TEXAS WOMAN'S UNIVERSITY
CONSENT TO PARTICIPATE IN RESEARCH

Title: **Comparison of Motor Skill Acquisition between Individuals with Neurological Disorders and Healthy 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 (TWU). The purpose of this research study is to see how well you can learn a novel leg reaching task via a custom computer program. We also want to know how well your nerve works and how well you walk. Our goal is to quantify the relationship between the individual's ability of learning a new motor task and her/his overall neurological function, movement coordination, and gait performance. You have been invited to participate in this study because you have a medical history of brain injuries as a result of stroke or multiple sclerosis (MS) disease, or you are a healthy individual. This study requires three visits to TWU and the total time commitment for this study will be about eight hours, four hours on the first visit and two hours on the second and third visit at TWU. Following the completion of the study you will receive a total of $60 gift cards for your participation if you have attended all three visits. 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. You will be asked to complete three visits, 1-14 days apart. All tests are done in the control-access, private laboratory rooms. It will take about four hours on the first visit and two hours on the second and third visit. During the first visit, we will measure how well your nerve works and your walking function (see details as follows). If you have had any disorder of the body nerve system such as a stroke or multiple sclerosis 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 any disorder of the body nerve system, 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 novel leg reaching task. The task is to control a computer mouse 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 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. Several one-minute rest breaks will be provided as needed during test. In each visit, it will take approximately a total of 15 minutes to complete a set of leg reaching task. You will then be asked to come back for another two visits 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 three visits to indicate your learning capacity.

For the measurement of nerve activity, we will put a recording electrode on your calf muscle in one leg. Then a low-intensity of electrical stimulation will be delivered to a nerve behind your knee to trigger your motor responses. 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 function, 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.

Potential Risks

Potential risks related to your participation in the study include skin irritation or redness caused by the adhesive tape and muscle soreness or fatigue. 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 from the testing should go away in 24-48 hours. If the soreness/fatigue does not go away, please contact the primary investigator.

Another possible risk to you as a result of your participation in this study is loss of confidentiality. 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 5 years from the end of the study. 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**.**

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. 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 survivors and their families. If you would like to know the results of this study, we will e-mail or mail them to you.*

Costs, Reimbursement and Compensation

If you decide to take part in this research study, you will not incur any additional costs. You will be paid for taking part in this research study. You will be paid a total of $60 if you have attended all three visits. Payment will be prorated according to the number of visits completed. 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 being paid 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, Ph.D 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@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 receive a summary of the results of this study, please provide an address to which this summary should be sent:

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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.