Remote Limb Ischemic Conditioning to Enhance Muscle Power, Dynamic Balance, and Walking Performance in Children with Cerebral Palsy

10/15/2020

Assent Form
Things You Should Know Before You Agree To Take Part in this Research

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IRB Study # 19-003232

Title of Study: Feasibility of remote limb ischemic conditioning combined with muscle power, balance, and gait training in children with cerebral palsy

Person in charge of study: Dr. Swati Surkar
Where they work: Department of Physical Therapy, ECU
Other people who work on the study: Dr. John Willson; Dr. Chia-Cheng Lin; Christina Moore, Sarah Sedaghat; Julia Stocker

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People at ECU study ways to make people's lives better. These studies are called research. This research is trying to find out if remote limb ischemic conditioning (RLIC), which refers to reducing blood flow to the arm or leg for brief periods of time and then letting blood flow back into the arm or leg by inflating and deflating the blood pressure cuff, can increase muscle power and motor skill learning in children with cerebral palsy (CP).
Your parent(s) needs to give permission for you to be in this research. You do not have to be in this research if you don't want to, even if your parent(s) has already given permission.
You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you.

Why are you doing this research study?

The reason for doing this research is to determine whether children with CP can tolerate the study protocol that includes reducing blood flow to the thigh combined with muscle power, balance, and treadmill training and to determine whether this combination therapy improves walking.

Why am I being asked to be in this research study?

We are asking your signed assent to take part in this research because you are in the age group of 12-13 years and have diagnosis of mild to moderate CP.

How many people will take part in this study?

If you decide to be in this research, you will be one of about 24 people taking part in it.

What will happen during this study?

The study involves total 16 visits in our laboratories located at College of Allied Health Sciences building. These visits will be within next 8 weeks.

Visit 1:

1. A trained research team member will obtain an informed consent.
2. If you are able to participate in the study and choose to sign the assent form, we will first record your demographic details such as name, age, date of birth, past medical history, medications etc.
3. After that we will record your baseline performance such as power and activation of your thigh muscle. Thigh muscle power will be tested with isokinetic strength testing device, HUMAC. You will be sitting comfortably in a chair with back supported, trunk securely fasten to the chair and hip and knee flexed to 90 degrees. You will then be asked to push with maximum force against the bar at the front of your ankle by extending your knee for 10 seconds. You will repeat this process for 3 times with 1-minute break between each trial. We will simultaneously record electrical signals from your thigh muscle using electromyography (EMG) system. For that we will place three small adhesive button size electrodes on your thigh and another small electrode on your knee joint. While you will extend your knee with maximum force for 10 seconds, we will simultaneously record the electrical signals from your thigh muscles during each of the three repetitions. We will repeat the power testing and EMG recording on your other leg. We will record the force that you will exert and muscle activation during each knee extension trial and the average of three trials will be considered as your thigh muscle power and amount of activation respectively.
4. You will then perform 5 trials of balance task. You will balance on a dynamic balance board for 30 seconds at a time with the goal of keeping the board as level to the ground as possible. You will have 30 seconds of rest between each trial during which you will be standing on a balance board.
5. We will assess your walking performance using gait analysis, 10-meter walk test and accelerometry measures. For gait analysis, we will place reflective markers on your legs and you be asked to walk on 10 feet long instrumented platform in our Human Movement Analysis Lab. The motion analysis system will capture your walking and we will analyze different characteristics of your walking. Then you will walk on an instrumented mat, GAITRide for 10-meters with self-selected and fast walking speeds and we will record your walking speeds and other walking characteristics such as step length, step width, cadence.
6. We will then place accelerometers on each ankle with the ankle bands. You will wear the accelerometers for 24 hours or before returning for the visit next day. The accelerometers will record your walking performance throughout the day.

   Visit 1 will last for 1.5 to 2 hours.

Visit 2:

1. We will collect the accelerometers from you.
2. You will then be randomly assigned to RLIC or sham conditioning group. The random assignment of treatment groups will be determined based on computer generated random selection. You will not know to which treatment group you are assigned until the end of the study.
3. You will undergo RLIC or sham conditioning.
   a. RLIC will be achieved via pressure cuff inflation to 20 mmHg above systolic blood pressure on the weaker thigh. Systolic blood pressure is the top number of blood pressure measurement. If the conditioning is not achieved with the pressure above 20 mmHg above your systolic blood pressure, the pressure will be increased until conditioning is achieved. However, the conditioning pressure will not exceed 200 mmHg.
   b. Sham conditioning will be achieved via pressure cuff inflation to 25 mmHg under on your weaker thigh.

4. There will be total 5 cycles of alternating 5 minutes of inflation and 5 minutes of deflation in both RLIC or sham conditioning groups.

   Visit 2 will last for 1 hour.

   Visits 3-14:

   1. You will first undergo conditioning.
   2. You will participate in trainings:15-20 minutes of balance training, 15 minutes of power training on both thighs, and 15 minutes of walking on the treadmill. There will be 5 minutes of rest between each task.
   3. For balance training, you will stand on the stability platform. There will be 30 seconds of trial during which you will try to maintain the platform in the center without holding on the handrails. After that, there will be 30 seconds rest during which you can rest by holding on the handrails. You will repeat this for 15 times. There will be two minutes of rest after 5 trials each.
   4. For power training, you will lie on you back on total body gym machine. Your hips and knees will be bent to 90 degrees and feet will be placed on foot pad. We will calculate the maximum amount of weight that you can lift while extending your both knees by pushing against the foot pad. We will use 70-80% of that weight as your power training intensity. You will perform 4-6 sets of power training with 6 repetitions in each set. There will be two minute of rest between each set.
   5. You will then perform treadmill training for 15 minutes. You will walk fast for 30 seconds and at normal pace for next 30 seconds. The fast and slow walking speeds will be determined from your walking performance on the GAITRide mat. Rest will be allowed in between the treadmill session if your lower limbs feel very tired or fatigued.

   The conditioning and training will be performed by a trained research team member. Another trained research team member will be constantly around the child to safeguard the child.

   Visits 3-14 will occur on alternate weekdays and last for 2-2.5 hours.

   Visit 15:

   1. Visit 15 will occur on the next day after visit 14. We will assess your post-study performance such as power and activation of your thigh muscle, balance and walking performance using the same process as during visit 1.

      Visit 15 will last for 1.5-2 hours.

   Visit 16:

   1. Visit 16 is a 4-week follow-up visit after visit 15. The purpose of this visit is to asses retention effects of the study protocol.
   2. We will assess your performance 4-weeks after study using the measures such as power and activation of your thigh muscle, balance and walking performance using the same process as during visits 1 and 15.

      Visit 16 will last for 1.5-2 hours.

This study will take place at research labs in CAHS and will last for 8 weeks.

Who will be told the things we learn about you in this study?

Only the research team members will have access to the information and data collected from your research visits

What are the good things that might happen?

Sometimes good things happen to people who take part in research. These are called "benefits." The benefits to you of being in this study may be that with the study protocol your walking performance may improve. There is a chance you will benefit from being in this research.

What are the bad things that might happen?

Sometimes things we may not like happen to people in research studies. These things may even make them feel bad. These are called "risks." The risks of this study may include discomfort, tingling or pain on your thigh due to pressure cuff; discomfort in your legs due to balance and treadmill training, and fatigue or soreness in your legs due to power training. You may or may not have these things happen to you. Things may also happen that the researchers do not know about right now. You should report any problems to your parents and to the researcher.

What if you or your parents don't want you to be in this study?

If you or your parents don't want you to be in this study, here are some other things that you may be able to do. 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.

Will you get any money or gifts for being in this research study?

You will be eligible to receive $300 compensation for total 16 visits through the Greenphire ClinCard. We will be compensating each participant $150 bi-weekly. If the participant is not able to complete all the visits, each visit will be prorated at $18.75.

Who should you ask if you have any questions?

If you have questions about the research, you should ask the people listed on the first page of this form. If you have other questions about your rights while you are in this research study you may call the Institutional Review Board at 252-744-2914.

If you decide to take part in this research, you should sign your name below. It means that you agree to take part in this research study.

_____ _____

Sign your name here if you want to be in the study Date

_____
Print your name here if you want to be in the study

_____ _____
Signature of Person Obtaining Assent Date

_____
Printed Name of Person Obtaining Assent

"By initialing in the following places, the parent/guardian and investigator indicate their opinion that the patient is too young or otherwise not able to give consent/assent."

____Parent/Guardian Investigator