Study Title: Stepped Care Model of Psychological Care for Aphasia

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PROTOCOL TITLE:

Stepped Care Model of Psychological Care for Aphasia

PRINCIPAL INVESTIGATOR:

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1.0 Objectives / Specific Aims

The aim of this pilot project is to collect preliminary data on the feasibility, acceptance, and efficacy of an SLP-administered psychosocial intervention for people with post-stroke aphasia. The main objective of this pilot project is to determine whether the intervention is feasible and acceptable to participants with aphasia and their care partners, and we predict that it will be. Regarding the efficacy of intervention itself, we hypothesize that the psychosocial intervention will result in lower levels of psychosocial impairment (e.g., symptoms of anxiety and depression, chronic stress), better quality of life, and better retention and adherence to rehabilitation activities (i.e., attending therapies).

2.0 Background

Aphasia is a language disorder that occurs in about one-third of stroke survivors and affects the ability to speak, listen, read, and/or write. Aphasia can have devastating effects on functional communication and quality of life. Consequently, stroke survivors with aphasia are at much higher risk for depression than stroke survivors without aphasia. Approximately 70% of stroke survivors with aphasia experience depression post-stroke (Kauhanen et al., 2000), whereas only about one-third of the broader stroke population experience depression after their stroke (Mitchell et al., 2017). Anxiety disorders are also common in aphasia with prevalence estimated at 44% (Morris et al., 2017). Moreover, psychosocial problems like depression and anxiety negatively affect aphasia rehabilitation outcomes (Fucetola et al., 2006) and quality of life post-stroke (Ayerbe et al., 2014; Donnellan et al., 2010) likely, in part, due to low retention in and adherence to rehabilitation activities.

Despite this high prevalence of mental health issues in people with aphasia, their mental health needs are not being met (Baker et al., 2021; Strong & Randolph, 2021). One reason for this problem is that there are not many psychological interventions that have been adapted for people with aphasia and experimentally validated for this population (Baker et al., 2018). Traditional psychological interventions are heavily language-based making them less accessible to people with aphasia. The stepped care model for psychological care after stroke described by Kneebone (2016) is a framework proposed in the United Kingdom (UK) to target mental health problems in patients based on their individual needs. All stroke survivors enter Level 1 of the stepped care model, which is meant to prevent emotional problems. At Level 1, patients receive screening/assessment for psychosocial issues, psychoeducation, goal setting, problem solving, and monitoring of mood. Patients are moved up to Levels 2-4, depending on their diagnosis (Level 2: mild-moderate psychosocial impairment, Level 3: moderate-severe symptoms, Level 4: severe symptoms with challenging behaviors). Within this framework, patients may receive interventions at Levels 1 and 2 by non-mental health professionals, including SLPs or other paraprofessionals (Montgomery et al., 2010; Ryan et al., 2019). A systematic review examining interventions that target psychosocial wellbeing in post-stroke aphasia identified psychological interventions that fit within Levels 1 and 2 of the stepped care model that may be appropriate for people with aphasia (Baker et al., 2018). However, because the included studies examined stroke patients with and without aphasia within the same sample, it was unclear to what degree the subpopulation of people with aphasia benefited from these interventions. Furthermore, whether these interventions could feasibly be implemented by SLPs was not addressed. SLPs are uniquely positioned to be a “first-responder” to people with aphasia’s mental health needs given their expertise in communication and their understanding

of the impact of aphasia on mental health and daily life (Ryan et al., 2019). Specifically, equipping SLPs with the skills to address psychosocial needs in people with aphasia at Levels 1 and 2 of the stepped care model could have a substantial impact on patient psychosocial and rehabilitation outcomes. However, of the few studies that have examined psychosocial interventions for people with aphasia, some are not meant to be administered by SLPs (Thomas et al., 2012), and all require sessions that are 1-2 hours in length (Ryan et al., 2017; Thomas et al., 2012; Thomas et al., 2019). Furthermore, to our knowledge, no SLP-administered psychosocial interventions for PWA have been tested in the United States. Given the state of the health system in the United States, a psychosocial intervention that requires several weeks of 1-2 hour sessions is unlikely to be feasibly implemented as part of standard clinical practice. Therefore, there is a need for a shorter intervention that SLPs can feasibly implement into their clinical practice with their patients with aphasia. Communication and collaboration of SLPs with mental health professionals is vital for the development of such an intervention. Therefore, a team-based approach to developing and testing a psychosocial intervention for people with aphasia to be administered by SLPs is essential. Our project will address this gap by testing an SLP-administered psychosocial intervention in a sample of people with aphasia that is designed collaboratively by an SLP and clinical psychologist. Intervention sessions are designed to be about 30 minutes, and thus, potentially more feasible for clinicians if it is found to be effective.

3.0 Intervention to be studied

Included participants with aphasia will engage in weekly sessions of an SLP-administered psychosocial intervention for 8 weeks. Activities to be completed throughout the intervention are outlined in detail below. Throughout the intervention, supported communications strategies will be used to facilitate communication with people with aphasia, according to their communication needs/aphasia severity.

The psychosocial intervention includes psychoeducation, behavioral activation therapy, education on sleep hygiene, and relaxation training. Psychoeducation has been shown to be effective at improving the clinical course, treatment adherence, and psychosocial functioning of depressed patients (Souza Tursi et al., 2013). In stroke, specifically, psychoeducation has been shown to improve functional outcomes of patients, reduce caregiver burden, and improve stroke survivors' quality of life (Cheng et al., 2018; Mou et al., 2021). Behavioral activation therapy is rooted in the idea that depression and low mood arise from a lack of reinforcement from the environment and the activities that one partakes in. Behavioral activation therapy has been shown to be an effective treatment for depression in adults (Chan et al., 2017; Mazzucchelli et al., 2009; Pinquarti et al., 2007; Scogin et al., 2005; Soucy Chartier & Provencher, 2013), comparable to the effects of cognitive behavioral therapy in treating depression (Cuijpers et al., 2013; Richards et al., 2016). It has also been tested in the UK with people with aphasia and has been shown to be effective and appropriate for this population as it does not rely as heavily on verbal communication as other approaches (Thomas et al., 2013; Thomas et al., 2019). Stroke survivors are at risk for sleep disturbances and poor quality of sleep (Zhao et al., 2022), which can affect their cognitive and psychosocial functioning. Education on sleep hygiene as part of stroke education may result in higher sleep quality and quality of life (Urcan & Kolcu, 2022). Finally, relaxation training has been shown to be an appropriate intervention for people with aphasia (El-Helou et al., 2022; Ryan et al., 2020) and has been shown to be effective in reducing post-stroke anxiety (Golding et al., 2015) and potentially an effective adjuvant to language therapy (Marshal & Watts, 1976; Murray & Ray, 2001).

Below we outline what will occur in each intervention session with participants.

Intervention Session 1: Session 1 will last approximately 30 minutes and focus on psychoeducation and an introduction to behavioral activation therapy. Session agenda:

- Assessments (5 minutes):
    - Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983)
    - Dynamic Visual Analog Mood Scale (D-VAMS; http://dvams.com/dvams/menu_home_dvams.htm; Barrows, 2013)
    - Simple Aphasia Stress Scale (SASS; Laures-Gore & Rice, 2019)
- Participants will receive psychoeducation focused on (10 minutes):
    - normalizing the participant's psychosocial symptoms (e.g., loss of identity, depression, anxiety) and emotions (e.g., grief, anger, guilt, fear, embarrassment, etc.), which are common after stroke.
    - Discuss common effects of stroke/aphasia on daily life (e.g., social isolation, relationships, work, daily activities).
    - Discuss ways that depression, anxiety, or low mood can affect rehabilitation (e.g., attendance, homework completion, low engagement/motivation, perhaps less neuroplasticity)
- Participants will be introduced to the concept of behavioral activation therapy and the goal to increase the number of enjoyable activities that the participant partakes in. Participants will be asked what types of activities they enjoyed before their stroke, the activities/roles in their lives that they value, and the barriers they've faced to engaging in these activities. A list will be started of activities they enjoy/value and used throughout the intervention. (15 minutes)
- **Homework**: activity monitoring for participants to track how they currently spend their time and their mood during each activity with the help of a care partner if available.

Intervention Session 2: This session will last about 35 minutes and will consist of ongoing behavioral activation therapy and education on sleep hygiene.

- Assessments: HADS, D-VAMS, SASS (5 minutes)
- The SLP will go over the activity monitoring assignment with the participant and schedule valued/preferred activities with the participant for the following week. Participants and the SLP will collaboratively problem solve as concerns about ability to engage in preferred activities arise. (20 minutes)
- The SLP will educate the participant on the importance of sleep and sleep hygiene practices that can improve sleep. The SLP will suggest ways the participant can instill proper sleep hygiene into their routine. (10 minutes)
- **Homework**: 1) engage in scheduled activities, 2) track mood after activities and take note of difficulties that arose in completing the activity, and 3) choose/implement one method for improving sleep hygiene.

Intervention Session 3: This session will last about 30 minutes and will consist of ongoing behavioral activation therapy and relaxation training.

- Assessments: HADS, D-VAMS, SASS (5 minutes)

- The SLP will go over the participant's homework to determine whether they completed the preferred activities and sleep hygiene homework. The SLP and participant will collaboratively problem solve to increase participation in these activities. Additional activities will be scheduled for the following week. (15 minutes)
- The SLP will educate the participant on relaxation techniques, including deep breathing, positive visualization, progressive muscle relaxation, mindfulness techniques, and phone/tablet applications or websites that may help with this practice. (10 minutes)
- **Homework**: 1) engage in scheduled activities with tracking, and 2) choose/implement one method for relaxation.

Intervention Sessions 4: These sessions will last about30 minutes and will consist of ongoing behavioral activation therapy.

- Assessments: HADS, D-VAMS, SASS (5 minutes)
- The SLP will go over the participant's homework to determine whether they completed the preferred activities and relaxation training homework. The SLP and participant will collaboratively problem solve to increase participation in these activities. Additional activities will be scheduled for the following week. (20 minutes)
- **Homework**: 1) engage in scheduled activities with tracking

Intervention Session 5: This session will last about 30 minutes and will consist of ongoing behavioral activation therapy and planning for maintenance of activities.

- Assessments: HADS, D-VAMS, SASS (5 minutes)
- The SLP will go over the participant's homework to determine whether they completed the preferred activities. The SLP and participant will collaboratively problem solve to increase participation in these activities without the weekly accountability. Additional activities will be scheduled for the following week. (20 minutes)

Three weekly booster phone calls: After the five intervention sessions and post-treatment assessments, we will conduct three weekly phone calls to discuss behavioral activation activities and problem solve any issues participants are having with completing pleasant/scheduled activities. These weekly phone calls will occur between the post-treatment assessment session and the 1-month follow-up session.

4.0 Study Endpoints (if applicable)

Primary Outcome:
The primary outcome measure will be HADS, which is a conventional, validated, and widely used measure of psychosocial functioning. This scale consists of 14 items, seven of which contribute to a depression scale and seven that contribute to an anxiety scale. Therefore, three scores can be derived from this measure: an overall score, depression score, and anxiety score. The overall score will be used as the primary outcome measure and this measure will be administered at baseline, at each weekly psychosocial intervention session, post-treatment, and at 1-month follow up.

Secondary Outcomes:
Secondary measures of psychosocial functioning that are specifically validated for the aphasia population will be administered as well, including the D-VAMS, SASS, Stroke Aphasia Depression Questionnaire-10 (SADQ-10; Sutcliffe & Lincoln, 1998) , Behavioural Outcomes of Anxiety Scale (BOA; Kneebone et al., 2012; Linley-Adams et al., 2014, Modified Perceived Stress Scale (mPSS; Hunting Pompon et al., 2018), Stroke Aphasia Quality of Life (SAQOL-39; Hilari et al., 2003), and Communication Confidence Rating Scale for Aphasia (CCRSA; Cherney et al., 2011; Babbitt et al., 2011). Most of these will be administered at baseline, post-treatment, and at 1-month follow-up (see below for a table with the timepoints for each measure and the rationale for inclusion). Two of these outcome measures will be also administered at the weekly sessions, including the D-VAMS and SASS.

A questionnaire related to attendance, retention and adherence to outpatient speech therapy services will also be collected at post-treatment to gather preliminary data on whether the psychosocial intervention was associated with good retention in/adherence to rehabilitation activities. This will be done by administering a questionnaire to participants asking questions about whether they are receiving rehabilitation therapy, and if so, whether they have been attending and following recommendations.

Qualitative interviews will also be conducted at post-treatment and 1-month follow-up to aid in intervention refinement as well. Care partners of participants (e.g., family, friends, spouse) will be invited to participate in the interviews as well.

Table 1. Study Measures

Test Name	Construct	Timepoints	Justification
Primary			
Hospital Anxiety and Depression Scale (HADS)	Measures presence of signs/symptoms of depression and anxiety	All sessions	Overall assessment of psychosocial functioning
Secondary			
Dynamic Visual Analog Mood Scale (D-VAMS)	Measures mood based on reported feelings for 7 scales of emotion	All sessions	A weekly measure of mood fluctuations throughout the study
Simple Aphasia Stress Scale (SASS)	Measures perception of current stress level	All sessions	A weekly measure of acute stress
Stroke Aphasia Depression Questionnaire-10 (SADQ-10)	Measures presence of signs/symptoms of depression in people with aphasia	Screening/Baseline, Post-treatment (Session 6), 1-month follow-up (Session 7)	Aphasia-validated measure of depression to compare with HADS outcome
Behavioural Outcomes of Anxiety Scale	Measures presence of signs/symptoms of anxiety	Screening/Baseline, Post-treatment (Session 6), 1-month follow-up (Session 7)	Aphasia-validated measure of anxiety to compare with HADS outcome
Modified Perceived Stress Scale (mPSS)	Measures perceived levels of stress in people with aphasia	Screening/Baseline, Post-treatment (Session 6), 1-month follow-up (Session 7)	Aphasia-validated measure of chronic stress to compare with other measures of psychosocial functioning

Stroke Aphasia Quality of Life (SAQOL-39)	Measures overall quality of life in people with aphasia	Screening/Baseline, Post-treatment (Session 6), 1-month follow-up (Session 7)	Aphasia-validated measure to examine whether intervention has an effect on quality of life
The Communication Confidence Rating Scale for Aphasia (CCRSA)	Measures how confident people with aphasia are at communicating in a range of scenarios	Screening/Baseline, Post-treatment (Session 6), 1-month follow-up (Session 7)	Aphasia-validated measure to examine whether intervention has an effect on communication confidence
Other Standardized Assessments			
Western Aphasia Battery-Revised (WAB-R)	Measures language abilities	Screening/Baseline	To determine eligibility for study and acquire language profile
Cognitive Assessment Scale for Stroke Patients	Measure cognitive abilities	Screening/Baseline	To examine relationships between cognition and primary/secondary outcome measures
Qualitative Assessments			
Rehabilitation Retention & Adherence	Measure whether they have been participating in rehabilitation activities and adhering to recommendations	Post-treatment (Session 6)	To determine whether psychosocial intervention may have had positive impact on rehabilitation retention/adherence
Participant and Care Partner Acceptability of Psychosocial Intervention	Measure participant and care partners' perceptions about psychosocial intervention	Post-treatment (Session 6), 1-month follow-up (Session 7)	To identify acceptability of the intervention by participants and their care partners and to refine intervention to meet patient needs

5.0 Inclusion and Exclusion Criteria/ Study Population

People with aphasia: People with aphasia will be screened for eligibility through an in-person meeting with a member of the research team after written consent is obtained. Screening will consist of administration of a questionnaire, language assessment, and review of medical records. Medical records will be reviewed to confirm left-hemisphere stroke, time post-stroke, and the absence of other neurological disorders (an exclusion criterion). Medical records will be accessed via Epic if the participant was treated at MUSC for their stroke or requested from their admitting hospital. If the participant is judged to not meet all inclusion/exclusion criteria, they will not be allowed to continue with the remainder of the study.

Inclusion Criteria

- 18-81 years old

- Native English speaker (English fluency by age 7)
- Aphasia as a result of a left-hemisphere ischemic or hemorrhagic stroke (WAB-R Aphasia Quotient < 93.8)
- At least 1-month post-stroke
- Confirmation of left hemisphere stroke per medical records
- Discharged from hospital
- Participant is willing and able to consent for themselves.

Exclusion Criteria

- Uncorrected hearing or visual impairment that prevents completion of experimental activities as determined by self-report
- History of other neurological disorder or disease beside stroke (e.g., dementia, traumatic brain injury) as determined by self-report and/or medical records
- Self-reported history of premorbid learning disability
- Severe auditory comprehension deficits (as indicated by a score of more than two standard deviations below norms on the Auditory Verbal section of WAB-R)

Care partners: Care partners of included participants with aphasia will be invited to participate in the post-treatment and follow-up qualitative interviews to get their perspectives on the intervention and its feasibility. If the participant with aphasia does not have an involved care partner, then no care partner will be included in the interviews.

Inclusion Criteria

- 18+ years old
- Care partner of an included participant with aphasia (e.g., close friend or family member that had frequent interactions with the participant during their participation in the study).

Exclusion Criteria – None.

Efforts will be made to ensure a representative sample of the broader Charleston area in terms of sex/gender and race/ethnicity, however, participants will not be excluded based on sex/gender or race/ethnicity, thus there is potential for an imbalance.

Children will be excluded because stroke in children is rare and presentation of language symptoms is different compared to adults due to brain plasticity and the course of language development.

6.0 Number of Subjects

Twenty participants with aphasia will be recruited for this study to account for attrition and screen failures. We ultimately aim to have 10 participants with aphasia complete the study. This sample size was

chosen because this is a feasibility/pilot study and 10 participants is a feasible sample that will allow us to gather preliminary data to aid in the development of the intervention. We will also recruit up to 10 care partners of participants with aphasia to participate in qualitative interviews after the intervention to gain their perspectives as well. Thus, a total of up to 30 participants will be recruited.

7.0 Setting

Assessment and treatment sessions will be conducted on MUSC's campus in a private treatment room at the College of Health Professions Building C. Screening/Baseline, Post-Treatment, and Follow-Up sessions will be conducted in-person. Treatment sessions will also be conducted in person; however, if necessary, treatment sessions can be conducted on Zoom. Qualitative interviews with care partners can also be conducted via Zoom if care partners are unable to attend in person and would like to partake in the qualitative interview.

8.0 Recruitment Methods

This study will recruit from the Registry for Stroke Recovery (RESTORE-Pro#00037803, IRB approved 9/6/14) which is a research tool sponsored by the National Institutes of Health (NIH) Center of Biomedical Research Excellence (COBRE) in Stroke Recovery with subjects consented for future contact to support stroke recovery research conducted at MUSC. RESTORE staff will query the registry for potential subjects and provide the Principal Investigator (PI) with the contact information of subjects who meet their criteria. The PI or research staff will contact subjects to further screen for potential enrollment.

We will also recruit participants through local advertisement (flyers) in local acute care/inpatient hospitals and outpatient rehabilitation clinics, including the MUSC CARES Medical Clinic. Local speech-language pathologists will be informed about the study and given flyers so they can inform their patients with aphasia about the study. If their patients express interest in participating and give permission to the SLP to share their contact information (name, phone number, and or email) to be contacted by study personnel, the SLP may send their name and contact information to the PI, Dr. Deena Schwen Blackett, who will then contact the patient to give more information and confirm their interest. Otherwise, interested parties can contact the PI via email or phone as listed on the flyer. We will also recruit participants from local stroke and aphasia support groups by attending in person to inform attendees about the study and/or by passing out flyers at meetings. A sign-up list at these meetings will be available for people interested in being contacted directly about the study (requesting name, email, and phone number). Otherwise, interested parties can contact the PI via email or phone as listed on the flyer.

Care partners of participants with aphasia will be recruited for qualitative interviews by asking them whether or not they want to participate in the interview. Only care partners of enrolled participants with aphasia who complete the intervention will be asked to participate.

9.0 Consent Process

Written informed consent will be obtained from all participants with aphasia in person at the start of the first screening/assessment session by a member of the study team in a private room. A member of the study team will go through the entire form with the participant to explain the study in lay terms and answer any questions, and the participant will be given the opportunity to read through the consent form as well. They will be informed that they may choose to withdraw from the study at any time and their decision will not affect their clinical care in any way. If the participant agrees to participate in the study, they will sign and date the combined informed consent and HIPAA authorization. A copy of the signed form will be provided to participants.

Care partners of aphasia will be invited to participate in the interview to get their perspectives on the intervention. The purpose of the qualitative interview will be provided along with a description of what their participation would entail. If care partners are interested in participating in the interview, they will provide verbal agreement to participate. We will request a waiver of signed consent for this group.

10.0 Study Design / Methods

This study is a within-subject, pre-post, repeated measures, mixed-methods design to test the feasibility and acceptance of a psychosocial intervention for people with post-stroke aphasia and to gather preliminary data on its efficacy on improving psychosocial outcomes and retention/adherence to speech therapy. Quantitative primary and secondary outcomes will be administered before and after the intervention and at 1-month follow-up. In addition, qualitative data (questionnaire and interviews) will be collected at the end of the intervention to assess feasibility, acceptance, effects on retention/adherence to speech therapy, and to aid in refinement of the intervention. This includes semi-structured interviews that will be administered to participants with aphasia and care partners. Screening/Baseline, Post-Treatment, and Follow-Up sessions will be conducted in-person. Treatment sessions will also be conducted in person; however, if needed for personal circumstances, treatment sessions can be conducted on Zoom. Qualitative interviews with care partners can also be conducted via Zoom if care partners are unable to attend in person. A full description of all sessions is provided below and a summary of sessions are provided in Table 2 below. In general, if participants get fatigued or emotion at any point during testing or the intervention, breaks will be provided and emotional support will be provided by research personnel, if appropriate.

Screening/Baseline Visit: This session will last approximately 2 hours and consist of obtaining consent for the study, testing for inclusion/exclusion criteria, gathering personal history, and getting to know the participant/establishing rapport. If, based on the completed screening tasks, participants are appropriate for the study, they will be evaluated for psychosocial functioning, communication confidence, and cognition.

The following measures will be administered in the first session:

- Screening assessments
    - Questionnaire (demographic variables, personal/medical history, speech therapy history, psychological history)
    - Western Aphasia Battery-Revised (WAB-R; Kertesz, 2007)
    - Request medical records
- Psychosocial assessments
    - Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983)
    - Dynamic Visual Analog Mood Scale (D-VAMS; http://dvams.com/dvams/menu_home_dvams.htm; Barrows, 2013)
    - Stroke Aphasia Depression Questionnaire-10 (SADQ-10; Sutcliffe & Lincoln, 1998)
    - Behavioural Outcomes of Anxiety Scale (Kneebone et al., 2012; Linley-Adams et al., 2014)
    - Simple Aphasia Stress Scale (SASS; Laures-Gore & Rice, 2019)

  - Modified Perceived Stress Scale (mPSS; Hunting Pompon et al., 2018)
  - Stroke Aphasia Quality of Life (SAQOL-39; Hilari et al., 2003)
- Communication Confidence Rating Scale for Aphasia (CCRSA; Cherney et al., 2011; Babbitt et al., 2011)
- Cognitive Assessment Scale for Stroke Patients (Barnay et al., 2012, 2014)

All assessment data will be collected via a secure data capture platform or on paper. The D-VAMS is an online-based assessment tool and data from that assessment will be exported to an .xml file and saved on the MUSC Network a cloud-based storage account to which only research personnel have access. Medical records will be reviewed to confirm the participant meets inclusion/exclusion criteria. Given that it may take time to obtain medical records to confirm eligibility (if the participant was not treated at MUSC for their stroke), if participants meet the rest of the eligibility criteria based on the questionnaire and WAB-R, then we will proceed with the remainder of the assessments in the Screening/Baseline session and confirm eligibility via medical records after the session.

Session 1: Session 1 will be scheduled once medical records are obtained and the participant's eligibility is confirmed. If possible, Session 1 will be scheduled within the same week as the first session and will last about 30 minutes. This session will focus on psychoeducation and an introduction to behavioral activation therapy. See detailed agenda for intervention sessions in Section 3 above entitled "Intervention to be studied".

Sessions 2-5: Session 2 will be scheduled approximately 1 week after Session 1 and following sessions will be held weekly. Each intervention session will last about 30 minutes. See detailed agenda for intervention sessions in Section 3 above entitled "Intervention to be studied".

Session 6 (Post-Treatment Testing): The post-treatment testing session will last approximately 2 hours and will consist of conducting all primary and secondary quantitative outcomes. Participants will also fill out a questionnaire with information about whether they were enrolled in speech therapy during their participation, whether they attended sessions and did their home programming. Finally, we will conduct a semi-structured qualitative interview to gather information about how feasible the intervention was for participants, their perceptions/opinions about it, and what they might want to see included that was not included.

The following assessments will be administered at the post-treatment testing session:

- Assessments
  - Hospital Anxiety and Depression Scale
  - Dynamic Visual Analog Mood Scale
  - Stroke Aphasia Depression Questionnaire-10
  - Behavioural Outcomes of Anxiety Scale
  - Simple Aphasia Stress Scale
  - Modified Perceived Stress Scale
  - Stroke Aphasia Quality of Life
  - Communication Confidence Rating Scale for Aphasia
- Questionnaire about retention/adherence to outpatient speech therapy

- Qualitative interview regarding perceptions of intervention with participants with aphasia and their care partners

Interviews will be audio recorded and transcribed for analysis. Audio recordings will be made on a Sony digital recorder and transferred immediately after the session to an MUSC Network computer or a cloud-based storage account to which only research personnel have access. Once transferred, audio recordings will be deleted off the recording device.

Weekly check-in phone calls: For the period of time between Session 6 (post-treatment) and Session 7 (1-month follow-up), we will conduct three weekly phone calls with the participant and/or the care partner to discuss behavioral activation activities and problem solve any issues they are having with completing pleasant/scheduled activities.

Session 7 (1-month Follow-Up): The following assessments will be administered a the 1-month follow-up testing session:

- Assessments
    - Hospital Anxiety and Depression Scale
    - Dynamic Visual Analog Mood Scale
    - Stroke Aphasia Depression Questionnaire-10
    - Behavioural Outcomes of Anxiety Scale
    - Simple Aphasia Stress Scale
    - Modified Perceived Stress Scale
    - Stroke Aphasia Quality of Life
    - Communication Confidence Rating Scale for Aphasia
- Qualitative interview regarding perceptions of intervention with participants with aphasia and their care partners

Again, qualitative interviews will be audio recorded and data will be handled the same way as for the post-treatment session.

Table 2. Schedule of Sessions

Session	Week	Description
Screening/Baseline	1	Consent Screening Pre-testing on primary & secondary outcomes
1	1	Daily assessments Psychosocial intervention
2	2	Daily assessments Psychosocial intervention
3	3	Daily assessments Psychosocial intervention

4	4	Daily assessments Psychosocial intervention
5	5	Daily assessments Psychosocial intervention
6	5	Post-testing on primary and secondary outcomes Retention/adherence to speech therapy questionnaire Qualitative interview
n/a	7	Weekly check-in call
n/a	8	Weekly check-in call
n/a	9	Weekly check-in call
7	10	1-month follow-up testing on primary and secondary outcomes Qualitative interview

To compensate participants with aphasia for their time and transportation costs, they will be paid $40 per session. If they participate in all 8 sessions, they will earn $320. Payment for study visits will be made using a pre-paid debit card, called a ClinCard. Participants will be given a ClinCard at the beginning of the study. After each session they participate in, they will receive $40 payment. Care partners of participants with aphasia will not be compensated for their participation in the interviews.

12.0 Data Management

With 10 participants with aphasia, we are statistically powered to conduct feasibility analyses. For our primary quantitative analysis, we plan to conduct paired-samples *t*-tests to compare each outcome measure with 2 time points: baseline vs. post-treatment and baseline vs. 1-month follow-up. Baseline vs. post-treatment comparisons will be used to examine preliminary effects of the intervention on our primary outcome measures (HADS depression scores, HADS anxiety scores), and the secondary outcome measures listed above. Baseline vs. 1-month follow-up comparisons will be used to examine any delayed or maintained treatment effects on the primary and secondary outcome measures. Quantitative feasibility data and psychosocial data will also be examined descriptively given the small sample size.

Data gathered from the retention/adherence to speech therapy questionnaire and the semi-structured interview will also be analyzed descriptively and qualitatively for emergent themes that can be used to further refine and develop the psychosocial intervention.

To maintain participant confidentiality, all participants will be given a participant study ID which will be used on all their study documents and data. Participant names and direct identifiers will be stored separately from collected data and participant names and study IDs will be linked in one password-protected document saved on an MUSC Network computer or cloud-based storage account. Data will be stored in a secure data capture platform, on an MUSC Network computer or cloud-based storage account, and/or on paper in a locked file cabinet in a locked room on campus to which only research personnel have access. Interviews will be audio recorded and transcribed

for analysis. Audio recordings will be made on a Sony digital recorder and transferred as soon as possible after the session to an MUSC Network computer or a cloud-based storage account to which only research personnel have access. Once transferred, audio recordings will be deleted off the recording device. Consent forms will be stored separately from the data collected in a locked file cabinet in a locked room to which only relevant study personnel have access.

The RESTORE registry (Pro#00037803), from which this study will recruit subjects, also serves as a data analysis tool by which interdisciplinary teams may share data across projects and provide MUSC's stroke recovery research community with a more complete registry with key stroke elements. Some subjects may have participated or will participate in other stroke related research studies at MUSC. Sharing data from this and other stroke research studies with RESTORE will allow for more targeted recruitment efforts in the future and could reduce the burden placed on subjects by reducing the duplicative efforts of collecting common data and physical function assessments requested by multiple studies and storing them in one centralized and secure location. The third Aim of this study leverages this ability, as other studies will be better able to target their recruitment based on the information collected in these assessments. Subjects are informed in the consent process if they enroll into the RESTORE registry, their data from this study will be shared. They are given the option to do so or not in the consent form. Subjects will be asked to sign a HIPAA authorization stating their health information may be disclosed to MUSC investigators requiring their data for their research projects upon approval by an Institutional Review Board.

15.0 Risks to Subjects

There is minimal risk to participants in this study. Participants with aphasia may experience occasional frustration during administration of the assessments if they are not performing as well as they like. If this occurs, breaks and emotional support will be provided by the research team. In addition, due to the emotional nature of some assessments and of the psychosocial intervention, participants may experience some negative emotions/psychological discomfort during discussions about adapting to life after a stroke. If this occurs, emotional support will be provided by the research teams and participants will be given a break, if needed. If participants demonstrate or reveal any concerns that would require more urgent mental health support, such as expressing thoughts of suicide, violence, or substance abuse, they will be referred to a mental health expert immediately. We have included a list of mental health referrals in the application in the General Comments 2.0 section of the IRB application. This list will be used to identify an appropriate provider, and the contact information will be provided to the participant. If a participant is demonstrating signs of a mental health emergency determined in consultation with the Co-Investigator and clinical psychologist, Dr. Lisa McTeague, then the participant will be taken to the Emergency Room or 911 will be called. In addition, if participants would benefit from ongoing mental health support/counseling after completion of the study then they will be given the list of mental health providers to choose from. Finally, though efforts will be made to maintain confidentiality, there is a small risk of a confidentiality breach of participant data (for participants with aphasia and care partner interview data). Participants will be warned of these risks during the consent process prior to their agreeing to partake in the research study.

16.0 Potential Benefits to Subjects or Others

Participants with aphasia may benefit from the psychological intervention in terms of their psychological well-being, however, this is not guaranteed as this is an experimental intervention. Although it may or may not benefit participants directly, the information we gather from this study could help us better address the psychological need of people with aphasia in the future as well. Care partners of participants with aphasia will not directly benefit from their participation in the

interviews, but their perspectives could help us refine and develop the intervention to help future patients with aphasia.

17.0 Sharing of Results with Subjects

Participants may request copies of their assessments for their own use or to provide to their primary care physicians or a mental health professional. Informal verbal request is all that will be required to obtain documents. All assessments are coded and labeled with a participant number. At the end of the study, participants will be provided with additional mental health resources and contact information for additional mental health services if, according to their assessments, they continue to have symptoms of depression, anxiety, or other psychosocial needs.

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