COMIRB
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Study Title: Low Load Resistance Training Using Blood Flow Restriction for People with Multiple Sclerosis

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about strength training using a specialized device called Blood Flow Restriction (BFR) in people with multiple sclerosis (MS) who have more advanced disability.

You are being asked to be in this research study because you have MS and you need assistance to walk.

Other people in this study

Up to *40* people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to participate in an 8-week strength training intervention that meets twice a week and is supervised by a physical therapist. The strength program will target muscles in your legs. A blood flow restriction (BFR) device will be used during all of the exercises. BFR training involves placing a cuff on the leg you are exercising in order to restrict blood flow. The cuff is attached to a specialized device that automatically detects the appropriate amount of pressure to place on your limb. You will be asked to perform three different exercises on each leg. The cuff stays inflated for the during each exercise but is deflated between exercises.

In addition to the 16 in-person visits with the physical therapist, you will also be asked to undergo strength and mobility assessments one time before the strength training program, and one time immediately following the program. Mobility tests will involve rising up and down from a chair for 30 seconds, walking for 25 feet or as far as you can walk, and performing a test for your balance. Strength assessments will be done with a device that measures the force of your muscle. You will also be asked to wear two activity monitoring devices for 10 days both before and after the strength training program. These small devices are attached with a Velcro strap around your waist and

hip and will monitor how much you walk or how much you propel your wheelchair, depending on you level of mobility. All tests are non-invasive.

You will also be asked to undergo a standard physical therapy exam at the initial visit and fill out online questionnaires about your physical function, fatigue, and quality of life online before each assessment visit. Finally, at the end of the treatment you will be asked to fill out questionnaires and participate in a one-on-one interview in order to let us know how satisfied you were with the treatment. The one-on-one interview will be conducted online and the audio will be recorded.

After being deemed eligible, signing this consent, and completing the initial assessment, you will be asked to briefly try the BFR device. A small proportion of people do not tolerate the pressure from the device. If you don't think you can tolerate the device at that point you will no longer qualify for the study. You will still be compensated for the study visit you attended (see "Will I be paid for being in the study?" Section below) but would not complete the rest of the study visits.

Your total participation should not be more than 10 weeks.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include temporary muscle pain and/ or fatigue from the strength testing or strength training. This is a rare risk and should also be only temporary. The risk is the same as with muscle testing or strengthening exercises during a standard physical therapy visit. You will be able to withdraw from the study at any time or stop the testing procedure if you are ever uncomfortable. If pain is detected during the testing procedure or an exercise that limits your ability to do the activity, you will not be asked to complete the testing, or the exercise will be modified so that you do not experience discomfort.

The risk of blood flow restriction includes muscle soreness at the area of the cuff, numbness during the treatment, and mild muscle soreness within 24-72 hours after the treatment. There is also a small risk of developing a blood clot in your leg because of the cuff pressure. If you don't have a history of blood clots or clotting disorders the risk is extremely small. If you do have a history of blood clots or clotting disorders you will be excluded from the study.

Other possible risks include a loss of balance during the exercise sessions or walking tests. There is a rare but serious risk of a loss of balance leading to a fall in which you could be hurt. You will be supervised and, if needed, closely guarded by a physical therapist with over 15 years' experience working with people with MS. Therefore, while you may lose your balance, the risk of a fall is very low. In fact, the risk of falling or loss of balance is no greater than during a routine physical therapy assessment.

The study team will access your medical records as part of this study. We will only access areas of your records that are necessary for the study and we will take all

precautions to make sure records stay confidential. However, there is a risk that people outside of the research team will see your medical or research information. We will do all that we can to protect your information, but it cannot be guaranteed.

Finally, during the COVID-19 Pandemic, there is an increased risk of exposure when leaving the home. Our study team has complied and will continue to comply with all guidelines recommended by the University of Colorado Anschutz Medical Campus (including, but not limited to social distancing and personal protective equipment) in order to keep you as safe as possible. If recommendations change while you are enrolled in the study, we will immediately comply and inform you of the changes.

What are the possible benefits of the study?

This study is designed for the researchers to learn more about the effects of a strength training program using blood flow restriction in people with MS who have difficulty walking. However, there is no guarantee that your health, including your walking and strength, will improve if you join this study. Also, there could be risks to being in this study. These risks are described in the section describing the discomforts or risks.

Are there alternative treatments?

There may be other ways of treating your weakness and walking problems associated with your MS. These other ways might include pool exercise, walking and biking programs, and other forms of strengthening exercises. You could also choose to get no physical therapy treatment at all.

You should talk to your physician and/or physical therapist about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

The Consortium of Multiple Sclerosis Centers is paying for this study.

Will I be paid for being in the study?

You will be paid $50.00 for each testing visit in this study. This will add up to a total of $100.00 if you complete both of the in-person testing visits. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed. If you don't qualify for the study based on not being able to tolerate the pressure from the cuff on the first day, you will still be paid for that visit. It is important to know that payments for participation in a study is taxable income. You will also be provided free parking for all of your site visits.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Mark Mañago immediately. His phone number is 303-724-0247. We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Mark Mañago. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Mañago at 303-724-0247. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Mañago with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

What happens to data collected in this study?

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include:

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Mark Mañago, PT, DPT, PhD, NCS
University of Colorado - Anschutz Medical Campus
13121 East 17th Avenue, Mailstop C244, Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:.

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- The Consortium of MS Centers, who is paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

What happens to Data that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Witness Signature:_____ Date:_____

Print Name:_____

◯ Witness of Signature

◯ Witness of consent process