TEXAS WOMAN'S UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Title: Effect of Brain Stimulation on Motor Skill Acquisition in Stroke Survivors and health individuals

Research Team:

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Summary and Key information about the Study

You are being asked to participate in a research study conducted by Shih-Chiao Tseng, PT, Ph.D. at Texas Woman's University. This research study is to determine whether low-intensive brain stimulation can enhance your learning of a leg movement task. We also want to know if brain stimulation can improve your nerve function and walking performance. Our goal is to understand any relationship between brain stimulation and overall movement control improvement. You have been invited to join this research if you have had a stroke before or you are a healthy adult aged 21 years or older. Research evidence shows stroke can induce permanent brain damage and therefore may cause a person to have trouble learning a new task. This in turn may significantly impact the recovery of motor function in stroke survivors. In addition, we also want to know how a healthy person learns this new leg task and see if her/his learning pattern differs from a stroke survivor.

This study comprises two phases: Phase I study investigates short-term effects of brain stimulation on leg skill learning and only requires two visits to TWU. The total time commitment for Phase I study will be about 6.5 hours, 3.5 hours on the first visit and three hours on the second visit; Phase II study is an expanded version of Phase I study to investigate long-term effects of brain stimulation on leg skill learning and requires to complete 12 visits of exercise training paired with brain stimulation over a four-week period and additional one visit for follow-up test. The total time commitment for Phase II study will be about 20 hours, a total of 18 hours for 12 exercise training sessions and two hours for a follow-up test. Following the completion of the Phase I and Phase II studies you will receive a total of $150 gift cards ($10/visit) for your participation if you have attended all required visits ($10/visit). The greatest risks of this study include potential loss of confidentiality and leg muscle soreness. We will discuss these risks and the rest of the study procedures in greater detail below.

Your participation in this study is completely voluntary, and you may withdraw from the study at any time. If you are interested in learning more about this study, please review this consent form carefully and take your time deciding whether or not you want to participate. Please feel free to ask the researcher any questions you have about the study at any time.

Description of Procedures

This study will take place at Texas Woman's University (TWU)-Houston campus and include two phases: Phase I involves a single-intervention study and Phase II involves a four-week intervention study. After enrolling to the study, you can choose to only participate in the Phase I study or choose to participate in both Phase I and Phase II studies.

Phase I Study

You will be asked to complete two visits, 1-14 days apart. It will take about a total of 6.5 hours of your time to complete all tests (3.5 hours for the first visit and 3 hours for the second visit, two visits). You will need to wear short-sleeve t-shirt, shorts, and a pair of sneakers for testing. During the first visit, we will measure how well your nerve works and how well you walk (see details as follows). If you have had a stroke before, on the first visit we will do some tests on you to make sure you have good feeling, balance, and motor responses in your legs. If all tests are good, you will fill out a form asking about your medical history. If you have not had a stroke, we will ask you a few questions to make sure you do not have any medical issues.

Next, we will ask you to learn a leg movement task at each visit. The task is to control a foot mouse and move a computer cursor from a start location to one of three targets displayed on the computer monitor. You will need to make forward, rightward or leftward foot movements to guide the cursor to one of the targets. The task itself is similar to the daily computer task performed by a hand mouse. In each visit, it will take approximately a total of 45 minutes to complete a set of leg reaching task. Several one-minute rest breaks will be provided as needed during test. You will then be asked to come back for the second visit within 1-14 days later to repeat the same task. Throughout practice, you will learn how to control the cursor using your foot. So we can compare your learning capacity over two visits to best indicate the change in your learning capacity over time.

We also want to know if you can learn this motor skill faster with cutaneous brain stimulation. You will receive weak electrical brain stimulation for 20 minutes during leg skill learning. The brain stimulation device that we used is similar to the commercial product that you see in the TV/magazine, called “transcutaneous electrical Nerve stimulation” in which electrical current is delivered by electrodes for pain relief and muscle stimulation. In this study, two electrodes, one placed on the top of your scalp and one placed on the forehead, will deliver weak electrical current for 20 min. Because we set the current intensity at a very low level, it will not cause any muscle twitches and you may only feel little tingling sensation in the first 10 seconds. Most of your time, you likely become accustomed to the stimulation and no longer feel the stimulation throughout the rest of the session.

Phase II Study

This study is an expanded version of Phase I study. You will be asked to complete 12 visits of exercise training paired with brain stimulation over a four-week period. It will take about a total of 18 hours of your time to complete all training sessions (1.5 hour for each visit/training for a total of 12 visits). You will need to wear short-sleeve t-shirt, shorts, and a pair of sneakers for training. Before and after four-week training, we will measure how well your nerve works and how well you walk (see details as follows). One week after completion of four-week training, you will be asked to come back to repeat the same tests. We will compare changes in your learning capacity and motor function before and after four-week training, and at one week after completion of training to best indicate permanent changes in your learning capacity and motor function over time.

Next, during each visit, we will ask you to continue learning a leg movement task same as the Phase I study. We will also ask you to learn a similar leg task, call stepping task during standing. This stepping task is very similar to the leg task in the Phase I study, but is a more advanced task that requires a good standing balance. The task is to control a computerized marker attached to the foot and move a computer cursor from a start location to one of three

targets displayed on the computer monitor. You will need to make forward, rightward or leftward stepping movements to guide the cursor to one of the targets. The task itself is similar to stepping motion during walking. In each visit, it will take approximately a total of 1.5 hour to complete two sets of leg task training during sitting and standing. Same brain stimulation used in the Phase I study (see above) will be delivered during the middle of the exercise training. Several one-minute rest breaks will be provided as needed during training. You will then be asked to come to the laboratory three times per week for four weeks in order to complete 12 training sessions.

For the measurement of brain activity, we will put a recording electrode on your calf muscle in one leg. Five low-intensity brain stimulations will be delivered to the scalp to trigger your motor responses. Most of the time, you will feel single muscle twitch due to the stimulation. It would take a total of 10 minutes to finish data collection.

For the measurement of nerve activity, we will put a recording electrode on your calf muscle in one leg. Low-intensity electrical stimulation will be delivered to a nerve behind your knee to trigger your motor responses. A series of small tendon vibration stimuli will be delivered during electrical stimulation to determine the sensitivity of your nerve. Most of the time, you will feel nothing or just light tingling sensation in the stimulated area. It would take a total of 40 minutes to finish data collection. Several one-minute rest breaks will be provided as needed during test.

For the measurement of walking, we will put sticky markers on both legs and ask you to walk normally across a 10-meter walkway for five trials. It would take approximately a total of 30 minutes to finish data collection. Several one-minute rest breaks will be provided as needed during test.

For the stepping reaction time test, subjects will stand on the force plates and will be instructed to step forward onto a target marked on the floor as soon as they sense electrical stimulation delivered to the posterior of the leg. It would take approximately a total of 40 minutes to finish data collection. Several one-minute rest breaks will be provided as needed during test.

Potential Risks

Potential risks related to your participation in the study include skin irritation or redness caused by the adhesive tape, mild tingling sensation caused by stimulation electrode, and muscle soreness or fatigue due to repeated task performance. You may feel frustration if not doing task well. Before test, we will thoroughly clean electrodes and markers. Immediately after test, the skin will be cleansed with non-alcohol wipes to avoid any adverse reaction. Muscle soreness/fatigue or irritation from the testing should go away in 24-48 hours. If the soreness/fatigue or the irritation does not go away, please seek medical care from your physicians. Positive feedback/practice and encouragement will be given to participants throughout the entire learning session to prevent frustration.

Another possible risk to you as a result of your participation in this study is release of confidential information. Once you are accepted into the study, you will be assigned a number that will be used from that point forward. All documents linking you to your assigned number will be locked in a file cabinet and the primary investigator will be the only one with access to this cabinet. These documents will be shredded after 5 years. The electronic data will be saved on an encrypted local desktop and backed up on an encrypted portable hard drive according to your assigned number. It is anticipated that the results of this study will be published in research journals in the future. However, no names or other identifying information will be included in any publication.

Your confidentiality will be protected to the extent that is allowed by law. Subject's information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. It is anticipated that the results of this study will be published in research journals in the future. However, no names or other identifying information will be included in any publication.

The researchers will try to prevent any problem that could happen because of this research. You should let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research.

Participation and Benefits

Your involvement in this study is completely voluntary, and you may withdraw from the study at any time. This study does not have direct benefits to study participants in general. However, clinical evaluations may provide useful information for the stroke subject regarding the overall status of the leg sensation, balance, walking, and lower extremity motor function. *Upon request, results from these clinical evaluations will be available to you after the completion of the study. Although there are no direct benefits to you as a participant, information learned from this study may help the education of health care providers and other stroke survivors and their families.

Costs, Reimbursement and Compensation

Your involvement in this study is completely voluntary and you may withdraw from the study at any time. Following the completion of the Phase I and Phase II studies you will receive a $150 gift card for your participation. Payment will be prorated according to the number of laboratory visits completed ($10/visit). You will need to provide your name, home address, and signature in "Participant Payment Log" approved by Research Office and Sponsor Program at Texas Woman's University in order for us to pay you. You may choose to participate without financial compensation if you do not wish to provide your home address for this purpose.

If you receive a bill that you believe is related to your taking part in this research study, please contact Shih-Chiao Tseng, PT, PhD at 713-794-2309 with any questions.

Questions Regarding the Study

You will be given a copy of this signed and dated consent form to keep. If you have any questions about the research study you should ask the researchers; their contact information is at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the TWU Office of Research and Sponsored Programs at 713-794-2480 or via e-mail at irb-houston@twu.edu.

Sign below only if you understand the information given to you about the research and choose to take part. Make sure that any questions have been answered and that you understand the study.

_____

Print Name of Participant

_____ _____

Signature of Participant Date

The above consent form was read, discussed, and signed in my presence. In my opinion, the person signing said consent form did so freely and with full knowledge of its contents.

_____ _____

Signature of Investigator Date

*If you would like to know the results of this study tell us where you want them to be sent:

Email or Address: _____

If you are interested in receiving the research information related to similar future studies in this laboratory, please indicate in the location below. Note that an indication here of your willingness to receive information for future research studies in this laboratory does not mean you are agreeing to participate and a specific Consent Document would need to be signed to participate in any future studies.

_____ I am willing to be contacted again regarding future studies in this laboratory.

_____ I am not willing to be contacted again regarding future studies in this laboratory.