Feasibility and acceptability of six-weeks of high intensity interval training in wheelchair users with SCI

Short Title: HIIT in Spinal Cord Injury (HIIT-SCI)

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Overview

An upper extremity form of high intensity interval training (HIIT) that is effective, safe, quick and has acceptable positive affect could be an attractive option for persons with SCI who are not presently exercising and have low fitness levels. The study will look at feasibility and acceptability of a 6-week HIIT program for persons with a spinal cord injury/dysfunction who are untrained. Additionally, the study will look at the effects of the training program on changes in activity levels. Participants will complete a 6-week HIIT training program in their homes, as well as two laboratory visits where aerobic and anaerobic fitness will be measured.

Research Activities and Consent

Potential subjects who contact the Human Engineering Research Laboratories (HERL) and express an interest in the study will undergo a brief telephone screening. The telephone screening will be used to provide the potential subject with more information and allow them to ask questions regarding the research study to help them determine their interest in participating. During the phone screening, we will ask them basic questions to see if they might qualify for the study. These questions will be based on the inclusion/exclusion criteria for the study, as well as questions about their current lifestyle. Prior to asking the participants these questions, we will make sure they understand why we are asking these questions and obtain their permission to do so. We will note the date and time of the permission obtained. We will use the Exercise Stages of Change Questionnaire, as well as questions about their current fitness activities to asses eligibility for the study. We want to make every effort to determine whether or not a participant would potentially qualify for the study prior to contacting their Primary Care Physician (PCP).

Obtaining the approval of a physician is highly recommended for anyone starting an exercise program, regardless of disability. We will rely on the potential subject's PCP in order to assess their readiness to participate in the research study. A participant's PCP will know their medical history, and will be able to evaluate their overall health. The physician's release form will detail the study and list all contraindications. In addition, the PCP may contact the study team should he/she need additional information prior to signing the release form. The study team will not access any medical records. "

Location of testing: (1) two in-lab visits at University of Pittsburgh, Endocrinology and Metabolism Research Lab (Montefiore Hospital); (2) subjects' homes or an agreed upon location where it's safe to store exercise equipment and for our research staff; (3) if necessary, there may be a visit at the Human Engineering Research Laboratories or a safe, agreed upon location for the purposes of retrofitting the add-on hand bike (this is detailed further below).

A subject who contacts HERL over the phone will be asked for their verbal consent to the screening procedure. The screening procedure will include asking the participant the inclusion/exclusion criteria. The screening procedure will also determine which training options are available for them (i.e., handcycle and/or add-on hand bike). For example, if a person meets all the inclusion/exclusion criteria and they weigh less than 250 lbs, they will have the option to train using a handcycle or an

add-on hand bike. If a person meets all the inclusion/exclusion criteria and they weigh more than 250 lbs, they will have the option to train using the add-on hand bike or not to participate. If the add-on hand bike option is selected, they will be asked to report the make/model of their wheelchair for retrofitting purposes. The study team feels that wheelchair make/model is sufficient information to determine whether the add-on hand bike can be retrofitted; however, an additional in-person visit may be scheduled for fitting purposes.

If the participant is eligible and would like to participate, the study team will send a physician release form to be signed directly by the physician (please see "Cover Letter for Physician Release" and "PCP Release" under the "Supporting Documentation" section). After the study team receives the signed release form, the participant will be scheduled for their Visit 1, Baseline Visit. Participants will be given the following instructions prior to their first lab visit:

1. Do not participate in any strenuous physical activity 24 hours prior to testing.
2. Do not eat a large meal 4 hours prior to testing, however a light snack is okay.
3. Do not drink alcohol or caffeine 4 hours prior to testing.
4. No smoking 1 hour prior to testing.
5. Wear comfortable, loose clothing that allows you to move your arms freely and that you can easily exercise in.

Visit 1: Baseline Visit

Eligible participants will be directed to come to the Endocrinology and Metabolism Research Lab to obtain written informed consent, complete study questionnaires, and perform baseline exercise tests. Participants will be considered enrolled in the study after they have signed the informed consent document.

Participants will complete the following questionnaires regarding demographics, pain and health measures, general health and function, and physical activity:

(1) Demographics questionnaire: May include information such as disability type, level of SCI, years with disability, age, gender, and information about their wheelchair (e.g. make, model, cushion, etc.).

(2) Numerical Rating Scale (NRS): Participants will complete this scale once for each upper limb joint (wrist, elbow and shoulder). Participants will be asked to rate their average, most severe, and least severe wrist, elbow and shoulder pain during the last 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 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.

(3) Wheelchair Users Shoulder Pain Index (WUSPI): 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, leading 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. Test-retest reliability of the total index score was 0.99 and Cronbach's alpha (internal consistency) was 0.98.

(4) Short Form Health Survey Walk Wheel (SF-36 WW): A 36-item general health and function questionnaire that has been validated for persons with SCI/D. 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.

(5) Physical Activity Scale for Individuals with Physical Disabilities (PASIPD): The PASIPD is a 13-item self-report instrument covering (1) leisure activities, (2) household activities, (3) occupational activities and (4) light, moderate, and strenuous sport and recreational activities. The scale asks individuals to report how many days and hours per week that they spend participating in these various physical activities and a total score is calculated that is expressed in a metabolic equivalent (MET). The maximum possible score on the PASIPD total score is 199.5 MET.

(6) Physical Activity Stages of Change: This is a brief, 5-item, yes/no questionnaire that assesses an individual's readiness to exercise.

(7) Exercise Participation Evaluation: This is a 4-item questionnaire developed by our study team that will be used to determine if the participant exercises, and if so, what type of exercise and how frequent.

(8) Profile Of Mood States (POMS): This is a validated questionnaire that contains a series of descriptive words/statements that describes feelings. The participant will self-report on each of these areas using a 5-point Likert scale to assess total mood disturbance.

Lastly, height and weight will be taken. Subjects will transfer to a mat table where they will lay on their backs. Once in this position we will measure their height with a measuring tape. Weight will be measured using a wheelchair scale. Participants will be weighed with their wheelchair and the wheelchair will be weighed without the subjects in them. The weight will be the difference between the two measurements.

Following completion of all study questionnaires, participants will begin exercise testing. Both exercise tests will be administered by an exercise physiologist and directly supervised by a physician.

Both tests have been widely used in previous research studies. The tests are outlined in further detail below:

(1) Maximal aerobic exercise test: the purpose of this test is to evaluate cardiac function and fitness. Additionally, this test will determine peak power output (PPO) which will later be used to set an individualized goal for the participant during the HIIT protocol to be completed in the second, and possible third and fourth visits. Prior to starting the test, participants will be fitted with a mask that analyzes the air that is being inhaled and exhaled (also known as "open circuit spirometry"). Cardiorespiratory measures (i.e., heart rate, blood pressure, oxygen consumption, respiratory exchange ratio, pulmonary ventilation, carbon dioxide expiration, etc.) will be recorded throughout this test. A heart rate monitor will be worn around the chest. Participants will be able to use a private space to put on the heart rate monitor. A member of the study team will verify the heart rate monitor is placed properly.

Prior to beginning the test, the Borg and Wheel scales will be explained to participants (please see “Borg Scale” and "Wheel Scale" under the “Supporting Documentation” section). Ratings of

Perceived Exertion (RPE) scales (such as the Borg and Wheel scales) rate how hard a person feels their body is working and is an accepted supplementary tool for exercise programs. Throughout the test, the participant will be asked to report their RPE by pointing to the corresponding number on the scale. The exercise test will be administered using an incremental, modified protocol on an electronically-braked arm ergometer. A study team member will choose one of two exercise protocols, depending on the answers to the questions on the demographics questionnaire.

For one protocol, the resistance will initially be set at 10W and will increase by 10W every minute until the participant can no longer continue, or until their respiratory exchange ratio exceeds 1.15. For the second protocol, the resistance will initially be set at 35W and will increase by 10W every minute until the participant can no longer continue, or until their respiratory exchange ratio exceeds 1.15. Both protocols will ask the participant to maintain an RPM of 55-65 revolutions per minute (RPM). If the RPMs drop below 55 for more than 20 seconds, the test will be completed.

(2) Maximum power output test: the primary purpose of this test is to evaluate the highest amount of power that the participant can produce in a short period of time. Other measures include heart rate, blood pressure, relative peak power, anaerobic capacity and anaerobic fatigue. The same ergometer will be used for this study that was used for the maximal aerobic exercise test. Initially, the resistance will be set at zero and will then be increased over the duration of the test. The actual test will last one minute in duration. For the first 30 seconds, the participant will crank on the cycle with minimal resistance. Then, the resistance will be increased to a maximal level and participants will crank as hard and as fast as they are able to for the last 30 seconds. After that the test is completed, the resistance will then return to zero and the participants will cycle at a comfortable pace to cool down.

Participants will rest a minimum of 20 minutes in between each assessment.

Following completion of the exercise tests, the study team will introduce the participant to the type of exercises that will be performed for the study. They will be able to use the ergometer in the lab to try out a brief HIIT protocol.

Activity Monitor Data Collection

Activity monitors will be given to participants to address aim 5 as equipment is available. The following study procedures will not be performed if the monitors are not available. The following procedures will be followed when monitors are available and activity data is going to be collected.

After the participants are introduced to the training, they will be given the two activities monitors that will be used to look at activity for the duration of the study. A SensorTag gyroscope will be secured to the participants wheelchair wheel in a position where it will not affect propulsion. This sensor will remain on the wheel for the duration of the study. Participants will also be given an ActiGraph GT9X accelerometer. This sensor will be worn on the wrist like a watch. The subject will be shown how to use the activity monitors (including donning/doffing, and operation), and provide ample time for practice. The subject will be asked to demonstrate how to use the devices to ensure compliance. Participants will be instructed to wear the activity monitor at all times as tolerated, including sleeping, or most of time, except for showering/bathing and swimming. Participants will be given instructions and details on how to use/wear the monitors.

At the regularly scheduled training visits, the trainer will monitor the function of the monitors. They will download data and replace sensor batteries as needed.

The baseline period of activity collection will be the time after the first study visit at Montefiore hospital until the first in-home training session occurs.

Visit 1 will take up to 3 hours to complete.

6-Week HIIT Protocol:

If the participant already owns a handcycle, we will make every attempt to fit their handcycle to the roller system that will be used for the study. If we are not able to retrofit their handcycle or if they do not own a handcycle, the study team will provide a handcycle for the duration of the program. If a participant is unable to transfer into the handcycle, then the study team will provide assistance and tips for how to get in and out. If a participant is still uncomfortable with transferring into the handcycle, then they may be provided with an add-on hand bike, or they have the option to not participate in the study. At the end of the study, the handcycle/hand bike and the roller system will be returned to the study team. Participants will be given a heart rate monitor, which they will be asked to wear and use for every exercise session for the duration of the study. They do not have to return the heart rate monitor at the end of the study. Participants will be provided with a bike computer that will be fit to the handcycle/hand bike and will be used solely for the purpose of recording power output and heart rate during the exercise sessions. Participants must return the bike computer at the end of the study.

The first exercise visit will be tentatively scheduled within one week of the first study visit. Exercise sessions will be scheduled, ideally, 3 times per week (every other weekday), with the total training protocol lasting 6 weeks. Two of the sessions will be supervised by a trainer and one session will be completed on their own. The trainer may go to the third session if the participant requests assistance getting in and out of the handcycle or attaching the add-on hand bike, however, they will not provide any coaching or verbal cues during exercise. During the last week (week 6), subjects can opt to have their supervised sessions via FaceTime or Skype (if they have a smartphone or computer). The exercise goal for all participants is to achieve 10 sets of 60 second bouts of arm cycling at 90% of their PPO (as determined in baseline testing), separated by 60 seconds of active recovery.

Further details regarding the supervised and unsupervised workouts are explained below.

(A) Supervised exercise sessions: the trainer will meet the participant at their home for each supervised exercise session. Prior to exercise, the trainer will measure/record the participant's heart rate and blood pressure. In addition, the trainer will make sure that there haven't been any recent changes in health or medical status (please see "Exercise Training Intake Form" in the "Supporting Documentation" section).

The trainer will guide the participant through a warm-up and stretching routine prior to exercising (approximately 10 minutes). The participant will be familiarized with the same Borg and Wheel RPE scales used during Visit 1, and the Feeling Scale (please see "Feeling Scale" in the "Supporting Documentation" section). The Feeling Scale (-5 very bad to +5 very good) is commonly used to measure affective response during exercise.

The trainer will prescribe individualized work and rest phases based on their PPO from their maximal aerobic test. In order to reach the HIIT goal mentioned above, the trainer will hold participants at 90% PPO as a constant target intensity to start, shortening the work phase (e.g. 10-15 seconds), and if necessary, lengthening the recovery phase (e.g. 75-90 seconds). These ramping parameters will be progressed and documented by the trainer for each session. The trainer will determine when to change their work and rest parameters based off of heart rate and self-reported RPE.

At the end of each session, the trainer will measure/record the participant's heart rate and blood pressure again. Power output and heart rate data is automatically stored in the bike computer during each exercise session. After each session, the data will be transferred to a study iPad/laptop via USB and then deleted from the device. These measures are collected to evaluate adherence to the prescribed HIIT intensities.

(B) Unsupervised exercise sessions: participants will be asked to repeat the same HIIT protocol they performed during the previous supervised session. The trainer will provide written directions for their convenience. Participants will be instructed to wear the heart rate monitor so that during the next supervised exercise session, the trainer will be able to retrieve/collect the data to store on one of our study devices for future analysis. The heart rate data as well as power output data will automatically be stored on the device in the same manner as during the supervised sessions. At the next supervised session, the trainer will retrieve the data from the device.

Visit 2

After completing the 6-week HIIT program, participants will be scheduled for a second/final lab visit. Visit 2 will be ideally scheduled within one week of finishing the 6-week HIIT program, but to provide scheduling flexibility, participants have up to two weeks to complete their second visit. We will try to schedule the follow-up exercise testing around the same time of day as Visit 1. Participants will complete the same exercise testing protocol that was completed in Visit 1. Participants will also complete the NRS, WUSPI, POMS and SF-36 WW questionnaires from Visit 1. Participants will be asked to complete a survey regarding their satisfaction of the HIIT program using the Physical Activity Enjoyment Scale (PACES). Participants will be provided with an open-ended questionnaire to discuss their feelings about HIIT, likelihood to continue, and what would be needed in terms of support to help them (or others like them) to keep doing HIIT. Activity monitors will be removed from the subject and wheelchair.

*Please note: some participants take longer than others to finish questionnaires; to decrease burden, participants will be allowed to complete the questionnaires over the duration of the first lab visit and the first home visit (for baseline measures) and last home visit and second lab visit (for post-trial measures).