Feasibility and initial efficacy of a wheelchair exercise-training intervention for persons with multiple sclerosis

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CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: Examining a Wheelchair Exercise-training Intervention for Persons With Multiple Sclerosis

Full Study Title: Feasibility and initial efficacy of a wheelchair exercise-training intervention for persons with multiple sclerosis

Study Sponsor: The National Institutes of Health

Principal Investigator: Stephanie L. Silveira, PhD, UTHealth

Study Contact: Stephanie L. Silveira, [redacted]

The purpose of this study is to use a randomized controlled trial (RCT) design to examine the feasibility and initial efficacy of a novel, stakeholder-informed exercise training program for wheelchair users with multiple sclerosis (MS). If you choose to participate in this study, you will be randomly assigned to complete the novel exercise training program or our evidence-based wellness program. The total amount of time you will be in this study is approximately 6 months.

There are potential risks involved with this study that are described in this document. Some known risks include emotional discomfort based on the question topics, which you can compare to the possible benefit of exercise on your overall health. The blood draw protocol is recognized by experts and considered to be safe. There may be potential benefits to you such as provide invaluable data on exercise training and wellness in persons with multiple sclerosis and you may experience positive changes in your fitness and overall health.

The alternative is to not take part in this study.

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth Houston).

If you are interested in participating, please continue to read below.

What is the purpose of this research study?

The proposed study will use a RCT design to examine the feasibility and initial efficacy of a novel, stakeholder-informed exercise training program for wheelchair users with multiple sclerosis (MS). The proposed exercise training program was developed in partnership with community members using semi-structured interviews, a community advisory board, and focus group feedback wherein community members provided insights to develop and refine an exercise training program that suit the needs and preferences of wheelchair users with MS. Participants will be randomly assigned to complete the novel exercise training program or our evidence-based wellness program. Ultimately, the proposed study extends this line of research and may initiate a significant paradigm shift in rehabilitation research and

practice by providing a critically needed home-based exercise training program for enhancing health, quality of life, participation, and independence of wheelchair user with MS.

The National Institutes of Health is paying UTHealth Houston for their work on this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site 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 is being asked to take part in this study?
You are being asked to take part in this research study because you have multiple sclerosis. This study is being conducted at UTHealth. About 24 people will take part in the study in Texas including approximately 24 people through UTHealth Houston.

What will happen if I take part in this study?
If you agree to take part in this study you will be randomized (similar to flipping a coin) to receive and complete the novel exercise training program or our evidence-based wellness program. It is not known whether the exercise program will be of benefit. There is a 50% chance you will be in the exercise training group and a 50% chance that you will be in the wellness group.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

Following receipt of this signed consent form, the research team will mail you a baseline assessment packet that includes an activity monitor with instructions and instructions for complete questionnaires online using a secure survey software. You will be sent information to complete a blood sample collection at a Quest Diagnostics location in your local community. All procedures will be carried out by trained members of the research team under the supervision of Dr. Silveira.

- Informed Consent: Prior to completing any assessments we will review the Informed Consent document with each participant. The member of the research team will explain each section of this document and answer any questions. You will be asked to sign this document usingREDCap before completing assessments and being enrolled in the study. You will be provided with a copy of the Informed Consent document for your records.
- Blood Draw (Assessment 1&2): You will be asked to complete a blood draw at a Quest Diagnostics location in your local community. They will draw 4mL of blood using a standardized protocol. This is about 1 teaspoon of blood. The biomarkers they will collect include HbA1c, cholesterol, glucose, triglycerides and insulin.
- Questionnaires (Assessment 1&2): You will be asked to complete a battery of questionnaires online using REDCap at each assessment. The battery of questionnaires includes a demographic and clinical characteristics questionnaire; the Patient Determined Disease Steps scale for assessing clinical disability status; the Godin Leisure Time Exercise Questionnaire; Fatigue Severity Scale; McGill Pain Questionnaire; Hospital Anxiety and Depression Scale; Multiple

Sclerosis Impact Scale 29 as a quality of life measure; and the Leisure Time Physical Activity Questionnaire for People with Disabilities. You may skip any questions that make you feel uncomfortable.

- Physical Activity Assessment (Assessment #1&2): You will be asked to complete a standard 7-day accelerometery protocol using Actigraph wGT3X-bt) accelerometers (https://actigraphcorp.com/actigraph-wgt3x-bt/). You will be asked to wear the accelerometer on your non-dominant wrist during moving hours for 7 days.
- Coaching Sessions: You will be asked to join a Zoom call with your MS Behavioral Specialist coach throughout the study. The calls will consist of obtaining feedback on your progress and discussing topics relevant to your progress in the assigned program. These calls will be recorded and kept on a HIPAA compliant OneDrive folder for three years for future training and random auditing purposes then destroyed.
- Formative Evaluation (Assessment #2): You will be asked to complete a brief survey, online regarding your perceptions and experiences in the exercise training program. You may skip any questions that make you feel uncomfortable. We will also invite you to complete an interview online, using Zoom that will last 20-30 minutes to provide feedback on the program you completed.
- Exercise Program: The exercise training program will be completed virtually for 16 weeks. The exercise program will be delivered by a trained member of the research team. The program is focused on strength training and aerobic exercise using an arm ergometer. The program includes an individualized exercise training prescription and instruction for increasing your physical activity incrementally over the 16-week period. Your coach will be available to answer your questions and support you throughout the program during regularly scheduled meetings delivered via Zoom. We will provide all equipment for completing the exercise program and you will be allowed to keep all materials when the study ends.
- Wellness Program: The wellness program mirrors the exercise program, but focuses on implementing health behaviors other than physical activity (e.g., diet and emotional wellbeing). All coaching chats and newsletters will occur with the same frequency as the exercise training intervention condition. We will provide you with a participant manual, logbook, calendar, and newsletters. You will work with your behavioral coach on goal setting specific to wellness behaviors.

How long will you be in the study?
If you agree to take part, your participation will last for 6 months, and will involve 2 assessments and a 16-week program, all delivered remotely.

What choices do you have other than this study?
You can choose to not enroll in this study.

What are the risks of taking part in this study?
There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

There is also a risk that you could have side effects from the exercise training program. These side effects may be worse and may be different than you would get with the usual treatment.

Some of the most common side effects include:

- There is a small risk that exercise may make your muscles soreness or that you might fall if you do not take precautions to prevent falling. Your coach will provide you with written and verbal instructions about how to prevent a fall when exercising. The coach will modify the exercises to meet your needs and ambulation level.
- Venous Blood Collection: There might be discomfort when the small needle is initially inserted into the participant's arm. While blood draws are normally a safe procedure, it is possible that short-term side effects can occur, such as dizziness, bruising, or fainting. Although the chances are remote, it is also possible that bruising around the vein, infection, or nerve damage can develop. All possible precautions to avoid infection will be taken including use of sterile disposable needles, gauze, and the practice of sterile techniques during blood sampling. All blood samples will be obtained by laboratory personnel who are trained in proper blood collection procedures.
- Information from your medical record will be obtained. Specifically, your name, date of birth, and contact information (i.e., e-mail and phone number).

There may be some risks that the research team members do not yet know about.

What are the benefits to taking part in this study?
There is some evidence in people with multiple sclerosis that exercise training can elicit positive changes in your fitness and overall health. However, you may not receive benefit but there is some evidence for benefits of exercise in persons with multiple sclerosis. This study may help the study team learn things that may help other people in the future.

Can you stop taking part in this study?
You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Dr. Stephanie Silveira at [redacted]

The research team or the sponsor can stop the study at any time. The research team or the sponsor may stop your participation in the study if your condition worsens, the study is stopped, you do not meet all the requirements of the study, or the study is not in your best interest.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

What happens if you are injured during the study?

If you suffer an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You or your insurance company will be billed for any treatment. You should report any such injury to Dr. Silveira [redacted]. You will not give up any of your legal rights by signing this consent form.

What are the costs and compensation related to taking part in this study?
There is no cost to take part in this study.

You will receive $75 for each assessment, with payment at each assessment even if you do not complete the entire study. You will have the opportunity for an additional $25 for completing the optional interview for a total potential compensation of $175. You will be issued a gift card following completion of each assessment. All information is stored in a secure fashion and will be deleted from the system once the study has been completed.

If you receive a bill that you believe is related to your taking part in this research study, please contact Stephanie Silveira at [redacted] with any questions.

How will privacy and confidentiality be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth Houston to use and disclose (release) your health information. The health information that we may use or disclose for this research includes: name and date of birth in conjunction with your blood test results. This information is required to set up your blood draw order and appointment with Quest Diagnostics. Any digital files will be encrypted and password protected. You can decide whether you want your name used in recorded coaching sessions and interviews. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Personal identifiers such as your name and medical record number will be removed from the information and samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent. If study results are published, you will not be identified in the publication.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying study data:

- Representatives of UTHealth Houston

- Representatives of the National Institutes of Health, the sponsor of the study
- Companies engaged with the UTHealth Houston for the commercialization of the results of the research study

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth Houston may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Dr. Stephanie Silveira in writing at [redacted]

This Authorization will expire 6 years after the end of the study.

Certificate of Confidentiality:
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers, or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Whom can you contact if you have questions about the study?
If you have questions at any time about this research study, please feel free to contact the Principal Investigator at [redacted], as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research

subject, and to discuss any concerns, comments, or complaints about taking part in a research study at [redacted]

Optional Interview:

☐ **Yes, I am interested in being contacted to take part in the optional interview.**

☐ **No, I am not interested in being contacted to take part in the optional**

interview. Are you interested in being contacted for future research studies?

Please check the appropriate box to indicate your preference. If you are interested in participating in future studies, the research team will retain information that will identify you, such as your name, phone number, mailing address, and/or email address.

☐ **Yes, I am interested in being contacted for future research studies.**

☐ **No, I am not interested in being contact for future research studies.**

SIGNATURES

Sign below only if you understand the information given to you about the research, and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time
Printed Name of Legally Authorized Representative	Signature of Legally Authorized Representative	Date	Time
Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time