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Informed Consent Form

Title: Cortical and spinal correlates of stroke gait rehabilitation

Principal Investigator: Trisha Kesar, PhD

05/07/2019

Emory University
Consent to be a Research Subject

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Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

Study Overview

The purpose of this study is to understand the effects of different types of walking training. This study is registered as a clinical trial on clinicaltrials.gov. You have been asked to participate because you are an able-bodied individual. We will utilize the data on able-bodied persons to compare with our findings on people with stroke. We want to study how walking speed, walking quality, and connections between your brain and muscles change after you undergo 1 session or 18 sessions of walking training. The findings from this study will help us to design better treatments for improving walking function in people with stroke. Note that as an able-bodied subject, you may participate in only a subset of the procedures listed in this consent form.

Procedures

As one of the 90 participants in this study, you will be requested to take part in study procedures as described here. Please ask if you have any questions about these procedures. You may participate in one of two study cohorts. Cohort 1 will comprise up to 18 training sessions with 2 to 3 sessions conducted in one week (over the course of 6-8 weeks). Cohort 2 will comprise up to 18 training sessions but with the frequency of sessions varying from 1 to 3 sessions per week and more time (several days or weeks) between consecutive sessions. You may also participate in both the study cohorts sequentially, if interested. The study team may also request your participation in pilot or methods-based experimental sessions that comprise the same study procedures described in this consent form but do not involve any intervention or training component. Each session will last for 2-3 hours.

Session 1 – Clinical Testing and Muscle Strength Testing:

During your first visit, all study procedures will be explained in detail. For able-bodied subjects, the clinical testing may not be performed or may only comprise a subset of the outcomes listed below.

A physical therapist may check your leg function and walking. We may measure how fast you walk over ground and on a treadmill, how far you can walk in 6 minutes, etc. In addition, during this session, we may measure how strong the muscles surrounding your knee and ankle are. To test your muscle strength, we will

use a chair that has a force measuring device. During the strength tests, we will use straps to keep your trunk, thighs, and lower leg stable. For testing the knee, we will ask you to 'kick out' or 'pull your leg in' with as much force as you can. For testing the ankle, we will ask you to pull your foot toward you or to push it away from you with as much force as possible. When you push with your muscle, we will also send a short (less than half a second long) electric current to your muscle through surface pads attached to the skin. This current will add to the force your muscle is producing and will help us to measure your muscles strength accurately. In addition, we may ask you to complete some questionnaires about your activity levels, community participation, balance confidence, cognition, etc. and provide small pedometers to measure your stepping activity.

Sessions 2 to 18 – Measuring and Training of Walking:

During these sessions, you will walk over ground and/or on a treadmill. When you walk over ground, an investigator will be close by to assist you if needed. During treadmill walking, throughout the session, you will walk wear a safety harness. A set of 7 special cameras placed around the room will be used to precisely measure your movements during walking. In addition, magnetic brain stimulation will be used to test the connections between your brain and your muscles at the beginning and end of the session.

Initial Setup and walking tests: Elastic bands will be wrapped around your thighs, calves, and pelvis. Small reflective balls will be attached to your shoes, your upper back, shoulder, hip, knee, and ankle joints with non-irritating skin tape. We will also attach small sensors to the skin over muscles of your thigh and calf with skin tape. These sensors will help us to measure how hard your muscles are working. To setup for electrical stimulation, we will attach pads to the muscles in front of your leg and your calf. We will deliver short (half-second long) currents to your muscles to check your response to the stimulation. The stimulation gives a tingling or 'pins and needles' sensation, but should not be painful. Based on your tolerance, we will set the strength of current to be used for stimulation during the session. To measure your walking, we will request you to walk in front of the cameras. When we test your walking, we will ask you to walk for short bouts (30-seconds). This part will take approximately 30 minutes.

Training of Walking: For this part, you will either receive the same type of walking training (Cohort 1 - fast treadmill walking with electrical stimulation) for all 18 sessions or different types of walking training (Cohort 2 - e.g. treadmill walking at slow or fast speed, training with or without stimulation, training with or without feedback, training comprising 10 to 30 minutes of walking, etc.) for each of the training sessions. When you receive the same type of training for all 18 sessions, at the beginning of training, as a warm-up, you will walk at your comfortable speed for 1-2 minutes. Next, for the walking training, you may complete five 6-minute bouts of treadmill walking at a fast speed. You can take a seated rest break between bouts. When you are walking on the treadmill, you can also rest your fingertips on the handrail if needed. Depending on the type of training it is, electrical stimulation timed with your walking pattern will be delivered to the muscles in front of and back of your legs. The electrical stimulation will help your muscles to work more strongly and at the correct time during walking. If needed, you can ask the investigator to reduce the strength of the electrical stimulation. After completing 6 bouts of treadmill walking, you will also walk for 6 minutes over ground at a fast speed. At the end of the session, you will be asked to walk on the treadmill at your comfortable speed for 1-minute. The training will take approximately 60 minutes including rest breaks. When you receive different types of training during each of the 18 sessions, the training will comprise a total of 10 to 30-minutes of different types of walking (e.g. walking at slow, fast, or variable speeds ranging from slow to fast, walking with or without stimulation, walking with both belts going at different speeds, walking with one belt going forward and the other backward, etc.).

We may ask you to rate how tired you feel at regular intervals during the session. Also, your heart rate and blood pressure will be checked at regular intervals. If you feel tired, you will be allowed to rest on a chair.

Testing the strength between your brain and muscles: At the beginning and end of the training, as well as weekly during training, we may measure the strength of the connections between your brain and muscles. We will record your muscle's responses to brain stimulation through small sensors attached on the skin of your legs and arms. We will use a large 8-shaped coil to deliver very short (less than half a second long) magnetic

pulses to your head. The coil will touch your head during the stimulation. We will find the areas of your brain that control the hand and leg muscles that we are measuring. While the magnetic pulses are being delivered, we may monitor your muscle's activity. We may provide you with cues to help you better relax the muscle or to lightly push with your muscle. You will hear a click every time the magnetic pulse is delivered. The magnetic pulse will feel like a gentle tap on your head. We may deliver single-pulses or a pairing of 2-pulses. Your hand, leg, or face muscles may twitch in response to the magnetic pulse delivered to your brain. Additionally, this part of the study is optional and you can choose to participate in the remaining study procedures and opt out of the brain stimulation portion of the study.

Testing the connections between your nerves and your muscles: At the beginning and end of the training, as well as during training, we may measure the strength of the connections between your nerves and muscles. We will record your muscle's responses to very short (less than half-second long) electrical pulses delivered over the nerves of your leg. Muscle responses will be measured through small sensors attached on the skin of your legs and arms. We will locate the point on the skin of your leg (e.g. behind the knee) where we get the best response from your muscles by moving a small electrode around and delivering small electric pulses. Next, we will stick stimulation pads to the skin over your muscles and deliver a series of electric pulses (1 every 3-5 seconds). You will be asked to relax your muscles or maintain a low level of muscle activity during this testing. In addition, we may deliver the electric nerve pulses in the same session and paired with the brain stimulation pulses described above.

Additionally, if you have already undergone a brain MRI scan as part of a different study, we will request your permission to share those MRI images for this current study as well. The MRI scans we are requesting permission to use may have been done under the IRB protocols IRB00081268 (Noninvasive brain stimulation to evaluate neural plasticity after stroke) or IRB00072542 (Using concurrent brain imaging and stimulation to characterize brain behavior in stroke). Your MRI scans and brain images will be used to guide the brain stimulation during our experiment and also to better understand the relation between brain structure, your response to brain stimulation, and your walking function.

Your participation in this study is completely voluntary. You can decide to discontinue your participation in this study at any time.

Risks and Discomforts

There may be side effects from the study or procedures that are not known at this time.
The most common risks and discomforts expected in this study are:

- There is a risk of falls during the walking testing or training. To avoid falls, a physical therapist will remain near you while you walk. You will wear a harness and be able to hold a handrail when you walk on the treadmill.
- You may experience fatigue and/or muscle soreness similar to the soreness that you might feel after you lift weights or exercise vigorously after a long break.
- Injuries such as muscle strains are possible.

The less common risks and discomforts expected in this study are:

- Minor skin irritation may occur from the adhesive tape.

Rare but possible risks include:

- During electrical stimulation, the potential for equipment malfunction is present, which might result in burns to the skin. However, the equipment used is highly reliable and prolonged exposure necessary to cause the risk of skin damage is highly unlikely with this experimental design. The risks associated with the measurement of the connections between your nerves and muscles are the same as the risks of electrical stimulation described here.

The risks caused by the brain stimulation (optional part of the study) are:

- Metal and conductive objects close to the coil may be damaged during magnetic brain stimulation. We will therefore exclude individuals who have implants in their head.
- You may feel twitches in the muscles of your arm, leg, or face during the magnetic brain stimulation, but these twitches should not be painful
- Rare cases of the development of seizures during or immediately after magnetic brain stimulation have been reported. People who have a history of seizures will be excluded from study.
- Some individuals experience headaches, scalp discomfort, dizziness, and/or light-headedness during or after the magnetic stimulation. If they occur, these effects are usually mild and short-lasting.
- A click may be heard during magnetic brain stimulation. Some individuals find the sound of the click uncomfortable. You will be provided with foam earplugs that may help to minimize any annoyance from this clicking noise.

If you are a woman: to protect against possible side effects of the magnetic brain stimulation, women who are pregnant or nursing a child may not take part in this study. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

These procedures are experimental, and the responses of individuals to the walking training may vary widely. You may experience small and short-lasting increases in your walking speed, endurance, or balance as a result of the walking sessions. Also, the long-term findings of this study can help us better understand the effects of rehabilitation, which can benefit other stroke survivors in the future.

Compensation

You will be get $_30_ for each completed study visit. If you do not finish the study, you will be paid for the visits you have completed.
Participation in this research study is at no medical cost to you. We will also reimburse for each session up to $10 for parking based on receipts provided

Confidentiality

Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include [the Emory Institutional Review Board, the Emory Office of Research Compliance, the Office for Clinical Research, etc.]. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You may search this Web site at any time.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

Research Information will go Into the Medical Record:
If you are or have been an Emory Healthcare patient, you have an Emory Healthcare medical record. If you are not and have never been an Emory Healthcare patient, you do not have one. Please note that an Emory Healthcare medical record **will** be created if you have any services or procedures done by an Emory provider or facility for this study.

If you agree to be in this study, a copy of the consent form and HIPAA patient form that you sign **will** be placed in your Emory Healthcare medical record. Emory Healthcare may create study information about you that can help Emory Healthcare take care of you. For example, the results of study tests or procedures. These useful study results will/will not be placed in your Emory Healthcare medical record. Anyone who has access to your medical record will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA Privacy Rule. On the other hand, some state and federal laws and rules may not protect the research information from disclosure.

Emory does not control results from tests and procedures done at other places, so these results would not be placed in your Emory Healthcare medical record. They will not likely be available to Emory Healthcare to help take care of you. Emory also does not have control over any other medical records that you may have with other healthcare providers. Emory will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let them know.

The researchers will review the results of certain study tests and procedures only for the research. The researchers **will not** be looking at the results of these tests and procedures to make decisions about your personal health or treatment.

In Case of Injury

If you get ill or injured from being in the study, Emory would help you to get medical treatment. Emory and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you believe you have become ill or injured from this research, you should contact Dr.Trisha Kesar at telephone number 404-712-5803 . *You should also let any health care provider who treats you know that you are in a research study.*

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study
You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;

- If you demonstrate excessive sensitivity or pain in response to the study procedures;
- or for any other reason.

Contact Information

Contact Trisha Kesar at 404-712-5803:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study procedures, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent

Please, print your name and sign below if you agree to be in this study. Please check the box to indicate your preference for opting to participate in the brain stimulation portion of the study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, to keep.

_____ I am willing to participate in all study procedures, including the brain stimulation portion of the study.

_____ I do not wish to participate in the brain stimulation portion of the study.

_____
Name of Subject

_____ _____
Signature of Subject Date Time

_____ _____
Signature of Person Conducting Informed Consent Discussion Date Time

_____
Name of Person Conducting Informed Consent Discussion