Examining the association between psychosocial factors and adherence to a home exercise program for upper extremity recovery in Veteran stroke survivors

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Subject's Name: **Date:**

Principal Investigator: Gabrielle Scronce

Study Title: Examining the association between psychosocial factors and adherence to a home exercise program for upper extremity recovery in Veteran stroke survivors

SUMMARY

You are being asked to volunteer in a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to understand reasons why people with stroke complete the home exercises prescribed for their arm and hand. Participation in this study will include 2-3 in-person visits. First, you will be asked to complete questionnaires, learn about and practice a home exercise program, and learn how to use a movement tracking sensor that looks like a watch on your wrist and connects with a smart phone. This will take approximately 3-5 hours total and can take place over either 1 or 2 visits. You will be asked to wear the sensor daily and take it off at night. You will be asked to complete your home exercise program. Then, you will return for a final visit that will last up to 1 hour during which you will be interviewed about things you think influenced whether or not you completed your home exercise program. Potential risks include irritation or discomfort from the sensor or physical and mental fatigue from engaging in the study activities. There is also the risk of loss of confidentiality with participation. The knowledge regarding motivators and barriers to completing a home exercise program 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 the study staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have had a stroke and have an upper limb impairment. The purpose of this study is to understand reasons why people with stroke complete the home exercises prescribed for their arm and hand. The study is sponsored by the Veterans Affairs Health Care System (VA). The investigator in charge of this study at is Gabrielle Scronce, PT, DPT, PhD. The study is being done at one site at Ralph H. Johnson VA Health Care System. Approximately 35 people will take part in this study.

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B. PROCEDURES

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

1. To make sure that you are eligible, we will ask you some questions, such as your age and your stroke history. We will also ask some questions to make sure that you will be able to take part in study activities that include wearing a sensor and seeing words, images, and numbers on a smart phone screen.

2. If you are eligible for the study, you will be asked to complete two tests in which you will be asked to move your affected and unaffected arms and hands to perform tasks such as moving a small block from one box to another and raising your affected arm as high as you can. These two tests will be videotaped for scoring. Then, you will be asked to answer questions about your perception of your strength, memory, mood, communication, ability to complete daily tasks, mobility, and ability to exercise. Then, you will be instructed in a home exercise program that you will be asked to complete daily. You will also be instructed in how to use a movement tracking sensor, which looks like a watch, on your wrist. The sensor will track the movement of your arm, and the amount of your movements will be shown on an application (app) on a smart phone. You will practice the home exercise program while wearing the sensor. This visit will take 3-5 hours total and can take place over 1 or 2 visits depending on scheduling availability and your preference.

3. We will provide you with the sensor to use during this study. You may choose to use your own smart phone, or one we will provide for this study. We will ask you to wear the sensor during the day and use the app on the smart phone to monitor the movement of your arm. First, you will wear the sensor to measure how much you use your affected arm and hand for 3 days when you do not complete a home exercise program and do not have therapy for your upper extremity. Then, we will ask you to complete your home exercise program outside of any therapy visits you may have. Completing the home exercise program will take about 1 hour per day for 7 days.

4. You will return the sensor and smart phone, if you used a study smart phone, at the final visit. Together with the PI, you will review your arm and hand movement as shown on the smart phone app. Then, we will ask you questions about your experience completing the home exercise program, including things that made it easy or hard to do. We will also ask for you to share more information related to questions asked at the first visit. We will use an audio recorder to record our questions and your answers. This visit will last about an hour.

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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

The first in-person study visit may last up to 5 hours and can be split into 2 visits if you prefer to have shorter visits.

After the initial visit, you will wear the sensor at home for 3 days without completing a home exercise program. You will need to take the sensor off at night to charge it and put it back on in the morning, which may take about 5 minutes. Then, you will be asked to complete a home exercise program each day for 7 days. The home exercises will take about an hour to complete each day.

The final in-person visit will take about an hour.

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 information 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. There is a minor risk of physical and mental fatigue from engaging in the study activity. You may take breaks during visits. The initial visit, which will last 3-5 hours, can be split into 2 visits of shorter duration if you prefer.

3. There is a minor risk of skin irritation from wearing the sensor. There is a minor risk of discomfort in

moving the arm/hand while wearing a sensor on the wrist. If you experience discomfort from the sensor, please remove the sensor.

4. Some questions that we will ask you are sensitive in nature. You can choose to skip questions that you do not wish to answer. We can also provide you with resources if you feel distressed.

E. MEDICAL RECORDS and/or CERTIFICATE OF CONFIDENTIALITY

Documentation of your participation in this study will be included in your Ralph H. Johnson VA Health Care System medical record, and results of research tests or procedures may be included in your Ralph H. Johnson VA Health Care System medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that may identify you to the extent allowed by law.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with hand and arm impairment after stroke.

G. COSTS

There will be no cost to you as a result of participation in this study. 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.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $50 at two visits. The first $50 payment will occur after completing questionnaires, learning and practicing the home exercise program, and taking the sensor home for the home portion of the study. The second $50 payment will occur once you have

completed the home portion of the study, returned the sensor, and completed the interview. The total amount that you will be paid for completing this study is $100.

Payment is provided through direct deposit to your bank account. You will be asked to complete one form to provide your bank account number and your Social Security number.

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, no 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.

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

Audio recording of your interview will be shared with the VA Centralized Transcription Services Program for transcribing.

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.

K. DISCLOSURE OF RESULTS

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

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L. PHOTOGRAPHS, VOICE AND/OR VIDEO RECORDING

The interview will be voice-recorded for further analysis, and the audio recording will be transcribed. Clinical assessments of arm and hand movements will be videotaped for scoring. Only approved study personnel will have access to recordings. After the research is complete, the audio and video data will be stored on VA secure storage and will be destroyed 6 years after completion of the research study.

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.

Q. FUTURE CONTACT

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 the Ralph H. Johnson VA Health Care System and MUSC stroke recovery research community with a database containing information about potential research participants including stroke type, disability status, and demographics, including Veteran status, to assist in recruitment. By including data from this study in RESTORE, Ralph H. Johnson VA Health Care System and 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.

If you consent to participate in RESTORE, researchers approved by the MUSC Institutional Review Board for Human Research to utilize RESTORE 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

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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 Health Care System. 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.

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. Gabrielle Scronce at (334) 590-6943**.

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 Health Care System'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.

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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