Study Title: Operant H-reflex Down-conditioning of Rectus Femoris in Post-stroke Stiff Knee Gait

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Consent to Participate in Research

Basic Study Information

Title of the Project: Operant H-reflex down-conditioning of rectus femoris in post-stroke Stiff Knee Gait
Principal Investigator: [James Sulzer, Assistant Professor, University of Texas at Austin]

Invitation to be Part of a Research Study

You have been asked to participate in a research study that uses electrical stimulation to stimulate muscle's reflex activity. The purpose of this form is to provide you with information that may affect your decision as to whether participate in this research study. The person performing the research will answer any of your questions. Please read the information below and ask any questions you may have before deciding to take part in this study. If you decide to be involved in this study, this for will be used to record your consent.

Important Information about this Research Study

Things you should know:

- The purpose of the study is to use electrical stimulation to elicit muscle's (rectus femoris) reflex, and see if this signal can be modulated by humans.
- In order to participate, you must be aged 18-75, have no history of cerebellar stroke, multiple stroke, able to walk by yourself, and provide informed consent.
- If you choose to participate, you will be asked to walk on the instrumented treadmill, get electrically stimulated, and asked to control your reflex signal provided via computer screen. This will take 1.5 - 2 hours per session for 35 sessions, 3 times per week over approximately 3 months.
- Risks or discomforts from this research are not greater than everyday life.
- There is no direct benefit, but you will be receiving monetary compensation for your participation and performance.
- Taking part in this research study is voluntary. You do not have to participate, and you can stop at any time.

More detailed information may be described later in this form.

Please take time to read this entire form and ask questions before deciding whether to take part in this research study.

What is the study about and why are we doing it?

The purpose of the study is to use electrical stimulation to stimulate reflex activity using surface electrodes on femoral nerve near the groin and see if this signal can be modulated by the participant. We will also use sensors to measure muscle activity from multiple muscles in your thigh. During the session, you will be asked to look at the monitor and lower down the moving bar below the given threshold. The moving bar would continuously change after each stimulation. This bar indicates muscle activity and the resulting muscle activity measures will be used to identify the learning ability of skill that could possibly act as a treatment for spasticity.

What will happen if you take part in this study?

If you agree to take part in this study, you will be asked to:

- You will visit our research facility located at UT Austin.
- You will have surface electrodes placed on various points on your lower body. We will focus on your pelvis and legs.
- We may need to remove hair from the area of electrode placement using a disposable razor
- After placing the surface electrodes you will be asked to perform certain movements in order to check the muscle signal
- To find spot for stimulation, 10 spots around femoral nerve region will be tested for adequacy.
- During the recruitment curve, different currents will be applied repetitively, at least 7 seconds apart from each other, via surface electrodes attached to your femoral nerve. The stimulation may result in some pain. The intensity of the sensation might fluctuate depending on the applied current.
- During the baseline session, current with optimal intensity will be applied repetitively, at least 7 seconds apart from each other, and you will be asked to hold still during this stage.
- During the control session, current with optimal intensity will be applied repetitively, at least 7 seconds apart from each other, and you will be asked to continuously lower the moving bar from the experimental monitor.
- During the very first assessment session, you may participate in a simulation environment of Operant H-reflex conditioning, which does not incorporate electrical stimulation and you'll be asked to use keyboard inputs to perform given tasks (e.g. lowering down slider bar, making slider bar green, or achieving high success rate).
- You will have access to emergency stop button during the sessions to stop the process in case of any discomfort.

How long will you be in this study and how many people will be in the study?

Participation in this study will consist of 35 sessions, which is composed of 4 assessment sessions and 31 operant conditioning sessions. Each session will last 1.5-2 hours. You will be asked to visit the lab at least three times per week, where the total duration of the study will last approximately 3 months. The last session, a follow-up session, will be conducted two months after the final conditioning session.

What risks and discomforts might you experience from being in this study?

As no additional therapy will be performed there is no additional risk of injury due to therapy. The stimulator will provide up to 30 W of power (up to 99mA of current) and will likely cause discomfort. The stimulation feels like a pinch. There is a risk of loss of confidential health information such as any conditions you may have. This type of information will be kept by the clinical study investigators in regulatory compliant storage. Your identity outside of this storage will be coded for anonymity. Potential risk of using treadmill is falling and harness will be provided for your protection. Although there are no known significant risks or side effects associated with MRI, you may experience dizziness or claustrophobia or heating. If you experience any of the feelings listed above, please inform the researcher and we will stop the experiment immediately.

During the MRI scans, there is a small chance that the researchers may see a problem that might be medically important. This is unlikely. If the researchers see a potential problem, they will send your images to the Imaging Research Center's Medical Director and a qualified radiologist. If the radiologist sees anything that might be medically significant, the Medical Director will contact you by phone to discuss the findings. Our research team, including the

radiologist and The University of Texas at Austin are not responsible for any medical exam or treatment. Since the scans themselves are not equivalent to a medical MRI, the images will not be shared with you or your physician.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in this study.

How could you benefit from this study?

You will receive no direct long-term benefit from participating in this study; however, it is possible that if you have spasticity, this training regimen may temporarily reduce it.

What will happen to the samples and/or data we collect from you?

As part of this study, we will collect surface electromyography (EMG) signal, and kinematic data using inertial measurement unit (IMU). To eliminate the risk of compromised participant data (including any information shared with other investigators via electronic databases), every effort will be made to safeguard the confidentiality of research records, including: Using or sharing data files free or information enabling individual identification of participants; maintaining lock-and-key access to paper records; and maintain computer data files with encryption, password protection, and behind firewalls.

How will we protect your information?

Only your physician will be able to link your name to your data. Anonymous data (without your name) may be presented at research meetings and published in research journals. The PI's data allocation is accessible only to the study staff and is password protected.

If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to you will be protected to the extent permitted by law. Your research records will not be released without your consent unless required by law or a court order. The data resulting from your participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with you, or with your participation in any study.

A description of this study 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 can search this web site at any time.

Since this study is funded by the NIH, the Department of Health and Human Services may have access to your study data.

What will happen to the information we collect about you after the study is over?

Any data which can be directly linked to you, or compromise your anonymity in this study, will be deleted within 6 months of the completion of study analysis.

How will we compensate you for being part of the study?

There will be a compensation in the rate of $20/session, and up to extra $10 depending on performance. Total compensation is up to $930 after the entire study is completed.

Compensation is provided as cash or an equivalent gift card. The compensation will be provided once every four weeks. Also, in the choice of participant, study can be done voluntarily without compensation. Specific extra compensation is described in the table below. For each block of 75 conditioning trials, we will provide additional compensation based on the success rate as detailed below:

>50% → $1.0
>60% → $1.5
>70% → $2.0
>80% → $2.5
>90% → $3.0

In addition, If the performance of all 3 blocks is >90%, we will add an extra $1 for that session's reward. In total, you may earn up to $10 extra per session. You may forgo compensation voluntarily.

Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual is equal to or exceeds $600 in any one calendar year, The University of Texas at Austin is required to report this information to the Internal Revenue Service (IRS). If the compensation you receive from participation in this research in combination with all other compensation received from The University of Texas at Austin is equal to or exceeds $600 in the current calendar year, you must provide IRS 1099 related information.

Who will pay if you are hurt during the study?

The risks involved in this study are minimal, and there are no foreseeable long-term effects as a result of the testing. The University has no program or plan to provide treatment for research related injury or payment in the event of a medical problem. In the event of a research-related injury, please contact the principal investigator. The University has no program or plan for continuing medical care and/or hospitalization for research-related injuries or for financial compensation.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Your decision to participate will not affect your relationship with The University of Texas at Austin or your care provider. You will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, please inform the staff who's running the experiment immediately.

Is it possible that you will be asked to leave the study?

You may be asked to leave the study if it is determined by the research team that it is unsafe for you to continue. If any of the following issues come up, we will have to ask you to stop participating:
- If the participant feels excessive physical pain from electrical stimulation.
- If the participant cannot walk by him/herself on the instrumented treadmill

Is it safe to start the study and stop before you are finished?

You are always free to stop participating in the study if you would like. Your decision to stop participating will not affect your standard medical care or any other benefit you would receive if you were not in a research study.

Contact Information for the Study Team

If you have any questions about this research, you may contact:

James Sulzer
Phone: 512-541-9036
Email: james.sulzer@austin.utexas.edu

Or

Kyoungsoon Kim
Phone: 512-201-5616
Email: kskim8913@utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board
Phone: 512-232-1543
Email: irb@austin.utexas.edu

Please reference the protocol number found at the top of this document.

Your Consent

By signing this document, you are agreeing to be in this study. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____
Printed Subject Name

_____
Signature Date