Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Stepped Care Model of Psychological Care for Aphasia

Concise Summary

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to evaluate the effects of a psychological well-being program for people with aphasia, which is a language impairment that can occur after stroke.

If you agree to participate, you will be screened to confirm that you can continue in the study. The screening session (~2 hours) includes completion of a questionnaire, language assessment, and psychosocial and other assessments. Your medical records will be requested to confirm eligibility as well. If you can continue based on the screen, you will participate in the psychological well-being program. The program consists of weekly sessions of about 30 minutes for 5 weeks and a follow-up session 1 month after the program is concluded (~2 hours). In total, participation will be approximately 10 weeks.

If effective, participation may improve your psychological well-being, but that cannot be guaranteed as this is an experimental program. Risks include frustration during sessions related to difficulty communicating, psychological discomfort surrounding discussions of emotions and adjustment to life with aphasia, and loss of confidentiality. If you choose not to participate, alternative treatments include mental health counseling or attending a support group.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As the study staff member 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 participate in this study because you had a stroke at least 1 month ago and have aphasia, a language impairment that can occur after stroke. This is a pilot study to research the effects of a new psychological well-being program on psychological well-being, quality of life, and clinical recovery from aphasia. A pilot study is a preliminary study that includes a small number of participants to determine if a larger study is feasible and worthwhile.

The study is sponsored by the South Carolina Clinical & Translational Research Institute (SCTR). The investigators in charge of this study at MUSC are Dr. Deena Schwen Blackett and Dr. Janina Wilmskoetter. The study is being done at 1 site. Approximately 20 people will take part in this study.

B. PROCEDURES

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

Screening Criteria
You will have the following tests and procedures to make sure that you are eligible:

- Questionnaire to obtain demographic information and self-reported history
- Language assessment

The researchers will also check your medical records to gather information about your stroke, neurological history, and other major medical conditions. You are eligible to participant if you have had a stroke in the left-hemisphere of your brain. The presence of other neurological disorders/disease besides stroke (e.g., dementia, traumatic brain injury) will exclude you from participation. We will also confirm the date of your stroke and take note of any other major medical conditions that could affect your performance in study activities.

If you meet the eligibility criteria, you will be allowed to continue with the psychosocial well-being program.

Psychosocial well-being program: This 5-week program will consist of approximately 30-minute sessions focused on ways to enhance your psychosocial well-being tailored to your individual circumstances and interests. You will receive education about psychological issues that are common among people with aphasia and ways to enhance your mood and psychological well-being, including sleep hygiene, behavioral activation (a behavioral intervention for depression), and relaxation training. At the start of each session, you will complete brief mood and psychological assessments, and the rest of the time will be dedicated to activities related to fostering psychosocial well-being. As part of the program, participants will be asked to complete "homework" related to activity monitoring and behaviors that could improve psychological well-being. Between the conclusion of the program and 1-month follow-up, we will also conduct weekly phone calls to check-in about how you are doing and problem solve any issues that come up.

A breakdown of the study timeline is shown below:

Week 1
(Screening/Baseline Session, ~2 hours, in-person visit):

- Consent
- Complete screening activities
  - fill out questionnaire
  - speech and language assessment (answering questions and following directions)
  - complete medical record request authorization form
- Complete assessments focused on mental health, mood, and quality of life (answering questions)
- Complete communication confidence assessment (answering questions)
- Complete cognitive assessment (answering questions and following directions)

(Session 1, ~30 minutes, in-person visit unless necessary):

- Complete weekly assessments focused on mental health and mood (answering questions)
- Psychosocial program activities (education on topics listed above, scheduling activities, problem solving)

Weeks 2-5

(Sessions 2-5, ~30 minutes each, in-person visits unless necessary):

- Complete weekly assessments focused on mental health and mood (answering questions)
- Psychosocial program activities (education on topics listed above, scheduling activities, problem solving)

(Session 6, ~2 hours, in-person visit):

- Complete assessment activities focused on mental health, mood, quality of life, and communication confidence (answering questions)
- Audio-recorded semi-structured interview with researcher, participant, and possibly a care partner (if they are available and interested): This interview will be approximately 30-60 minutes and will include questions on your thoughts about and experiences with the psychosocial program and your participation in the study and your thoughts/experiences about mental health in aphasia. The questions and your answers during this interview will be audio recorded. The recording will be transferred to secure storage and deleted off the recording device after the session and later transcribed for analysis. We plan to use these data to refine the program and understand how we can better address mental health needs in aphasia.

Weeks 7-9

Three weekly check-in phone calls – these will be used to help you maintain the practices learned during the psychosocial program and help you problem solve if you encounter difficulty doing so. For example, you will be asked about whether you've been able to complete your scheduled activities, implementing sleep hygiene practices, or using relaxation techniques.

Week 10 (Session 7, 1 month after completing program, ~2 hours, in-person visit):

- Complete assessment activities focused on mental health, mood, quality of life, and communication confidence
- Audio-recorded semi-structured interview with researcher, participant, and possibly a care partner (if they are available and interested): This interview will be approximately 30 minutes and will include similar questions to the interview in Session 6, but more focused on your experience since completing the program.

In-person visits will take place on MUSC's campus in the College of Health Professions Building C. If necessary, treatment sessions (Sessions 1-5) can be conducted remotely on Zoom.

C. DURATION

Participation in the study will take 8 visits over a period of 10 weeks. The screening/baseline, post-treatment, and follow-up sessions will last about 2 hours and the 5 treatment sessions will last about 30 minutes each. Time dedicated to home activities ("homework"), like activity monitoring and the scheduled activities, will vary by person.

D. RISKS AND DISCOMFORTS

D1. *Patient assessment.* You may have a negative reaction to language and psychosocial testing. For example, this can be caused when persons realize that their performance on a given test is worse than they would have expected. This may cause frustration or irritability. You may also experience fatigue during the longer assessment sessions. We always make sure that ample time is allotted for testing, and you will be allowed breaks as needed.

D2. *Emotional discomfort.* You may experience emotional or psychological discomfort when emotions and psychological well-being are assessed or discussed throughout the study. Emotional support will be provided as needed.

D3. *Loss of confidentiality.* Despite efforts to keep your data/information confidential, there is a risk of a loss of confidentiality of your personal information as a result of participation in this study.

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 any MUSC medical record.

F. BENEFITS

Your participation in this study may improve psychological well-being, but that cannot be guaranteed. While aspects of the psychosocial intervention have been shown to improve psychological well-being, it is not guaranteed or promised that you will personally notice any improvements. You could benefit from the education provided throughout the study on strategies to help with psychosocial well-being. However, you may not have any benefit of participating in this study. This study has the potential to help future patients if the intervention is found to be effective.

G. COSTS

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

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $40 for each session for a total of $320.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system will be explained on an additional sheet.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. Other options would include initiating or continuing speech therapy, mental health counseling and/or joining a virtual or in-person stroke and/or aphasia support group.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) will 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 Registry for Stroke Recovery (RESTORE- Pr000037803). 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 participants 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.

____ YES, I agree to allow the data collected in this study to be included in the RESTORE Database.

____ NO, I do not agree to allow the data collected in this study to be included in the RESTORE Database.

K. DISCLOSURE OF RESULTS

Clinically relevant research results will be disclosed to you upon request after your participation has concluded. You may request copies of your assessments for your own use or to provide to your primary care physician or other member of your healthcare team. Informal verbal request is all that will be required to obtain documents. At the end of the study, you will be provided with additional mental health resources and contact information for additional mental health services if, according to your assessments, you continue to have symptoms of depression, anxiety, or other psychosocial needs.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study included information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- IRB approved Investigators requiring your data for their research projects;
- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you

choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form upon. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

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. 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

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. 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. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

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.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact ***Deena Schwen Blackett, PhD, CCC-SLP at 513-325-6737***. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

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Signature of Participant Date