

Study Protocol

Official Title: Strategy Training for People with Aphasia After Stroke

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Scientific Background

Strategy training, delivered during acute inpatient rehabilitation, shows promise for promoting independence and improving executive functions after stroke. Strategy training teaches individuals to identify and prioritize problematic daily activities, identify the barriers impeding activity performance, generate and evaluate strategies to address these barriers, and generalize their learning through iterative practice. Thus, strategy training teaches a process that can be applied to “real-life” activities long after rehabilitation is completed. However, to date, strategy training, as described here, has not been evaluated in people with communication impairments after acute stroke. Yet, approximately 30 to 40% of people in the acute phase of stroke sustain communication impairments, underscoring the importance of evaluating strategy training in this population. The overall aim of this study is to examine the feasibility of an adapted form of strategy training for people with communication impairments who are admitted to inpatient rehabilitation. These analyses will address a critical gap in current rehabilitation research, namely the exclusion of people with communication impairments in acute stroke rehabilitation clinical trials and provide pilot data to inform the design of future inclusive clinical trials seeking to reduce disability after stroke.

Study Objectives

The objective of the study is to assess the feasibility and estimated effects of an adapted strategy training intervention among people with communication impairments after acute stroke inpatient rehabilitation. These data will serve as pilot data to inform the design of a future clinical trials for people with cognitive impairments after stroke, including people with communication impairments.

Study Design & Methods

The study uses a descriptive case series design examining an adapted strategy training intervention that incorporate supported conversation principles developed by Kagan and colleagues (Jensen et al., 2015; Kagan, 1995; Kagan, 1998a, 1998b). Participants are recruited from inpatient rehabilitation facilities within a single academic health center. Participants provide informed consent prior to initiating any research activities. In the case of severe cognitive impairment, designated proxies provide informed consent and participants provide voluntary assent. A trained research assistant approaches participants who appear to meet criteria based on medical record screening, then obtain informed consent and complete screening assessments for participants who expressed interest in participating. All research procedures were approved by the university’s institutional review board.

Intervention

The study built on a previously published strategy training intervention protocol (Skidmore et al., 2017; Skidmore et al., 2015), enhanced with supported conversation principles (Kagan et al., 2001). The core elements of the strategy training protocol are 1) participant-selected activities; 2) participant-directed self-evaluation of performance of these selected activities; 3) participant application of a global strategy (Goal-Plan-Do-Check) to improve performance; 4) therapist use of guiding instruction and feedback to assist participants in self-evaluation and strategy development; and 5) participant-directed application of learned skills to other daily life activities (Skidmore et al., 2017; Skidmore et al., 2015). The strategy training intervention uses a

participant workbook to guide the participant's application of each of these elements, and to support continuity across sessions.

Supported conversation is an approach that places the burden of responsibility for effective communication on the conversation partner, not the person with aphasia (Kagan, 1995; Kagan, 1998a, 1998b; Kagan et al., 2001). This is done by intentionally working to acknowledge and reveal the competence of the person with aphasia and by providing methods to support understanding to allow them to successfully communicate their ideas (Simmons-mackie, 1998). In this study, the adapted protocol incorporates tools such as white boards, letter boards, picture boards, Polaroid photos, and iPad technology, combined with simple verbal and visual cues for communication support. Multi-modal communication, or the use of multiple methods of communication simultaneously, is used to communicate key ideas.

The adapted strategy training intervention protocol was developed by experts in strategy training and experts in speech-language pathology intervention. Trained occupational therapists administered one intervention session per day, in addition to usual rehabilitation, for a total of 10 to 15 sessions.

Assessment

After informed consent and determination of eligibility, a trained, independent team of assessors supervised by a neuropsychologist administer baseline assessments. Demographic information, medical history and comorbidity (Charlson Comorbidity Index), stroke severity (National Institutes of Health Stroke Scale), and aphasia severity (Boston Diagnostic Aphasia Examination Severity Scale) are collected at baseline.

We assess feasibility by examining participant-therapist communication and change in disability scores (for comparison with previous trials that excluded people with aphasia).

The Measure of Participation in Conversation (Kagan et al., 2004) assesses participant-therapist communication during the strategy training sessions by characterizing the degree to which the participant attempts to communicate with the therapist (interaction). Interaction is scored on a scale of 0-4, with higher scores indicating greater participation in communication. Each treatment session is video recorded and later scored by an experienced speech-language pathologist (AA, RC). The reviewing therapists are independent of the strategy training intervention team but are familiar with the study aims. We established a priori that a mean of 2 or greater would indicate feasibility (Kagan et al., 2004).

To assess change in disability, we compare Functional Independence Measure (FIM) scores (Stineman et al., 1996) between study baseline and at inpatient rehabilitation discharge. We established a priori that a Cohen's d_m effect size of 0.5 or greater would indicate feasibility and would warrant further investigation in a larger trial. A moderate effect size of 0.5 would be smaller than the effect sizes seen in a previous strategy training trial ($d=1.06$) (Skidmore et al., 2015) but would still suggest meaningful improvement in outcomes.

Eligibility Criteria

Inclusion criteria are 1) acute stroke and 2) subsequent aphasia as indicated by a) a National Institutes of Health (NIH) Stroke Scale item 9 (Best Language) score of 1 or 2 (indicates the presence of aphasia) (Brott et al., 1989); and 2) Boston Diagnostic Aphasia Examination Severity Scale score of 1 or greater (excludes only people with no functional expression or auditory comprehension) (Goodglass et al., 2001). Participants with any type of expressive, receptive, or global aphasia are included, as long as the above criteria are met.

Participants are excluded if they met criteria for major depressive disorder, bipolar disorder, psychotic disorder, or if they had a previous diagnosis of dementia.

Statistical Considerations

As this is a small descriptive case series study minimal statistical analyses are planned. To assess feasibility, we will calculate descriptive statistics (means and standard deviations). To characterize changes in disability, we will examine change in FIM scores and Cohen's d_{rm} effect sizes using the repeated measures method described by Lakens (Lakens, 2013).