CONSENT FORM TO BE PART OF A RESEARCH STUDY

TITLE OF RESEARCH: Telehealth high intensity interval exercise and cardiometabolic health in spinal cord injury

IRB PROTOCOL: IRB-300005921

PRINCIPLE INVESTIGATOR: Gordon Fisher, PhD

SPONSOR: National Institute of Nursing Research (NINR) / National Institute of Health (NIH)

General Information	You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of this study is to assess the effects of a home-based telehealth high intensity interval training (HIIT) arm crank exercise training program for improving cardiometabolic health (*blood pressure, blood glucose and blood lipis, aerobic fitness, and muscle strength*) in individuals with spinal cord injury (SCI)
Duration & Visits	You will have 3 visits for baseline assessments. Then you will have 3 visits for post-exercise assessments for a total of 6 visits. The post-exercise assessments are 16 weeks after the baseline assessments. If you are in the HIIT group you will have 32 sessions of training during those 16 weeks. You will be involved in the study for a total of 16 weeks (6 months).
Overview of Procedures	You will be scheduled for 3 days of exercise and health measures. Day 1 will be scheduled at the Lakeshore Foundation and consist of assessment of body fat, energy expenditure, blood pressure, and completion of quality of life survey. Day 2 will consist of a glucose tolerance test at UAB. Day 3 will be scheduled at the Lakeshore Foundation and consist of exercise testing that will measure strength, aerobic fitness and power. (All of these tests are explained further in the consent form.) Following these assessments you will be randomized (assigned to a group by chance) to either a no-exercise control group or a home-based telehealth HIIT arm crank exercise group for 16 weeks. Following 16 weeks of no-exercise or home-based telehealth HIIT you will repeat the 3 days of exercise and health measures.
Risks	The most likely risks include the possibility of injury during exercise testing or training, pain or bruising from the blood draw, and loss of confidentiality.
Benefits	Direct benefit to you is receiving health information (body composition, blood lipids, blood glucose and insulin, aerobic capacity, and muscular strength). Participation may provide valuable information to the medical and rehabilitation community about the benefits of home-based telehealth exercise for improving cardiometabolic health.
Alternatives	The alternative is to not participate in this study.

Purpose of Research

The purpose of this study is to determine the effects of a home-based telehealth high intensity interval arm crank exercise training program on changes in cardiometabolic health and physical function in individuals with

spinal cord injury. A secondary purpose is to conduct interviews upon completion to determine overall perceptions of the exercise program, program likes and dislikes, perceived satisfaction and value, usability of the equipment and technology, and factors that may influence adherence to the exercise program.

There will 40 participants enrolled in this study.

Explanation of Procedures

Screening Procedures. These procedures are administered to see if you are eligible to participate in this study. The consent form will be read to you by telephone.

***Women who are pregnant are excluded from participation in this study due to the low-level X ray from the DXA procedure.**

Questionnaire: The questionnaire will take about 10 minutes and you will be asked for information on your own medical history.

If you are eligible to continue in the study, you will be randomly picked (like the flip of a coin) by a computer to participate in the home-based telehealth HIIT or the no-exercise control groups and you will undergo several other procedures (listed below) over the course of the study.

Baseline and Post-Exercise Assessments will consist of 3 visits each. These clinical and physiological tests will be conducted at week 0 (baseline) and week 17 (post-exercise training).

Day 1 - Body composition will be assessed using Dual-energy X-ray Absorptiometry (DXA), Resting Energy Expenditure (REE) will be assessed using indirect calorimetry, and arterial elasticity and blood pressure using pulse wave velocity. These procedures will be performed at the Lakeshore Foundation. Details of each technique are outlined below.

- ***Dual-energy X-ray Absorptiometry (DXA) scan***. For this test, the participant will lie still on a padded table while a measuring device passes overhead and uses low-level X-rays to measure total body fat mass, lean mass and bone mineral density. The test will take 10-15 minutes.

- ***Resting Energy Expenditure (REE).*** This test measures how many calories an individual burn, and whether these calories are fat calories or sugar calories. The participant will be instructed to lie as still as possible while a clear, plastic hood is placed over his/her head and shoulders. Samples of the air the participant breathes in and out will be collected for 20 minutes following a 10 minute equilibration period.

- ***Blood Pressure and Arterial Elasticity***. This test will measure your resting blood pressure using a standard blood pressure cuff and a stethoscope. Additionally, we will use a non-invasive pulse wave contour device to assess arterial elasticity. A tonometer will be placed over the radial artery for about 30 seconds and the elasticity will be determined.

Day 2 - Glucose tolerance and insulin sensitivity will be assessed using an oral glucose tolerance test (OGTT). This will be conducted at UAB in the Clinical Research Unit.

- ***Oral Glucose Tolerance Test*.** Two oral glucose tolerance tests (OGTT) will be performed to measure participant's glucose tolerance and insulin sensitivity. The participant will need to come to the Clinic after an overnight fast, drink a sugary beverage, and provide several blood samples (one before he/she drinks the beverage and one every 30 minutes for the duration of the test). The total amount of blood taken will be ~one tablespoon.

Day 3 – Muscle strength will be assessed using one-repetition maximum. Cardiovascular fitness will be assessed using a VO2 peak test and Anaerobic power will be assessed using the Wingate Anaerobic Power test on an arm crank ergometer. This will be performed in the Exercise Physiology Lab at the Lakeshore Foundation.

- ***Muscle strength*.** Maximal load that can be lifted in one repetition (1RM) will be assessed in both limbs for chest press, elbow flexion, and should flexion maneuvers. This test will take approximately 30 minutes.

- ***Peak Oxygen Uptake (VO_{2peak})*.** All subject will undergo a progressive peak oxygen assessment to determine aerobic capacity at the Lakeshore Foundation Exercise Physiology Facility. Subjects will be instructed to perform arm crank ergometer (Lode) at 30W for 2 min. Every 2 min thereafter, power output will be increased by 30W until voluntary fatigue. Peak aerobic power will be defined as VO_2 at the point of failure to maintain 60-65 rotations per minute. Minute ventilation, oxygen uptake and carbon dioxide production will be continuously analyzed and recorded by an open-circuit spirometry system (ParvoMedics). Heart rate will be continuously assessed using a polar heart rate monitor. Rate of perceived exertion during exercise will be assessed using the BORG scale. This test will take approximately 20 minutes.

- ***Wingate Cycle Test*.** All subjects will perform the Wingate Anaerobic Power test. Subjects will sit in a chair (fixed to the ground) and remain seated throughout the entire test. The seat height and back will be adjusted so that the crank position on the opposite side to the body and the hand grasping the handles, allowing the elbow joint to almost fully extend (165-175°) and the shoulders in line with the center of the ergometer's shaft. A fly wheel braking force corresponding the 5% of the participants body weight will be used. Prior to each test, participants will complete a 5 minute warm up at 25W, which will include 3 short sprint efforts followed by 5 min recovery. Following the warm up participants will be instructed to hand cycle as fast as possible, verbal encouragement will be given to all participants to maintain their highest possible cadence throughout the test. Peak power, mean anaerobic power, fatigue rate, and relative peak power will be assessed following each test. 30% of peak power obtained during the Wingate Test will be used to prescribe the interval workload for the HIIT group. This test will take approximately 15 minutes.

Home-Based Telehealth Exercise Intervention will include implementation of HIIT training performed on an arm crank cycle ergometer. The *teleexercise* will be delivered through a custom, wireless Internet-based system that will be installed in the participant's home. The equipment within this system includes a tablet

computer with Bluetooth® and wireless Internet capability mounted to an adjustable floor stand (Standzfree Universal Stand, Standzout); wearable physiologic monitor (Bioharness 3, Zephyr) that provides real-time monitoring of heart and respiration rate data to the tablet via Bluetooth® connection; and custom-designed web application that allows physiologic data and video feed to be recorded from the tablet to a secure web-based dedicated server. This platform allows the exercise trainer (telecoach) to monitor each participant's physiologic data in real-time (up to 5 second delay) while simultaneously video-conferencing and providing written instructions to the participant. Telecoaches will utilize this system to provide immediate feedback regarding exercise intensity and movement quality during each exercise session. All exercise sessions will be performed on an upper body ergometer (UBE-BDP Table Top Upperbody Exerciser, Hudson Fitness).

HIIT training will be delivered two times per week for 16 weeks (32 sessions). Each session will be separated by at least 24-hrs. Participants will be allowed to choose the days and times that they feel exercise will fit into their schedule. The HIIT protocol will be determined based on peak anaerobic power measures during an arm crank Wingate Cycle test. HIIT will consist of 20 minutes of exercise consisting of four minutes of arm crank exercise at 5% of peak anaerobic power followed by 30 seconds at 30% of the peak anaerobic power; this cycle will be repeated four times, ending with two minutes of recovery at 5% of peak anaerobic power. The participants will be coached and monitored remotely via the telehealth system. Heart rate and respiratory rate will be monitored throughout each session.

Post Exercise Phase: (*all baseline phase assessments will be repeated in the following order)

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Additional Information

Your de-identified private information and de-identified biospecimens (private information and biospecimens with all identifiers removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Incidental Findings

We are performing Dual-energy X-ray Absorptiometry (DXA) imaging solely for the research purposes described above. It is not a clinical scan intended for diagnostic or therapeutic purposes. Under no circumstance will the investigator, research staff, or imaging staff interpret the scan as normal or abnormal. They are unable to make any medical comments about your scan. The scan will not be looked at or read for any healthcare treatment or diagnostic purpose. If you want your scan to be reviewed by a physician so that the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge.

Risks and Discomforts

Strength Exercise and Testing. There is a remote possibility of musculoskeletal injury that is, relating to muscles and skeleton resulting from strength exercise. Also, you may experience some temporary discomfort from exertion during exercise. Exertion from intense exercise may cause you to feel "light-headed", and this can lead to fainting. To reduce the risk you should eat a light meal and drink water prior to attending each exercise session. Heart complications or blood vessel problem such as a tear in the lining of the large blood vessel (aorta) that exits the heart are extremely rare, but possible during intense exercise.

Endurance Exercise and Testing. During the endurance capacity test there may be discomfort while wearing the mask that may include dry mouth and a feeling of claustrophobia. There is also a rare risk of insufficient blood flow to the heart or cardiac arrest during the test but you will be carefully monitored during the testing and exercise sessions. In addition, continuous oxygen consumption measurements prevent verbal communication, but you will be using hand signals
in case you have discomfort during the test. You may stop the tests whenever you feel it is necessary.

Blood Sampling. Risks associated with the intravenous glucose tolerance test and blood draw for measuring blood lipids are similar to those with any blood draw. There will be some discomfort when the needle is placed in your arm for blood drawing. A total of 64 cc of blood (about 6 tablespoons) will be collected during these tests. An experienced, registered nurse will be on hand at all times during this test. Infection or bruising could occur due to the puncture of the vein for blood drawing. The vein will be punctured only one time during each test.

Dual-energy X-ray Absorptiometry (DXA) scan. In this study you will be exposed to a very low level of radiation during a DXA scan. The DXA scan takes approximately 20 minutes and will be performed 2 times: once before and once after 16 weeks of either intervention. The total radiation from the two DXA scans is equivalent to a day or two of background radiation. Background radiation is normally received from sources such as cosmic rays and natural radioactivity in building materials and the ground. A small risk of cancer and other radiation effects, which may not be known at this time, may develop from each imaging exam received.

Time Commitment. The most significant cost will be your time. Participating in this study will require six on-site UAB and Lakeshore visits. To minimize this inconvenience, Dr. Fisher will try to schedule testing around your usual schedule as much as possible.

Randomization. You will be assigned to either a home-based telehealth high intensity interval exercise group or a no-exercise control by chance, and the interventions you receive may prove to be less effective than the other study intervention for improving your metabolic health.

Benefits

Direct benefits to you from your participation in this research will include information on your blood lipids (e.g. your cholesterol), your glucose tolerance (and possible risk for diabetes), and your body's fat mass, muscle mass and bone mineral density. Also, your participation may provide valuable information to the medical and rehabilitation community about how exercise affects metabolic health outcomes and reduce the risk of cardiometabolic diseases in individuals with SCI.

Alternatives

The alternative is to not participate in the study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others?
All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

Your consent form will be placed in your medical record at UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient), a medical record will be created for you to maintain results of research tests or procedures.

All information within your medical record can be viewed by individuals authorized to access the record.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Who may use and give out this information?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information?
All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).

Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, *University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Healt*h, as necessary for their operations; the UAB IRB and its staff
- the billing offices of *UAB and UAB Health Systems affiliates and/or Children's of Alabama* and its billing agents

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Voluntary Participation and Withdrawal

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed.

If you are a UAB student or employee, taking part in this research is not a part of your UAB class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

There will be no cost to you from participation in the research. All study-related examinations and medical treatments will be provided at no cost during the study.

Payment for Participation

No payment will be provided for screening. If you are eligible and enroll in the study, you will be compensated $100 after randomization and then $200 after completion of the study. Participants will have the option to accept the cash or use the money towards a 4 month membership at the Lakeshore Foundation ($50 per month with one time $100 orientation fee).

Payment for Research-Related Injuries

UAB and NINR/NIH have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

New Findings

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Questions

If you have any questions, concerns, or complaints about the research or a research-related injury, please contact the study doctor. You may contact Dr. Gordon Fisher at (205) 996-4114 or Dr. Ceren Yarar-Fisher at (205) 996-6896.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information provided above and agree to participate in this study. You will receive a copy of this signed consent form.

Signature of Participant Date

Signature of investigator or other person obtaining consent Date