DT5140

Consent Research

RESEARCH CONSENT FORM

Title: Low-Volume, High-Intensity Interval Training during Inpatient Stroke Rehabilitation: A Feasibility Trial

Sponsor: Dr. Alexandra Arickx, M.D.

Principle Investigator: Alexandra
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Goals of the research

The purpose of this study is to determine if a type of exercise, called high-intensity interval training, performed on a seated stepper, is safe and doable for people who have had a stroke while in inpatient rehabilitation. High-intensity interval training involves switching between hard and easier levels of exercise.

Quick facts about the research

- Testing will occur on the KU inpatient rehabilitation unit.
- Your study participation includes two sessions. One is a submaximal exercise test and the second session will be a single bout of high intensity interval training.
- Research is voluntary, and this study will occur at no cost to you.

Other things to consider

- You will receive $50 after you complete the assessments at the end of your exercise intervention.
- Even if you don't get personal benefit from being in the study, you will be helping researchers learn about better exercise interventions for stroke recovery.

Please review the rest of this document for details about these topics and important things you should know if you decide to join. Before you sign up for the study, please ask the study team to answer all your questions.

DETAILED INFORMATION

This research study will take place at The University of Kansas Acute Inpatient Rehabilitation Facility with Alexandra Arickx, M.D. as the researcher. We will ask up to 25 people to participate in this study.

Why is this study being done?
People with stroke experience low aerobic fitness levels compared to those without a stroke. Exercise can improve overall heart, lung, and muscle health, and also improving your walking performance. Exercise is not routinely prescribed as healthcare teams do not yet know what kind of exercise may benefit individuals best after stroke. The purpose of this research study is to determine if a type of exercise, called high-intensity interval training, performed on a seated stepper (Figure 1), is safe and doable for people who have had a stroke while in inpatient rehabilitation. By the end of the study, we hope to provide increased information to healthcare teams and those living with stroke on high-intensity interval training during inpatient rehabilitation.

Figure 1. Picture of the seated stepper.

How long will I be in the study?
This study involves two visits for a total of about 2 hours of your time.

What will I be asked to do?
If you decide to be in the study, the researchers will ask you to do the following while you are admitted to the Kansas University Inpatient Rehabilitation Unit:

- Answer questions about your heart health and physical activity prior to your stroke
- Participate in one session of submaximal exercise testing and one session of high intensity interval training.
- Submaximal exercise testing lasts about 12 minutes. The test starts easy and then gets more difficult with each stage.
- Participate in a single bout of high intensity interval training
- Rate your exercise at the end of the second session.
- Avoid eating a large meal or drinking caffeine two hours prior to the research study visit.

You may be asked to repeat a study assessment if there is an unexpected event that occurs during data collection. An example might be an equipment malfunction.

Visit 1: Visit 1 will take about 1 hour to complete. We will have you:

- Answer questions about your heart health.
- <u>Perform a submaximal exercise test</u>
    - To test your fitness, you will perform a submaximal effort exercise test, meaning you will not exercise as hard as you are able. You will use a seated stepper and your arms and legs move back and forth in a stepping

pattern.
    - You will have a heart rate monitor placed on your arm so we can monitor your heart rate.
    - Research staff will monitor your blood pressure at rest, during exercise, and after the exercise session.
    - The submaximal exercise test will start easy and then gets harder with each stage.
    - You will perform the submaximal exercise test until one of these occur:
        - 1) you complete all stages of the submaximal exercise test,
        - 2) you reach 85% of your age- predicted maximal heart rate
        - 3) you request to stop.
    - During the test, we will ask you how hard you feel you are working.
    - Once you have finished the exercise test, you will cool down for approximately 2 minutes. This test takes less than 20 minutes.
- After the submaximal exercise test, you will rest up to 15 minutes. We will then ask you to practice the interval training on the stepper for no more than 10 minutes.

Visit 2: Visit 2 will take about 1 hour to complete. During this visit, you will:

- Perform a short ~2-minute warm-up, 10-minutes of high-intensity interval exercise, and a ~2-minute cool-down on the stepper.
- We will monitor your heart rate continuously during exercise and for 30 minutes after. Heart rate will be collected using the Polar application, which will use an arm monitor to measure heart beats per minute
- We will also record your blood pressure before and immediately after exercise, and up to 30-minutes after exercise.
- We will ask you to complete a short ~10-minute questionnaire on your exercise experience and rate how hard the exercise was.

What are your responsibilities if you participate in this study?

You will be asked to:

- Complete two study visits
- Do your best to follow instructions from the study team
- Tell us if you have any changes in your health or medications
- Tell us if you have any questions or concerns about the study

What are the possible risks or discomforts?

You may experience:

- Temporary fatigue, soreness or stiffness from exercise testing or exercise training
    - This could increase your risk of falling. If you notice these symptoms, you should inform study staff.
- Feel lightheaded, faint or nauseous from the exercise
    - You may be at higher risk if you are dehydrated, have not eaten enough, or have low blood sugar. It is important for you to stay hydrated for exercise.
- Experience mild discomfort on your arm during blood pressure recordings. If this happens, the cuff can be deflated.

There is a low risk that you could:

- Have a serious heart problem such as developing an abnormal rhythm, heart attack or have another stroke during exercise.

Possibility of Unknown Risks

There may be other side effects or risks that are not yet known.

Are there benefits to being in this study?

You may or may not directly benefit from this study. We hope that the information gained from this study will provide information to healthcare teams and those living with stroke on performing high-intensity interval training in inpatient rehabilitation.

Will it cost anything to be in the study?

All study procedures outlined in Visit 1 and Visit 2 will be provided at no cost to you as these are not routine standard of care and are not billed to you or your insurance.

Any other medical visits and procedures you have performed that are unrelated to the study such as your medications, blood draws, physical therapy, and/or occupational therapy will be billed to your insurance through normal hospital billing practices. Your insurance may not cover some or all of the services if you are part of a research study. Pre-Certification is not a guarantee of payment. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study.

You can still be in the study even if your insurance denies coverage for your routine medical treatment or if you are uninsured. The hospital has a financial assistance program which it makes available to all patients who qualify. If you do not qualify for financial assistance, you will be responsible for all bills that are not payable by the study. The study staff will be able to provide more information to you.

The stipend given at the end of visit two will be provided to you by the study team through ClinCard (as described below).

Will I get paid for participation?

Payments will be made to you with a prepaid debit card. If you complete the entire study, payment will be $50.00. The study team will be responsible for paying you this money at the end of your participation in this study.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year. If you do not provide a valid social security number or tax identification number, 30% of your

payments will be set aside by KUMC and sent to the IRS for withholding on your behalf You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

What happens if I get hurt or sick during the study?

If you have a physical injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party. You will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form. If you have a serious side effect or other problem during this study, you should immediately contact Dr. Ann Wingard at 512-925-0447 and let your nurse know.

How will my information be protected?

The researchers will keep your identity confidential, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Your study information will be kept in a HIPAA-compliant secure database, which only approved study team members have access to. These steps will lessen the risk that your personal identity and information will be seen by others who shouldn't have it.

If you sign this form, the research team will collect, use and share your private health information as described below. If you decide not to sign this form, you cannot be in the research study.

Study data includes information from your study activities and from your medical record. Your health care providers may release your private health information to Dr. Arickx and the research team. The team may use any and all of your information needed for the study. Your medical records may contain your name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

Your participation in this study and your study information may be put into the University of Kansas Health System electronic medical record and combined with your health information from your clinical care. The health system may use and share this information for other purposes described in the Notice of Privacy Practices.

You may not be able to see your records relating to the study until after the study is over and the results are known. Any research information that is put in your medical record

will be kept indefinitely.

The research team may share your study data with people outside KUMC. These groups or agencies may make copies of study data for audit purposes. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may not protect it. These groups may include:

- Federal agencies that oversee human research (if a study audit is performed)
- KU Medical Center Institutional Review Boards and any other committees responsible for overseeing the research
- Staff of the KU Medical Center Human Research Protection Program
- The KU Medical Center Research Institute
- KU Medical Center employees providing service or care to you
- Federal and State agencies, such as the U.S. Food and Drug Administration
- (FDA), Department of Health and Human Services (DHHS), the National Institutes of Health (NIH), and other US and non-US government bodies that oversee or review research

Your permission to use and share your health information will not expire unless you cancel it. To cancel your permission, please write to Dr. Alexandra Arickx, M.D.at 3901 Rainbow Blvd., Mailstop 1046, Kansas City, KS 66160. If you cancel your permission, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of treatment.

They are permitted to use and share information that was gathered before they received your cancellation.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Will I be told about research results?

Overall results will not be shared with you. You will be told about any study results that directly affect your medical care.

How will my research information and specimens be used in the future?
In the future, researchers at KUMC and at other locations might re-use the information from this study for other research. If this happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

Can I stop being in the study?
You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of any benefits to you. The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Could my participation be stopped early?
This study might be stopped, without your consent, by the investigator. Your participation also might be stopped by the investigator if it is in no longer safe for you or if you do not follow the study requirements.

Who can I talk to about the study?
Before you sign this form, Dr. Alexandra Arickx or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns, or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 6616

CONSENT
Dr. Alexandra Arickx or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily agree to be in this research study. You have read the information and had your questions answered.
You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Time Date

OPTIONAL CONSENT FOR ADDITIONAL USES OF VIDEO RECORDINGS/PHOTOGRAPHS

Please check on and initial and date below:

You agree to voluntarily give your permission for the researchers in this study to use videos and photographs of you collected as part of this research study to be used in scientific publications, presentations, and/or for educational or training purposes. You understand that no identifying information beyond that contained in the video recording and/or photographs will be provided to educational/scientific audiences; however, your facial features may be seen.

☐ Yes, you agree to the use videos/photographs of you as described above. _____
Signature

☐ No, you do not consent to videos/photographs of you as described above. _____
Signature

Would you like to be added to a stroke registry where you can be contacted for future studies?

☐ Yes, you would like to be contacted for future studies. _____
Signature

☐ No, you would not like to be contacted about future studies. _____
Signature

If you decide at any time that you do not want videos or photographs of you used for scientific, educational, or training purposes you may contact the researcher in charge of this study