Study Protocol

Official Title: Adapting acceptance and mindfulness-based behavior therapy for aphasia

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Scientific Background

Post-stroke aphasia has profound and lasting negative effects on health-related quality of life at levels greater than cancer, Alzheimer's disease, or Amyotrophic Lateral Sclerosis. Aphasia is a language disorder caused by acquired brain injury that affects 30-40% of stroke survivors and more than 2.5 million people in the United States. For stroke survivors with aphasia, their psychosocial responses to the sudden and unexpected loss of language promote or inhibit their ability to adapt, adjust, and recover after stroke.

To a large extent, practicing rehabilitation professionals are currently unprepared to address the relationship between psychosocial adjustment and aphasia rehabilitation. Traditional evidence-based language interventions fail to address psychosocial factors, and speech-language pathologists report feeling unprepared to address counseling needs during aphasia rehabilitation. In addition, mental health professionals report feeling unprepared to work with people with aphasia. Ultimately, workforce training based on effective behavioral interventions is required to address the specific unmet needs of this vulnerable and underserved population. The first step in this endeavor is to develop and pilot integrated interventions that simultaneously address the counseling and communication needs of stroke survivors with aphasia.

The current Stage I project seeks to develop a new intervention will that integrate language compensation training and Acceptance and Commitment Therapy (ACT). ACT is a behavioral intervention designed to improve psychological flexibility, allowing people to take action consistent with their values, even in the presence of persistent emotional distress. Psychological flexibility predicts quality of life and mental health in a variety of populations. In small-scale efficacy studies, ACT has improved psychological flexibility in stroke survivors, and has resulted in large effect sizes when combined with compensatory training in people who stutter. Yet, no prior work has adapted ACT to meet the specific needs of people with aphasia, excluding a large and vulnerable subset of stroke survivors from accessing an effective intervention.

ACT is an ideal match for stroke survivors with aphasia and integrating language compensation training and ACT is more than the sum of its parts. ACT will only be fully accessible to people with aphasia if modified to include communication supports. In addition, language compensation training works by training alternative communication techniques (e.g., writing, gesturing, self-cueing) to maximize functional communication. However, stroke survivors with aphasia must demonstrate psychological flexibility for such training to be effective. They must reconceptualize what it means to communicate and overcome potential fears of how they will be perceived. They must become comfortable using communication techniques in distressing situations they would rather avoid (e.g., communicating with unfamiliar and rude store employees). ACT improves psychological flexibly via approaches such as teaching clients to develop a more flexible response repertoire when pursuing valued life directions and mindfully gaining distance from self-critical thoughts. Improving communication skills and psychological flexibility together will simultaneously address the unmet communication and psychosocial needs of stroke survivors with aphasia.

Study Objectives

Objective: To develop and pilot an "ACT for Aphasia" treatment manual designed to improve communication participation, psychosocial adjustment, and quality of life for stroke survivors with aphasia.

Aim 1: Collaborate with a Stakeholder Advisory Board (SAB) to develop and refine an ACT for Aphasia treatment manual via an iterative design process.

We will work with a SAB of stroke survivors with aphasia and caregivers to develop an initial version of the manual, then refine it using a successive cohort design. The first cohort will consist of 5 participants with aphasia, who will be interviewed after treatment completion. A second cohort (N=16) will complete the revised intervention and provide feedback via interviews to

inform a second manual revision. This will result in a comprehensive, iteratively refined, stakeholder-driven treatment manual.

Aim 2: Establish intervention feasibility and acceptability
Feasibility will be assessed through intervention adherence, recruitment, participation, and completion rates. Acceptability will be assessed using the Client Satisfaction Questionnaire – 8 post-treatment; ACT for aphasia will be considered acceptable if the group mean is ≥28 for the second cohort. As a secondary aim, preliminary effect sizes will also be estimated on pre-post measures of successful communication participation, psychological distress, and quality of life, along with point estimates and standard deviations to inform power analyses for a Stage II efficacy trial.

Study Design & Methods

Participant assignment: given the early phase of this research and the lack of control conditions or groups, there will be no random assignment. Participants will be enrolled in the study as they are referred and found to be eligible, with the first five participants being enrolled in the first study cohort during year 1 while the remainder of participants will be enrolled in the second cohort across years 1 and 2.

Screening procedures:
We will partially assess eligibility prior to informed consent, and finalize screening for eligibility after informed consent via interview and standardized assessments.

Pre-treatment assessments:
Participants will be assessed with a primary outcome measure (the Client Satisfaction Questionnaire-8) and several secondary outcome measures (screening questions, the Communication Participation Item Bank, the Aphasia Communication Outcome Measure-ACOM, the Stroke and Aphasia Quality of Life, the Acceptance and Action Questionnaire – ABI, the Kessler K6 non-specific distress scale, the Acceptance and Action Questionnaire II, the Modified University of Washington Resilience Scale (added for the second study cohort only), and the Comprehensive aphasia test).

Intervention description: the ACT for Aphasia treatment manual will be a 10-session intervention created by modifying an existing ACT manual provided by Dr. Meyer. To meet the specific needs of stroke survivors with aphasia, ACT will be modified in two main ways.

First, the intervention will include modified language and communication supports to address the unique communication challenges faced by people with aphasia that could impede engagement with ACT content. Multi-modality communication supports will be provided by the treating clinician (e.g., writing out key words to support verbal content, summarizing and providing repetitions, providing session summaries to review between sessions). Manual creation will follow existing practice recommendations for modifying counseling interventions for PWA (e.g., simplifying language and increasing use of visual metaphors) which will be reviewed by the SAB.

Second, ACT will be further augmented via individualized language compensation training and a focus on identifying and addressing communication-based barriers to life participation. Language training will focus on active compensatory strategies such as self-cuing, use of alternative modalities (gesture, writing), and use of commonly available technology (e.g., smartphone dictionaries, text-to-speech). The details of this language compensation training will also be determined based on input from the Stakeholder Advisory Board (SAB), and will be revised after reviewing performance and interview feedback from each successive cohort.

Post-treatment phase:
In this phase, participants will be given the same series of assessments received in the pre-treatment phase. In addition, they will have an interview to provide feedback about the intervention and suggestions for improvement.

Post-treatment interviews providing feedback for protocol revision will be administered by trained study staff within three weeks of treatment completion.

Interviews will use a semi-structured, ethnographic interview approach and be video-recorded. These interviews will ask specific questions about the participant's experience and perspective regarding each functional domain of the intervention (i.e., the "Open Up," "Be Present," and "Do What Matters" components of ACT and the individualized language compensation training), and will be asked for suggestions and improvements about the specific content and techniques employed.

Eligibility Criteria

Inclusion Criteria:
Participants will be age 18 or older with an existing diagnosis of aphasia subsequent to left hemisphere stroke as confirmed by a) registry referral sources or b) personal copies of medical records (provided by the participant following informed consent).

Exclusion Criteria:
Exclusionary criteria at enrollment include a history of other acquired or progressive neurological disease, significant language comprehension impairments, significant semantic memory impairments, unmanaged drug /alcohol dependence, and severe diagnosed mood or behavioral disorders that require specialized mental health interventions.

Participants with severe language comprehension impairments will be excluded, as the intervention relies on a base level of comprehension to understand instructions and counseling content. Therefore, participants will be excluded if their spoken language comprehension mean modality T-score on Comprehensive Aphasia Test falls below 40. Furthermore, we will exclude participants with semantic memory deficits (8/10) on the Comprehensive Aphasia Test. We will also exclude participants with active drug/alcohol dependence and progressive neurological disease such as dementia or primary progressive aphasia, as these comorbid factors could affect treatment response and require alternative specialized interventions.

Sample Size Justification

Given the pilot nature of this study, sample size was chosen to determine acceptability and feasibility of our novel intervention without a formal power analysis.

Total sample size (N=21; N=5 for Cohort 1 and N=16 for Cohort 2) is considered to be realistic based on level of project staffing and previous experience recruiting PWA in the Pittsburgh area.

The sample size for Cohort 1 was chosen to provide preliminary feedback for the first version of the treatment manual.

The sample size for Cohort 2 is considered adequate for providing a precise estimate of treatment acceptability. This is because even with an overly conservative attrition rate of 25%, final completion rates would still be N=12, which meets minimum recommendations for providing reasonably precise confidence intervals for continuous variables (Julious, 2005)

Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharm Stat. 2005;4(4):287-291. doi:10.1002/pst.185.