

Subjects will perform nine training exercises. For each exercise, subjects will perform one repetition of each exercise at 60% of their 1 RM holding the high-frequency (40 Hz) vibrating dumbbell in a static arm posture. This posture will be at the point where the force generating output of the targeted muscle group is maximized. This point is at the 'End' range of motion (ROM) for each of the dynamic upper limb exercises with the exception of the biceps curl which occurs when the elbow is flexed at 90 degrees. Subjects will be asked to hold the 40 Hz vibrating dumbbell in the position for as long as they can until they reach a pain-free level of muscle exhaustion. The amount of time subjects hold on to the dumbbell will be recorded for each exercise and ideally will be 30-45 seconds, a standard isometric training goal for increasing muscle hypertrophy. Falling below or above this time will result in changes in the amount of dumbbell weight added or removed for the next session.

Two sets of each exercise will be performed alternating between the left and right sides. The resisted exercise phase is estimated to take about 40-50 minutes with total session time of 60-65 minutes. For the two exercises that require a supine position, the subject will transfer to a weight bench provided to them for the duration of the study and returned to HERL after the study ends. Subjects may choose to

use another surface in their home for these exercises if it is determined to be safe and appropriate by the trainer or other member of the study team. For the rest of the exercises, subjects will exercise while in their wheelchair. A lap belt will be provided to subjects who do not have one and will be used to secure their pelvis in the wheelchair and to provide a more stable base of support while exercising. Emphasis will be placed on maintaining a neutral thoracic and cervical posture and avoiding scapular elevation during seated exercises. Depending on the amount of trunk control present, subjects may use their opposite limb to brace their trunk (either forearm pressed against their thighs or placed on an adjacent table) for exercises involving forward trunk flexion (e.g. bent over rows, triceps extensions and side flies). Verbal cuing and spotting from the trainer will be provided during the sessions to monitor positioning and safety with the exercises.

The trainer will only facilitate and supervise the exercise training. The trainer who will be conducting the training sessions will guide the subjects through each exercise set and ensure that the correct weights, timing, vibration frequency, arm postures and technique are being used to maximize subject safety. He/she will also perform survey-based data collection and research procedures. Training procedures will be stopped immediately by the trainer if a subject complains of pain or extreme discomfort during the exercises. The subject will be instructed to check in with his/her physician before resuming training.

The trainer will reassess the intensity of the training parameters at the end of each session and adapt as necessary. He/she will keep a training log for each subject and session that documents the training parameters (e.g. hold times completed each session), total session duration time, and changes made to increase/decrease efforts for the next session. Health parameters, such as heart rate and blood pressure will be collected. An automatic blood pressure monitor will be placed on the upper arm of the subject to measure their blood pressure. An automatic pulse ox monitor will be placed on the finger of the subject to measure their heart rate. The trainer will also take general notes on the sessions and the exercises, as well as the plan for the next exercise session.

Each training session is expected to take up to 1.5 hours.

Training Intensity Assessment and Adjustments

Training intensity will be adjusted progressively with add-on dumbbell weights that will be added to the vibrating dumbbell. Subjects will be asked to hold onto the vibrating dumbbell tightly for as long as they can for each exercise. If they are unable to hold on tightly for at least 15 seconds, the weight for the next session will be decreased, whereas if they are able to hold onto the dumbbell for greater than 60 seconds, the trainer will stop the exercise and the dumbbell weight will be increased for the next session. The amount of weight increased and decreased will be determined by the trainer and will be reviewed and verified by a member of the senior study personnel.

The trainer will meet with the senior study personnel (PT and PI) at minimum once a week to review subjects' training progress, performance, any complications, concerns or complaints that the subject expresses, and any changes in the health status of the subjects who had been seen over the course of the week. Senior personnel will re-assess and modify the training procedures as appropriate.

During the last week of training (week 12), the trainer will give subjects a survey to assess satisfaction with the training program to collect their feedback on factors such as tolerance, perceived strength, performance and health benefits, efficiency of training, choice to continue training, and if they would recommend this form of exercise to others.

The follow-up outcome assessment visit, which take place at our laboratory, will be conducted by the PhD student and overseen by the PI.

Visit 2 (midway visit)

Participants will come back to the lab 6-8 weeks from the beginning of the intervention. The follow-up visit intake form will be completed to identify any changes in the participants health or medical status, lifestyle or any other changes that could impact the participants ability to complete the exercise program. At this visit we will test their strength in the same way that it was tested on initial visit. Additionally, they will fill out the pain measure forms, the health and satisfaction form and the carpal tunnel questionnaire that were filled out at the first visit.

This visit is expected to take no more than 2 hours to complete.

Visit 3 (end of the exercise program)

At the end of the 12-week intervention period, subjects will come back to the lab for the final visit. This visit will be scheduled 12-14 weeks after the start of the intervention. However, even if a participant is unable to come back at 12 weeks exactly, the exercise program will still end at 12 weeks.

The follow-up visit intake form will be completed to identify any changes in the participants health or medical status, lifestyle or any other changes that could impact the participants ability to complete the exercise program. At this visit subjects will complete all the measures that were completed during the first visit. This includes the pain measures, measure of health and function, carpal tunnel questionnaire, strength, power output and functional measures. These tasks are expected to take up to 5 hours to complete.

As stated above, three exercise sessions will be scheduled each week. We expect that this schedule will be modified due to scheduling conflicts, illness, etc. and it is possible that subjects may sometimes complete less than three visits per week. All visits that are changed or missed will be documented in the research record but will not be considered protocol deviations so long as they are completing a minimal number of sessions (10) per six-week period. If a subject completes less than 10 exercise sessions in a 6-week period they will be removed from the study.

As stated above, testing sessions at the HERL lab will be scheduled at 6 and 12 weeks from the baseline visit. We expect that this schedule will be modified due to scheduling conflicts, illness, etc. For this reason, subjects will be given a 2-week window (6-8, 12-14 weeks) in which to complete these visits. Testing sessions within this window will not be considered protocol deviations.

Eligibility Criteria

Inclusion Criteria:

(1) have a neurological impairment secondary to a SCI or disease at T2 or lower
(2) greater than 6 months post injury
(3) use a manual wheelchair as primary means of mobility (at least 30 hrs. per week)
(4) 18 to 65 years of age
(5) provide signed medical release by primary care physician to engage in a high-intensity resistance training exercise program
(6) live within 60 minutes driving time (1 hour) from the research center
(7) able to perform a transfer independently to and from a wheelchair
(8) have normal range of motion in the upper limbs.

Exclusion Criteria:

(1) history of fractures or dislocations in the shoulder, elbow and wrist from which the subject has not fully recovered or joint replacement of any of the joints in the upper extremities
(2) upper limb pain that interferes with the ability to propel or transfer
(3) recent hospitalization for any reason (within the past three months)
(4) pregnant women
(5) history of coronary artery disease, coronary bypass surgery or other cardiorespiratory events

Statistical Plan

Distributions of all data will be examined. Should outliers or distributions that are nonlinear in nature be present, appropriate transformations will be performed. Means and standard deviations, or medians and ranges, as appropriate, will be calculated for all variables. A repeated measures ANCOVA will be used to examine primary (strength) and secondary outcome measures (pain, quality of life, power, transfer ability, propulsion characteristic) for the three time points. For significant models, post-hoc analyses with Bonferroni corrections will be used. Total number of training sessions completed will be entered as a covariate if necessary. The training progress (e.g. hold times) and training adaptations made and documented by the trainer during each session will be analyzed using graphical methods to further assess training effects that occur overtime.