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COVER PAGE

PROTOCOL TITLE:

Novel training environment to normalize altered finger force direction post stroke

PRINCIPAL INVESTIGATOR:

Na Jin Seo, PhD

Trial registration:

Clinicaltrials.gov NCT03995069

Subject's Name: **Date:**

Principal Investigator: Na Jin Seo

Study Title: Novel training environment to normalize altered finger force direction post stroke

SUMMARY
You are being asked to consent to participate in a research study. Your consent is voluntary. The purpose of this study is to determine if 3-dimensional grip training is an effective tool in restoring hand function post stroke. The participation will last 2.5 months. You will be asked to come to the laboratory to practice controlling grip force 3 times a week for 6 weeks. You will see your performance on a computer screen. You will also be asked to come to the laboratory for additional 4-7 visits for assessments of your hand/arm function.
Potential risks include physical and mental fatigue, discomfort, and skin irritation from engaging in the study activity. The potential benefit is that the training may help recover hand functional recovery, although this cannot be guaranteed. The knowledge regarding the potential of using this grip training to improve recovery may guide rehabilitation for stroke survivors in general. Your alternative is not to participate in the research and continue with your normal treatment as recommended by your doctor.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to volunteer for a research study because you have experienced a stroke at least 3 months ago and have a hand impairment. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to determine if 3-dimensional grip training is an effective and safe tool in restoring hand function post stroke. This study is sponsored by the Veterans Affairs (VA). The investigator in charge of this study is Na Jin Seo, Ph.D. Portion of Dr. Seo and her research team's salaries will be paid by this grant. This study is being done at one site at Ralph H. Johnson VA Medical Center. Approximately 60 people will take part.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will have the physical exam and medical history to make sure that you are eligible.
2. If the physical examination and medical history show that you are eligible for the study, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are Group A (people in this group will see their grip forces in 3-dimensions on a computer screen) and Group B (people in this group will see their grip forces in 1-dimension on a computer screen).
3. Both groups will be asked to come to the laboratory 3 times to get initial assessments. Assessments include moving the hand as quickly as possible, gripping hard or soft, and

reaching for, grasping, and releasing an object upon cues. The movements will be timed and videotaped. Muscle and joint sensors may be taped on your skin during these movements. Each assessment will take 1-5 hours.

4. Both groups will have approximately 2-hour grip force training session, 3 times a week for a total of 6 weeks. You will be asked to grip in different directions during this training.
5. Once every two weeks during the 6-week training, you will repeat the hand movement assessments.
6. After the 6-week training, you may be asked for an interview with a member of the research team to discuss the impact of the training on your daily living activities. The interview will take approximately 30 min.
7. One month after the 6-week training, you will repeat the hand movement assessments.

You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures.

While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra blood drawing, extra X-rays, or potential drug interactions. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

C. DURATION

Participation in the study will take about 22 to 25 visits over a period of 2.5 months. Most visits will take 2-3 hours.

D. RISKS AND DISCOMFORTS

1. **Loss of confidentiality:** There is a risk of a loss of confidentiality of your personal information as a result of participation in this study. Researchers will take appropriate steps to protect any information collected about you. The data from your test results will be de-identified once it has been collected and before it is stored. This means your individual results would not be able to be linked to you by others who review the results of this research. Identifiable data will not be shared and will be stored securely.
2. **Randomization:** You will be assigned to a group by chance. The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

3. There is a minor risk of physical and mental fatigue from engaging in the study activity.
4. There is a minor risk of discomfort from having muscle activity sensors or joint position sensors taped on your skin during hand movement assessments. There is a minor risk of skin irritation from adhesives used to affix muscle activity sensors or joint position sensors during hand movement assessments.
5. There is a risk of fall from standing or walking, although you will be wearing a whole body harness to prevent such events.
6. **Unknown Risks**: The training may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your healthcare providers if you have any questions about the risks of usual care.

E. MEDICAL RECORDS and/or CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in your Ralph H. Johnson VA Medical Center's medical record.

F. BENEFITS

The potential benefit to you is that the treatment you receive may prove to be more effective than the other study treatment or than other available treatments, although this cannot be guaranteed. The knowledge regarding the effectiveness of force training may create a new therapy option for people who had a stroke and may benefit stroke survivors in general.

G. COSTS

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these copayments for VA care and medications that are not part of this study.

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H. PAYMENT TO PARTICIPANTS

You will be paid $25 for each of the 7 assessments and $15 for each of the 18 training sessions in this study. If you complete all assessments/training, you will receive $445. If you do not complete the study, you will keep the payments you already received and will not receive additional payments. The payment will be in cash.

The IRS requires a tax form be filed if your compensation exceeds $600.00/year. However, if the payment for participation will be made through Austin Financial Services Center. This will require the use of your Social Security Number and it may generate IRS Form 1099 automatically, regardless of amount.

If you have transportation restrictions (inability to safely drive yourself, lack of caregiver who can provide transportation, inability to safely take public transportation) that would prevent you from otherwise being able to participate in this study, we can request approval for transportation assistance. We can also discuss alternative methods that cost less (e.g., accommodation) up to a thousand dollars.

I. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. The standard therapy for your condition is occupational therapy or physical therapy.

J. DATA SHARING

Data will be shared with collaborating sites, Medical University of South Carolina (MUSC) and the VA Centralized Transcription Services Program. De-identified data will be shared with another collaborating site, North Carolina State University (NCSU), for analysis.

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

We would like to include data collected in this study and from other stroke related studies you may participate in with the MUSC Registry for Stroke Recovery (RESTORE-Pro00037803). RESTORE provides MUSC's stroke recovery research community with a database containing information on research participants including stroke type, disability status, and demographics to assist in recruitment. By including data from this study in RESTORE, MUSC researchers will have access to a

more complete database with key elements of physical function characteristics for more targeted recruitment efforts in the future. Additionally, this could reduce the burden placed on subjects by reducing the duplicative efforts of collecting common data and assessments requested by multiple studies and storing them in one centralized and secure location.

If you consent to participate in RESTORE your data from this study, including your personal health information, will be included in the registry. You will be asked to sign a Release of Study Records Form to share data from other stroke related studies in which you have participated. If you authorize this release your information from those studies will become part of the RESTORE registry study.

K. DISCLOSURE OF RESULTS

Your test results will be disclosed to you upon your request.

L. PHOTOGRAPHS, VOICE AND/OR VIDEO RECORDING

Interview will be voice-recorded for further analysis. The assessment will be videotaped for quality assurance of the assessment. Only approved study personnel will have access to them. After the research is complete, the audio and video data will be stored for 5 years and be destroyed.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

O. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

P. CLINICAL TRIALS.GOV

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 can search this Web site at any time.

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Q. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

Yes, I agree to be contacted

No, I do not agree to be contacted

CONSENT

Your privacy is very important to us and the researchers will make every effort to protect it. Results of this research will be used for the purposes described in this study. These results may be published, but you will not be identified.

The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. There are times when we may have to show your records to other people from Federal agencies that oversee our research such as the Department of Health and Human Service's Office of Human Research Protections (OHRP), the Food and Drug Administration (for FDA regulated research only), the Government Accountability Office (GAO), the VA Office of the Inspector General (OIG), the VA Office of Research Oversight (ORO), our local VA Research and Development Committee, and other study monitors may look at or copy portions of records that identify you. Also, all records in South Carolina are subject to subpoena by a court of law. Any information shared with these outside groups may no longer be protected under federal law.

The VA will provide necessary medical treatment to a research subject injured by participation in a research project. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by the Ralph H. Johnson VA Medical Center. Financial compensation is not available for such things as lost wages, disability or discomfort due to an injury.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

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The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

VOLUNTEER STATEMENT

Dr./Mr./Ms has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

If I have any more questions about my participation in this study or study related injury, or if I have comments, concerns or complaints, I may contact: **Dr. Na Jin Seo at** [redacted].

If I have questions about my rights as a study participant, or I want to make sure this is a valid VA study, I may contact the Medical University of South Carolina's Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. I may call the MUSC IRB (843) 792-4148, or the Ralph H. Johnson VA Medical Center's Research Compliance Officer at (843) 789-7399, if I have questions, complaints or concerns about the study or if I would like to obtain information or offer input.

By signing this document below, I voluntarily consent to participate in this study. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.		
Participant's Name	Participant's Signature	Date
Name of person obtaining consent	Signature of person obtaining consent	Date