Study Title: Using an Adaptive Rower for People Using Motorized Wheelchairs to Improve Cardiovascular Fitness

Document Date: 06/05/2024

UNIVERSITY OF SOUTH CAROLINA

CONSENT TO BE A RESEARCH SUBJECT

Using an Adaptive Rower for People Using Motorized Wheelchairs to Improve Cardiovascular Fitness

KEY INFORMATION ABOUT THIS RESEARCH STUDY:
You are being asked to take part in a research study because you are a motorized wheelchair user over the age of 18. The study is being done by Collin Cochcroft, an undergraduate student in the Department of Exercise Science, at the University of South Carolina. Collin is supported by his mentor, Dr. Elizabeth Regan. The University of South Carolina, Department of Exercise Science and the Magellan Scholar Program are sponsoring this research study. The purpose of this study is to determine the impact of the adaptive rower on cardiovascular fitness in motorized wheelchair users. This study is being done at the Rehabilitation Lab at the Public Health Research Center at the University of South Carolina in Columbia and will have up to ten subjects.

Below is a short summary of this study to help you decide if you want to be in this study. More details about this study are listed later in this form.

STUDY PROCEDURES:
Participation entails an initial evaluation visit, twelve exercise visits (scheduled approximately two times per week) and a final evaluation visit over a 7-8 week period.

During the initial evaluation, you will complete a few surveys about your mobility and perform an exercise endurance test using an arm bike. You can stay in your wheelchair for these assessments. On the initial visit, you will also receive training in using the adaptive rower and fitted with trunk or grip supports as needed. The adaptive rower uses your own chair, where you use a releasable lap bar to stabilize your body for the exercise. There are several options for handles for rowing, and trunk and grip support, if needed.

During the exercise sessions, you will exercise for 10-20 minutes depending on your exercise tolerance, at a moderate intensity, with rest breaks as needed. Researchers will provide coaching, feedback, and any adjustments to the rowing setup. You will wear a heart rate monitor around your torso to gather your heart rate.

After the twelve exercise visits, you will return for final assessments where you will repeat the surveys and exercise endurance test, and complete two more surveys about the rower's ease of use and your enjoyment.

DURATION:
Participation entails an initial evaluation visit, twelve exercise visits (scheduled approximately two times per week) and a final evaluation visit over a 7-8 week period.

RISKS AND BENEFITS:
Using the rower can cause muscle soreness and tiredness common to new exercise activities. Less likely risks are joint or muscle injury, skin injury from friction on your chair or overheating. If you have a spinal cord injury above thoracic level 6, there is a risk of autonomic dysreflexia. You will be monitored for all of these concerns and the lab is temperature regulated. There is also the risk that information collected about you would not remain private. The study will take several steps to prevent this.

You may benefit from taking part in this study by improving your cardiovascular fitness over the duration of the 6-week study. Additionally, the findings from this study may help create alternative methods for wheelchair users to reach adequate cardiovascular fitness.

Alternatives include chair-based fitness classes in the community or online.

COSTS:
There will be no costs to you for being in this study other than any costs related to getting to and from the research site.

PAYMENT TO PARTICIPANTS:
You will be paid a $25 amazon gift card for completing the initial evaluation measures, at least one exercise session and the final evaluation measures.

CONFIDENTIALITY OF RECORDS:
Information obtained about you during this research may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. All records in South Carolina are subject to subpoena by a court of law. The investigators associated with this study, the sponsor, and the Institutional Review Board will have access to identifying information. Study information will be securely stored in locked files and on password-protected computers.

RESEARCH RELATED INJURY:
In the event you are injured while taking part in this research study, a member of study team will provide first aid using available resources. If needed the team will arrange for you to be taken to the nearest emergency medical facility. The University of South Carolina has not set aside funds to pay you for any injury, problem or related medical care that may arise from being in this study. Any study-related injury should be reported to the study team right away.

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

VOLUNTARY PARTICIPATION:
Taking part in this research study is voluntary. You are free not to take part, or to stop taking part at any time. If you withdraw from this study, the information you already have given to the study team will be kept private. If you wish to withdraw from the study, please call or email the main researcher who is listed on this form.

Concerns about your rights as a research subject are to be directed to, Lisa Johnson, Director, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 414D, Columbia, SC 29208, phone: (803) 777-6670 or email: LisaJ@mailbox.sc.edu.

I have been given a chance to ask questions about this research study and my questions have been answered. **If I have any more questions about my taking part in this study, or a study related injury, I am to contact Elizabeth Regan at (704) 609-2409 or email eregan@mailbox.sc.edu.**

I agree to take part in this study. I have been given a copy of this form for my own records.

If you wish to be in the study, you should sign below.

Signature of Subject / Participant	Date
Signature of Qualified Person Obtaining Consent	Date