Study name: **Effects of RLIC on Motor Learning in Middle-Aged and Older Adults**

Name of legacy study protocol in Washington University HRPO system: **Remote Limb Ischemic Conditioning to Enhance Learning**

ClinicalTrials.gov ID: **NIHR01HD086930-Aim3**

NCT03582943

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Informed Consent Form

Latest revision of document: 10/30/17

Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: Remote Limb Ischemic Conditioning to Enhance Learning

Principal Investigator: Catherine Lang

Research Team Contact: Maggie Bland 314-633-8450

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant. By signing this form you are agreeing to participate in this study.

- If you have any questions about anything in this form, you should ask the research team for more information.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are an adult. The purpose of this research study is to determine if remote limb ischemic conditioning (RLIC), which refers to reducing blood flow to the arm for brief periods of time and then letting blood flow back into the arm by inflating and deflating a blood pressure cuff on the arm, can increase performance and learning. The treatment effects of remote limb ischemic conditioning will be compared to the effects of a sham treatment, in which no ischemia is generated. The immediate goal is to test the combination of RLIC with motor training in neurologically intact adults. The long term goal is to test if RLIC augments the learning that occurs during a rehabilitation training exercise in people who have motor deficits following stroke.

We hypothesize that people in both groups will demonstrate improved performance on the motor tasks with practice but that people in the RLIC group will demonstrate greater improvements in performance compared to people in the sham group.

If eventually effective, RLIC could have a profound effect on the rehabilitation and recovery of motor function in people with stroke.

WHAT WILL HAPPEN DURING THIS STUDY?

Your participation is for research purposes only. It will involve 9 visits to our laboratory where we will measure your ability to learn two motor tasks. The visits will be within a span of 6 weeks.

The first 2 visits are priming days (D1 and D2) and will take approximately 1.5 hours and 1 hour, respectively. The following 5 visits are training days (D3-D7) and will take approximately 1.5-2.0 hours. The final two visits are follow-up days (F/U1 and F/U2) which take place two and four weeks after D7

and will last approximately 30 minutes.

Day 1:

1. A trained clinical interviewer will provide informed consent and conduct a structured clinical interview.
2. If you are deemed eligible and choose to sign this consent form, you will first be asked to complete a form about your medication history.
3. You will be randomly assigned (like flipping a coin) to either group 1 or group 2.
    a. You will not know whether you are in group one or two.
    b. Group 1 will undergo RLIC treatment and group 2 will undergo sham treatment.
4. You will perform 3-5 trials of a balance task and 4-6 trials of a motor task to determine your baseline level of function.
5. You will undergo one set of RLIC or sham treatment.
    a. Group 1 RLIC treatment will be achieved via blood pressure cuff inflation to 20 mmHg above systolic blood pressure, on the non-dominant arm.
    b. Group 2 sham conditioning will be achieved via blood pressure inflation to 10 mmHg under diastolic blood pressure, on the non-dominant arm.
    c. One set of RLIC or sham conditioning consists of 5 cycles of alternating 5 minutes of inflation, 5 minutes of deflation.

Day 2:

1. You will undergo one set of RLIC or sham treatment.

Days3-7:

1. You will undergo one set of RLIC or sham treatment.
2. You will participate in motor training on a balance task and a motor task for 15-25 minutes each, rest breaks taken as needed.

Follow up 1 and 2:

1. You will perform 3-5 trials of a balance task and 4-6 trials of a motor task.
2. You will <u>not</u> receive RLIC or sham treatment during the follow-up sessions.
3. You will fill out a survey indicating whether you think that you received RLIC or sham treatment.

All visits will take place in a private room in Dr. Lang's research suite which can be found within The Rehabilitation Institute of St. Louis.

As a part of this study, some physical health information will be collected and used. This will include your past medical history, exercise history, and list of medications that you are currently taking. You are free to skip any questions that you would prefer not to answer. Some new health information may be created during the research. This could include measures of your motor performance.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 130 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to 6 weeks. This timeframe includes nine visits. Visits will range from 30 minutes to 2.0 hours in length. Visits 1-7 will be completed with 1-3 days between them. Visit 8 (F/U 1) will take place 2 weeks after the 7th visit (D7), and visit 9 (F/U 2) will take place 4 weeks after the 7th visit (D7).

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Remote Limb Ischemic Conditioning			
	Likely	**Less Likely**	**Rare**
Mild risk	Boredom	Arm discomfort or bruising	None
Serious risk	None	None	HTN (high blood pressure), altered blood glucose levels
Life-threatening risk	None	None	None

Motor Training Risks			
	Likely	**Less Likely**	**Rare**
Mild risk	Boredom	Fatigue or discomfort of legs	Falling
Serious risk	None	None	None
Life-threatening risk	None	None	None

You may stop the RLIC treatment at any time if your arm discomfort becomes too painful.

With regards to questionnaires, there is a mild risk that you will feel uncomfortable answering some of the personal information.

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure, and we think the risk of accidental disclosure is very small. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study.
However, we hope that, in the future, other people might benefit from this study because this research will help us to learn whether RLIC can improve the rate or extent of motor and cognitive learning.

WHAT OTHER OPTIONS ARE THERE?

Other than not taking part in the study, there are no other alternatives.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.
You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. You should receive a check in the mail within 2-4 weeks of your participation. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

Monetary compensation:
Amount: $100 after completion of the 9th visit.
If you are unable to complete all visits or if you choose to withdraw prior to completing all components of the study, the amount that is due to you will be pro-rated. (e.g. $11.11 for each day completed).

WHO IS FUNDING THIS STUDY?

The National Institute of Health is funding this research study. This means that Washington University is receiving payments from the National Institute of Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the National Institute of Health for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator 314-633-8450 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about payment for medical treatment for injuries relating to your participation in research will be made by Washington University**.** If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law.

However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- University representatives, to complete University responsibilities
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures
- Washington University's Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will store all paper/hard copies of data in locked filing cabinets in Dr. Catherine Lang's research suite. The research suite is locked when laboratory members are not present. Your identity on these records will be indicated by a code number rather than by your name, and the information linking the code number to your identity will be kept separate from the research records. Documents with your name will be kept in a separate locked filing cabinet. Transportation of paper/hard copy records will only be done by study team members and data will not be left unattended.

Electronic records will be stored in password protected computers in password protected files to which only the research team members have access. Research data will be associated with our code number and not your name or other personal information. When research team members leave their computer, they will not leave study data files open and will log off of their computer. The screening log will be kept on password protected computers in a password protected file, with access limited to research team members. Transportation of electronic records will only be done by study team members and will not be left unattended. Laptops containing study data are password protected and will be stored in locked filing cabinets when not in use. No research will be stored on jump drives.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?".

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
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    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared if necessary for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at http://hrpo.wustl.edu/participants/ under Withdrawing from a Research Study.

Can someone else end my participation in this study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because in our judgment it would not be safe for you to continue.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Maggie Bland 314-633-8450 or Catherine Lang 314-286-1945. If you feel that you have been harmed in any way by your participation in this study, please contact Maggie Bland 314-633-8450 or

Catherine Lang 314-286-1945.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found by clicking "Participants" on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 10/29/18.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that he or she understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)