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Study Title	Incorporating strategy training into naming treatment to improve generalization in aphasia
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PARTNERS HUMAN RESEARCH COMMITTEE DETAILED PROTOCOL

Study Title: Incorporating strategy training into naming treatment to improve generalization in aphasia

I. BACKGROUND AND SIGNIFICANCE (including progress report and preliminary studies)

a. Historical background

Aphasia is an acquired communication disorder that results from damage to brain regions responsible for various language processes⁶³. Aphasia is a common sequela to stroke^{2,63} and can result in partial or total loss of spoken and written communication ability^{2,62}. Despite improvements over the past several decades in the treatment of aphasia, roughly 1 in every 250 people in the United States is currently living with aphasia⁶³, many of whom will live with the disorder for the rest of their lives. People living with aphasia often become dependent on their caregivers²⁸, do not return to work²⁸, experience depression⁴, and withdraw from activities that bring them joy and fulfillment²¹. Therefore, it is urgent to identify treatments that will result in meaningful improvements in the language abilities of people with aphasia (PWA).

There are eight clinical subtypes of aphasia, distinguished from one another by differences in their degrees of impairment in verbal fluency, auditory comprehension, and word/phrase repetition^{2,62}. Despite these differences, all PWA experience one common impairment: naming³⁶. Naming, also referred to as 'lexical retrieval' or 'word finding,' refers to one's ability to verbally identify objects⁶⁵. Successful naming requires a person to recognize a concept/object and then retrieve the word that matches the concept from their mental lexicon⁶⁵. Not only is successful naming essential to effective communication, but the severity of a PWA's naming impairment has been shown to be associated with the overall integrity of the language system⁷ as well as with measures of connected speech^{72,73}. The centrality of naming to effective communication and various language processes make naming an extremely common focus of aphasia treatment.

b. Previous Studies and Research Rationale

Nearly all naming treatments for PWA can be categorized as either restorative or compensatory^{32,50}. Restorative naming treatments target language-processing systems⁵ at the word level and reflect the impairment-focused 'body structures and functions' domain of the *International Classification of Functioning Disability and Health*^{32,91} (ICF). Research shows that most restorative treatments improve PWAs' naming ability for objects that are explicitly trained during treatment, as well as objects that were not trained but are *semantically related* to those that were^{10,12,17,18,50,54}. However, most restorative naming treatments do not improve PWAs' ability to name objects that are *not* semantically related to the trained objects^{29,70}. As it is impossible to train the entire universe of objects during a PWA's course of treatment, the lack of consistent generalization to untrained objects brought about by restorative naming treatments is a critical limitation. There is also inconsistent evidence that restorative naming treatments improve PWAs' word finding ability during spontaneous, connected speech (e.g., conversation)^{10,12,15,17,29}. Considering that PWA and their family members identify improved conversational speech as a highly desired rehabilitation outcome^{19,90,92}, the lack of generalization to connected speech is another critical limitation of restorative naming treatments.

In contrast to restorative treatments, compensatory treatments aim to help PWA overcome their naming deficit by training the use of verbal and/or non-verbal acts to supplement their verbal

output or mend communicative breakdowns, such as gesture training, circumlocution, augmentative-alternative communication methods, and the Life Participation Approach^{16,44,71,79}. Compensatory treatments take a function-focused approach to improving PWA's language abilities and reflect the 'activity' and 'participation' domains of the ICF^{32,91}. While researchers agree that compensatory acts are effective in improving functional communication, evidence shows that PWA most consistently use these acts during treatment, but do not transfer their use to spontaneous, everyday communication^{5,76,79}. Therefore, as with restorative intervention, compensatory treatments most reliably lead to treatment-specific gains, but do not result in consistent generalization into everyday communicative contexts.

Several recent studies have explored the potential value of combining restorative and compensatory approaches as a way to engage multiple language systems at once and improve generalization^{14,47,71}. Promisingly, these studies show that combined approaches result in gains at both the impairment and functional communication levels^{14,32,47,71}, providing critical support for this type of practice. Research has also begun exploring the relationship between treatment outcomes and different learning processes^{60,61,78,88} and approaches^{31,85} in PWA. Learning is the primary mechanism by which individuals reacquire old skills and acquire new skills, and thus is a critical component of rehabilitation⁴³. Our recent work suggests that PWAs' outcomes and ability to generalize new knowledge and behaviors depends on whether or not they develop effective strategies that support learning^{31,85}.

Vallila-Rohter and Kiran (2015) conducted a study in which they compared learning outcomes and natural strategy development between PWA and age-matched controls who completed an implicit categorization task⁸⁵. In the task, participants had to categorize a series of stimuli into two categories. Since each stimulus had ten physical features, participants had to consider multiple features before making their decision. Those who were able to consider multiple features together, which is considered the optimal strategy^{34,58}, would learn to categorize more accurately. The authors examined what strategy the PWA and controls naturally developed during the task, as no strategy instructions were given. They found that while some PWA (~10%) naturally developed the optimal learning strategy, the majority (~90%) did not⁸⁵. The authors also found that PWA achieved lower categorization accuracy than their age-matched peers, likely due to their predominant use of suboptimal strategies⁸⁵. These findings provide evidence that PWAs' overall learning success depends on their ability to develop optimal strategies during the learning process, although they are unlikely to develop these strategies on their own.

Gallée and colleagues (2020) conducted a study in which they compared outcomes between two groups of PWA who completed a course of tablet-based naming treatment³¹. One group of PWA was trained to employ an optimal strategy, which was to engage in effortful word retrieval during treatment tasks (considered an optimal behavior), and the other group did not receive this training³¹. The goals of the study were to examine (1) whether an optimal behavior such as engaging in effortful word retrieval could be trained successfully in PWA, and (2) whether strategy training would lead PWA to use the optimal behavior both in the clinic *and* in their home environment. The authors found that the strategy-trained group successfully learned the optimal behavior, as evidenced by decreased cue use and increased response time during task completion³¹. They also found that measures of cue use and response time in the strategy-trained group did not differ between the clinic and the home environment, indicating that the strategy-trained group engaged in the optimal behavior even when a clinician was not present to encourage them to do so, which in turn led to superior gains³¹. This recent work from our lab provides evidence that PWA (1) have the ability to learn an optimal strategy as a result of strategy training, and (2) have the capacity to carry-over use of the strategy beyond the clinic environment, which offers the potential to enhance treatment outcomes.

c. Rationale Behind the Proposed Research

We predict that a treatment approach that incorporates *restorative*, *compensatory*, and *strategy training* components would greatly improve generalization in PWA. Therefore, we propose a treatment protocol that involves: (1) a restorative component aimed at improving PWAs' naming ability, and (2) a strategy training component aimed at improving generalization of a compensatory verbal behavior. In the proposed study, the *restorative treatment component* will be Semantic Feature Analysis^{11,12,50,93} (SFA), a well-regarded naming treatment. The *compensatory behavior* will be circumlocution, a verbal behavior in which PWA describe an object's features if they are unable to name it². Circumlocution is known to facilitate naming²⁹ and assist listener comprehension^{3,29,84}. The features PWA often produce when circumlocuting overlap with many of the features included in SFA. The *strategy training component* will consist of explicit teaching about *when* and *how* to use circumlocution, and practice applying it in moments of naming difficulty. We believe that strategy training will aid in PWAs' consistent and effective adoption of circumlocution as a compensatory behavior to facilitate naming and improve listener comprehension. The results of this study are expected to demonstrate that incorporating strategy training into naming treatment has the power to promote generalization of impairment- and participation-level gains in aphasia. Quick identification of naming difficulty and use of circumlocution will lead PWA to spend less time searching for specific words (improved efficiency) and more time producing informative speech (improved informativeness), which will increase their ability to confidently participate in conversation.

II. SPECIFIC AIMS

Aim 1. Evaluate the effectiveness of naming treatment that incorporates strategy training on naming outcomes. Approach: We will administer a 176-item naming assessment pre- and post-treatment.

1a. Measure patients' naming accuracy for trained and untrained objects. Hypothesis: Consistent with prior studies, we expect that naming treatment will yield medium to large effects for trained objects^{55,66,70}. Additionally, we hypothesize that strategy training will result in an increase in circumlocution-facilitated naming for untrained objects, and yield medium effects for untrained objects.

1b. Determine whether patients with aphasia learn the strategy and consequently demonstrate a change in their language behavior in moments of naming difficulty. Hypothesis: We hypothesize that strategy training will lead PWA to correctly identify the strategy's components post-treatment. We also hypothesize that strategy training will lead PWA to produce more feature words (i.e., engage in circumlocution) during moments of naming difficulty. Specifically, we expect to find medium to large effects on the number of feature words PWA produce during naming attempts post-treatment.

Aim 2. Evaluate the effect of strategy training on patients' language production during connected speech. Approach: We will collect and transcribe connected speech samples, including spoken descriptions of pictures, weekly activities, and personal memories⁷³, pre- and post-treatment. Hypothesis: We hypothesize that strategy training will lead PWA to produce more object and feature words during connected speech. We expect medium to large effects on object words, feature words, and measures of communicative effectiveness⁶⁴.

III. SUBJECT SELECTION

a. Inclusion/exclusion criteria.

Eligible individuals will:

- Experienced a single left-hemisphere stroke,
- Have aphasia due to stroke,
- Be in the chronic stages of their aphasia, at least 6 months post onset of stroke,
- Be between the ages of 18 and 89 years of age, and
- Be a proficient English speaker,
- Have no history of neurodegenerative disease, severe motor speech disorder, significant mental illness, psychiatric disorder, drug/alcohol abuse, or neurological condition that could influence their cognitive, language, and memory systems.

Participants may have concomitant medical problems such as heart disease or diabetes; however, at the time of their participation they will be medically and neurologically stable and at least wheelchair ambulatory.

Participants with a history of minor head injury or short-term loss of consciousness are eligible to participate, however a brief history of these instances will be obtained in order to control for potential secondary impacts to learning and memory systems. Similarly, history of developmental learning disorders will be obtained, as this can affect learning and strategy development/compensatory systems, which are a focus of our research study.

Additional inclusion/exclusion criteria include the following: Eligible individuals must achieve a score of 4 or greater on the Auditory Verbal Comprehension Score, which is a subtest of the Western Aphasia Battery-Revised (WAB-R) for full enrollment/participation in the study. Eligible individuals must also name 1-146 of the 176 items correctly on the initial administration of the naming assessment for full enrollment/participation in the study. Individuals who name 0, or greater than 146 items will be excluded. These criteria will be assessed at the initial study visit, after informed consent has been obtained.

b. Source of subjects and recruitment methods

Individuals with aphasia will be recruited by referral from physicians, speech-language pathologists, and neuropsychologists. We will mail and email recruitment letters to neurologists and speech pathologists in the greater Boston area. Interested professionals will describe the study to the potential participants and ask them to contact the researcher if they are interested in participating in the experiment.

Individuals with aphasia will also be recruited from the MGH Institute of Health Professions Aphasia Center. SLPs will share study flyers with individuals with aphasia and ask if individuals are interested in meeting a member of the research team to learn more about the study. If they express interest, a member of the research team will be invited to come to the end of an upcoming scheduled therapy session to talk more about the study, or Aphasia Center staff can coordinate a meeting between the individual and a member of the study staff. It will be clearly communicated that the treating Speech language pathologist has no affiliation to the research study and that expressing or not expressing an interest to speak to research staff, in no way impacts the therapy services they receive in the MGH IHP Aphasia Center.

In addition, individuals with aphasia will be recruited via word of mouth, flyers, flyers/presentations at local aphasia centers, and emails to community health centers and via listservs (the American Speech-Language Hearing Association (ASHA) Special Interest Group 2 Neurogenic

Communication Disorders listserv, as well as the ASHA Special Interest Group 14 Cultural and Linguistic Diversity listserv). We will also recruit via Rally and the MGH IHP IRB-approved Recruitment Database.

IV. SUBJECT ENROLLMENT

a. Methods of enrollment. We plan to enroll 20 individuals with aphasia in a single-subject design intervention study in which all participants receive the same intervention protocol.

b. Procedures for obtaining informed consent. Once interest in participating in the study is expressed, one of the co-investigators involved in this study will establish contact with potential participants over the phone or via email. The research project will be explained and interested persons will be invited to the research site to discuss the study. The purpose, procedures, possible benefits and risks of the study will be explained to all potential participants. Potential participants will also be instructed that they can withdraw from the experiment at any time.

A trained study staff member, who is not a member of the participant's medical team, will present eligible participants with information describing the purpose of the project, the experimental procedures, potential risks and benefits, and time required. Informed consent will be completed during this meeting. The participant will be given a copy of the signed informed consent, and the original document will be retained by the PI and stored in a locked filing cabinet in the PI's lab. The participant and his/her spouse/next of kin will be invited to the laboratory to discuss the experiment with a member of the research team with expertise in aphasia. In this meeting, research staff will explain the experiment using simple language. She/he will also have sample materials from the experiment such as pictures of stimuli to help explain experimental paradigms. Extra care will be taken to ensure that subjects understand the nature of the experiment. We will offer to read the consent form to these individuals as reading can be difficult and information will be reiterated verbally. Individuals and family members will be encouraged to interrupt, ask questions, and seek clarifications. They will be given time to assess presented information and formulate questions. Individuals with aphasia are considered capable of making informed decisions and provide consent as indicated in the National Aphasia Association Bill of Rights (2005). Therefore, family members may be present when experimental procedures are explained, but individuals with aphasia will be giving or declining to give written informed consent. Regarding consent for video/audio recording, participants will be informed that they can participate even if they do not consent to video/audio recording.

Though we do not anticipate this to occur frequently, if a participant cannot write or is physically unable to sign the consent form, they can make their mark on the signature line in the consent form. People who cannot make their mark on the consent form can indicate consent by other means, e.g., orally, nodding their head, etc. The means by which consent was given by the subject will be documented in the consent form and research record.

For participants participating via Enterprise Zoom, the consent form will be reviewed with the participant and their family member in the same manner, and virtual consent will be confirmed via screenshare. The participant will be sent a copy of the signed consent form via mail.

c. Treatment assignment and randomization. All study participants will receive the same treatment procedures. No assignment or randomization is required.

V. STUDY PROCEDURES

a. Study visits and parameters to be measured: Participants will have the option to participate at the MGH IHP, at their home, or via Enterprise Zoom.

Once participants are consented, the typical study sequences include (*also in Figure 1*): Each step is described in additional detail in the section that follows.

- 1) Pre-treatment: Completion of pre-treatment cognitive-linguistic assessments, naming probes, and spontaneous speech probes (sessions approximately 2 hours in length over an average of 3-5 days to mitigate any effect of fatigue on assessment performance).
- 2) During Treatment: Participation in the treatment for a period of eight weeks. All participants will receive the same treatment. Participants will receive in-person therapy at the MGH Institute of Health Professions, home visits, or virtual sessions (via Zoom). Participants will attend three 70-minute treatment sessions per week for eight consecutive weeks. Treatment sessions will be conducted by a certified SLP. Starting on Week 2, the first treatment session of each week will begin with a 30-minute assessment, consisting of a naming probe, a connected speech probe, and a strategy knowledge probe, in which the participant will be asked to provide the six strategy components. Treatment will stop at the end of the eight weeks, or after three consecutive naming probe performances over 90% accuracy, whichever occurs first.
- 3) Post-treatment re-administration of assessments: Participants will complete the same cognitive-linguistic assessments, naming probes and spontaneous speech probes as they did pre-treatment within 20-30 days following the last treatment session. Sessions will last approximately 2 hours in length over an average of 3-5 days.
- 4) Post-treatment tests of retention: Participants will attend two additional post-treatment sessions one month and two months after the final treatment session. During each post-treatment session, participants will complete a 176-item naming assessment, one connected speech probe, and a strategy knowledge probe.

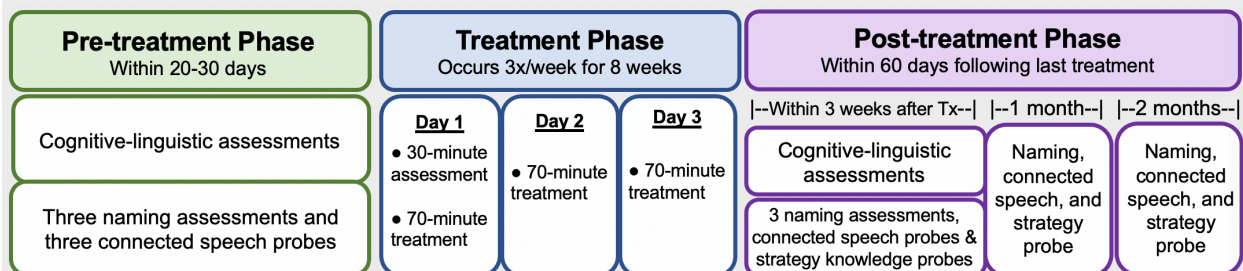


Figure 1. Treatment Timeline

Phase 1) Pre-treatment:

a) Cognitive-linguistic assessments. Eligible and consented participants will complete a battery of standardized cognitive-linguistic assessment, including:

- The Western Aphasia Battery-Revised (WAB-R)⁴⁶,
- General Health Questionnaire-12³⁵,
- Stroke and Aphasia Quality of Life Scale⁴¹,
- Subtests of the Cognitive Linguistic Quick Test-Plus (CLQT+)³⁹,
- The Metalinguage in Aphasia Assessment⁴⁰ (MetAphAs),
- The Communication Confidence Rating Scale for Aphasia (CCRSA),
- The Scenario Test⁸⁶

All assessments will be administered via paper and pencil, unless the participant is participating remotely. If they participate remotely, a fully encrypted device will be utilized but all responses will still be collected via paper and pencil.

b) Naming assessments and connected speech probes: Participants will complete three pre-treatment naming assessments to establish a stable baseline⁸³ (*Figure 1*). During each baseline session, participants will complete a 176-item naming assessment and one connected speech probe. The 176-item naming assessment has objects from eight categories: *animals, clothing, household objects, fruits and vegetables, occupations, other foods, tools, and transportation*^{37,45,51}. Participants will be asked to name each object. To elicit connected speech, we will ask participants to verbally describe a picture, weekly activity, and/or personal memory (e.g., *Tell me all about your weekend*). *Naming assessment and connected speech probe coding:* We will calculate naming accuracy from the naming assessments and transcribe participants' pre-naming verbalizations in order to later analyze and characterize their pre-treatment naming attempts. We will also transcribe and analyze participants' connected speech samples using Correct Information Unit (CIU) analysis⁶⁴, which provides measures of communicative efficiency and informativeness. *Treatment and naming probe object selection:* Participants' performance on the three pre-treatment naming assessments will determine which objects are either: trained during treatment, included in weekly naming probes, or untrained and used to test for generalization post-treatment. Any objects a participant is unable to name on one, two, or three assessments will be included in the participant's object list. Of the included objects, we will create separate treatment and naming probe object lists taking into account the objects' semantic category and complexity.

Phase 2: Treatment

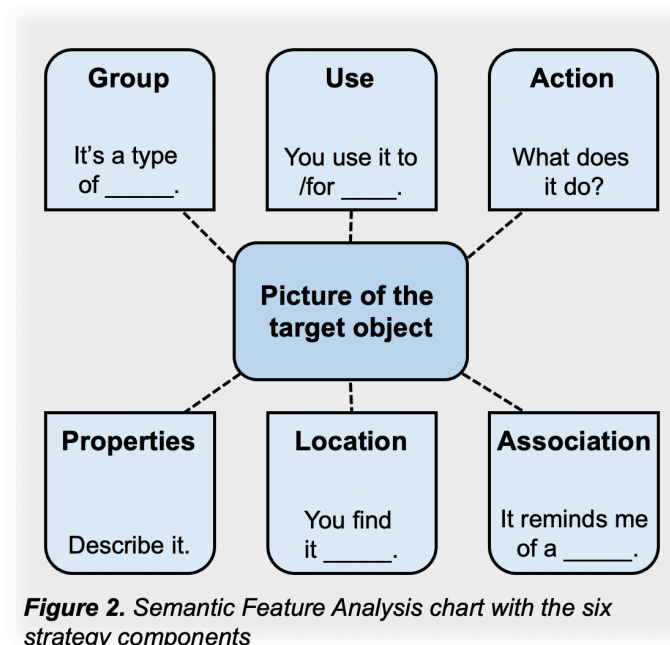
Each treatment session will have three sections:

- *Strategy Education (~ 15 minutes),*
- *Naming Treatment Plus Strategy Application (~40 minutes),*
- *Strategy Debrief (~15 minutes).*

Strategy Education. The clinician will:

- **(a)** provide education on object naming,
- **(b)** work with the participant to develop strategies to quickly identify instances in which they are unable to name an object,
- **(c)** teach the participant to immediately begin generating feature words, i.e., circumlocuting, once they realize they are unable to name an object, and
- **(d1)** teach the participant the six types of feature words they can produce during circumlocution (i.e., the six SFA framework components, *Figure 2* below). The clinician and the participant will work together to learn and memorize the six components. Once the participant is able to independently identify four of the six components across three sessions, *Strategy Education* will change as follows.

- The clinician will review steps **(a – c)** and then,
- **(d2)** ask the participant to list the components. The clinician will provide reinforcement and cues for any strategy components the participant is unable to independently identify. The clinician will also ask the participant to describe any recent instances in which they had success using the strategy at home or out in the community.



Naming Treatment Plus Strategy Application.

- **(e)** The clinician will place a picture of an object from the treatment list in front of the participant and ask whether the participant can name it. If the participant says no, the clinician will ask them what they should do next (circumlocute) and encourage them to do so. If the participant says yes, they will name the object and the clinician will ask the participant what they would have done *had they been unable* to name it (circumlocute) and encourage them to do so.
- **(f)** The clinician will encourage the participant to provide as many features as they can during circumlocution. This step engages the participant in *independent feature generation*, identified as the “active ingredient,” of SFA³⁷.
- **(g)** The clinician will ask the participant to identify which of the strategy’s components their description included (e.g., If they described a **dog** as, “an **animal** that **barks**,” they would identify their description as having included the **category** and **action** strategy components). This step reinforces their knowledge of the strategy’s components.
- **(h)** The clinician will ask the participant to identify which of the strategy’s components were **not** included in their description (in this example, *description, location, association, and function*), and to generate one additional descriptive feature using the remaining strategy components. This step reinforces the strategy’s components and gives the participant

additional opportunities for independent feature generation. The clinician will give the participant another opportunity to name the object if they had been unable to name it during (e) above.

This process (e – h) will be repeated for approximately eight treatment objects (~5 minutes per object). Alternate methods. If/when a participant is unable to independently produce any feature words about an object, the clinician will provide cues to guide them. Cues will be given from least to most facilitative, starting with general questions (e.g., *What does it do?*), to a binary choice (e.g., *Does it bark or meow?*), and eventually providing the correct feature response (e.g., *It barks.*)³⁷.

Strategy Debrief. The final portion of the session will include a debrief, which is regarded as a critical step in the learning process and enables learners to gain insight from direct experience and apply it to future situations^{52,77}.

- (j) The clinician will ask the participant for their reaction and opinion about the treatment session.
- (k) The clinician will provide positive reinforcement²⁶ by describing at least two instances during *Naming Treatment Plus Strategy Application* in which the participant effectively applied the strategy.
- (l) Finally, the clinician and participant will identify opportunities at home in which the participant could envision employing the strategy. The purpose of the debrief is to reinforce the strategy's applicability in all environments.

Phase 3 Post-treatment re-administration of assessments: Participants will complete the same cognitive-linguistic assessments, naming probes and spontaneous speech probes as they did pre-treatment within 20-30 days following the last treatment session.

Phase 4 post-treatment tests of retention: Participants will attend two additional post-treatment sessions one month and two months after treatment completion to evaluate retention. During these study visits, participants will complete naming assessment and a connected speech task in which we will ask participants to verbally describe a picture, weekly activity, or personal memory description (e.g., *Tell me all about your weekend*).

b. Drugs to be used: N/A

c. Devices to be used: N/A

d. Procedures/surgical interventions: N/A

e. Data to be collected and when data is to be collected

Pre- and post-treatment data: All pre-treatment and post-treatment cognitive-linguistic assessment data will be collected during pre- and post-treatment assessment sessions. This data will be collected on each respective assessment material's proper test booklet. Data from pre- and post-treatment naming probes will include naming accuracy and circumlocution attempts (i.e., naming attempts). Data from pre- and post-treatment spontaneous speech probes will include verbatim transcriptions of each participant's responses to the spontaneous speech probes (e.g., *Tell me all about your weekend*). Naming and spontaneous speech probe data will be collected

during the three pre-treatment and six post-treatment sessions. Audio recordings of naming probes will be randomized and coded for accuracy.

During treatment data: During treatment, we will collect treatment session data and weekly probe data. Weekly probe data will be the exact same as the pre- and post-treatment naming and spontaneous speech probe data (naming accuracy, circumlocution attempts, verbatim transcriptions), in addition to strategy knowledge data probes (i.e., asking participants to identify as many of the six strategy components as possible). These weekly probes will occur once per week for the eight weeks of treatment. During the Strategy Education section of treatment, data will include quantification of strategy component knowledge (out of a possible six). During the Naming Treatment Plus Strategy Application section of treatment, data will include: Percent of items participant correctly identified whether they would be able to name the object before attempting to name it, naming accuracy before feature generation, number of features generated by the participant per item, number of correctly matched features with feature types per item, number of additionally identified feature types per item, and naming accuracy after feature generation. During the Strategy Debrief section of treatment, data will include: transcription of participant's reaction and opinion of treatment session and number of home-based opportunities identified by the participant in which they could use the strategy.

VI. BIOSTATISTICAL ANALYSIS

a. Specific data variables being collected for the study.

Cognitive-linguistic assessments (pre-treatment and post-treatment): Language and cognitive assessments will be scored based on standardized norms and methods of administration and scoring provided in testing manuals. Cognitive-linguistic assessments and in-person treatment sessions will be videotaped to provide a measure of reliability of scoring and administration of assessments and treatment.

Naming, spontaneous speech, and strategy knowledge probes (pre-treatment, during treatment, and post-treatment): We will collect (1) naming accuracy, (2) verbatim pre-naming verbal naming attempts, (3) verbatim responses to spontaneous speech probes, and (4) number of identified strategy components.

Treatment data: We will collect data on: (1) number of identified strategy components and (2) number of feature words during moments of naming difficulty.

b. Study endpoints. The participant's participation with the study will end when they request to withdraw from the study, or after the post-treatment assessments have been completed, whichever occurs first.

c. Statistical methods.

We will use visual inspection⁶⁸, mixed-effects modeling, and effect size calculations to analyze all results. For visual inspection, we will use the conservative dual-criterion method^{20,27,82}. We will use mixed-effects modeling to estimate the extent to which treatment-specific factors (fixed effects), pre-treatment cognitive-linguistic measures (random effects), and participant-specific factors (random effects) explain post-treatment naming and connected speech outcomes. We will calculate effect sizes by subtracting a participant's average pre-treatment score from their average post-treatment score and dividing by the pre-treatment standard deviation⁸.

Aim 1a. Measure PWAs' naming accuracy for trained and untrained objects. We will calculate effect sizes to measure the effect of treatment on participants' naming accuracy for trained objects, untrained semantically-related objects, and untrained semantically-unrelated objects between pre- and post-treatment. *Hypotheses:* Consistent with prior studies, we expect that naming treatment will yield medium to large effects for trained objects. Additionally, we hypothesize that strategy training will result in an increase in circumlocution-facilitated naming for untrained unrelated objects and yield medium effects for all untrained objects, regardless of semantic relatedness.

Aim 1b. Determine whether PWA learn the strategy and consequently demonstrate a change in their language behavior in moments of naming difficulty. *Analyses:* We will use visual inspection to examine participants' identification of the strategy components from Treatment Week 2, to Week 8, to post-treatment sessions. We will calculate effect sizes to measure the effect of treatment on the total number of feature words produced during naming assessments and on the average number of feature words produced per naming attempt during assessments, from pre- to post-treatment. *Hypotheses:* We expect that strategy training will result in participants' ability to identify all six strategy components by Week 8 and at least four of the strategy components during maintenance/retention sessions. We also hypothesize that strategy training will lead PWA to produce more feature words (i.e., engage in circumlocution) during moments of naming difficulty. Specifically, we expect to find medium to large effects on the number of feature words PWA produce during naming attempts.

Aim 2. Evaluate the effect of strategy training on patients' language production during connected speech. *Statistical Analyses:* We will calculate effect sizes to measure the effect of treatment on number of object words, feature words, CIUs, and CIUs/minute participants produce during connected speech tasks. *Hypotheses:* We hypothesize that strategy training will lead PWA to produce more object and feature words during connected speech. We expect medium to large effects on object words, feature words, CIUs, and CIUs/minute during connected speech from pre- to post-treatment.

Additional analyses: We will create mixed-effects models using treatment-phase data (e.g., strategy component identification) as fixed effects, and pre-treatment cognitive-linguistic measures (e.g., CLQT+ results) and participant characteristics (e.g., aphasia severity) as random effects to further understand post-treatment outcomes. We will calculate normalized change scores to measure participants' overall improvement relative to their baseline performance and maximum possible change⁵⁶. We will report changes between participants' pre- and post-treatment WAB-R Aphasia Quotient⁴⁶ scores using the benchmarks proposed by Gilmore and colleagues³³.

d. Power analysis (sample size, evaluable subjects). We will recruit 20 PWA subsequent to single left-hemisphere stroke with the goal of collecting complete data on ten participants, which is adequate for single-subject design^{68,69}.

VII. RISKS AND DISCOMFORTS

a. Complications of surgical and non-surgical procedures. Language and cognitive assessments and therapy tasks are noninvasive and pose no medical risks. Participants may experience some frustration during the course of the study, however, this frustration is not expected to be more than that what would be faced in situations requiring focused, sustained

attention for learning. A researcher will be present to answer any questions or concerns participants might experience.

All materials (history forms, data obtained during behavioral tasks) are for research purposes only and will be kept in confidence. Forms containing personally identifying information (history forms and data collected during cognitive-linguistic assessments) will be kept in a locked filing cabinet at the MGH IHP to which only the PI and approved study staff have access.

In-person sessions will occur in The Aphasia Center at 2 Constitution Wharf, Boston, MA, 02129, or in quiet rooms in building 79/96 the MGH IHP's research building. Rooms are equipped with wall-mounted cameras (Eagle 1.3 Megapixel camera), which will be used to video/audio recording assessment and treatment sessions. For in-person and at-home sessions, video/audio recordings will be collected using password-protected Enterprise Zoom on an encrypted, password protected laptop. For virtual sessions, video/audio recordings will be collected using password-protected Enterprise Zoom, and study staff will launch the video conferencing in a private and secure area. All digital data (i.e., video/audio recordings) will be transferred to a secure network or web-based electronic lab notebook, LabArchives, and/or Dropbox, maintained by Partners, which can only be accessed by the PI and approved study staff via electronic ID. These digital files will be coded with identification codes and will not contain personally identifiable information. Deidentified standardized assessment scores will be transferred from paper forms to digital forms in RedCap. Video data will be recorded and kept on a secure network maintained by Partners and accessed only by approved researchers. Deidentified video clips will be kept for education purposes (teaching within MGB only). If we do utilize videos, participant faces will be blurred/obscured as to remain de-identified. Video and audio recordings will be retained for seven years and then be destroyed.

b. Drug side effects and toxicities: N/A

c. Device complications: N/A

d. Psychosocial (non-medical) risks: N/A

e. Radiation Risks: N/A

VIII. POTENTIAL BENEFITS

a. Potential benefits to participating individuals. It is hoped that the treatment will result in behavioral gains for around 80% of enrolled subjects, as demonstrated through improved performance on naming batteries and cognitive-linguistic assessments administered post-treatment.

b. Potential benefits to society (e.g. increased understanding of disease process). The current study is designed to address the important issue of language rehabilitation after aphasia-inducing stroke. Speech-language therapy is the treatment for aphasia, and relies heavily on behavioral therapies that implicitly engage systems of learning. Additional research is needed to demonstrate which types of therapies are efficacious for patients and how potential modifications to instruction method might impact therapy outcomes.

IX. MONITORING AND QUALITY ASSURANCE

a. Independent monitoring of source data

The PI or study staff will conduct ongoing review of data to ensure completeness, accuracy and compliance with protocols. Quarterly review will ensure that participant inclusion is in adherence with enrollment criteria, that records of subject enrollment are up to date, and that procedures and study visits are being completed as proposed. Review will be completed by the PI or study staff. In the event of an adverse event, the event will be immediately reviewed. Continuing reviews will be submitted in accordance with the IRB.

b. Safety monitoring (e.g., Data Safety Monitoring Board)

Protection of subject privacy: Forms containing personally identifying information (history forms and data collected during cognitive-linguistic assessments) will be kept in a locked filing cabinet at the MGH-IHP to which only the PI and approved study staff have access.

Deidentified assessment and treatment data will be transferred to a secure network maintained by Partners, which can only be accessed by the PI and approved study staff via electronic ID. These digital files will be coded with identification codes and will not contain personally identifiable information. A single subject file kept on the secure network, under additional password protection will be the only location that stores the link between study codes and subject identifying information. Deidentified standardized assessment scores collected on paper will be transferred from paper forms to digital forms and entered into RedCap, a HIPAA compliant, web-based software application hosted by Partners. Data will also be stored on Lab Archives and Partners Dropbox.

Video data will be kept on a secure network maintained by Partners and accessed only by approved researchers. Deidentified video clips will be kept for education purposes within MGB. If we do utilize videos, participant faces will be blurred/obscured as to remain de-identified. De-identified data are kept for possible future analyses, which will be submitted for approval. If we re-analyze data in the future, we will notify and submit an application for approval from the IRB.

Sending data to outside collaborators: Accuracy and response data from assessments and treatment tasks may be sent to research collaborators outside of Partners. We plan to contribute de-identified assessment results and spontaneous speech responses to the AphasiaBank by TalkBank (<https://aphasia.talkbank.org/>), which is a shared database of multimedia interactions for the study of communication in aphasia. Access to the data in AphasiaBank is password protected and restricted to members of the AphasiaBank consortium group. All data will be coded with study codes only and will not contain identifiers.

Receiving data from outside collaborators: No data will be received from outside of Partners.

d. Adverse event reporting guidelines: Since the risks associated with participation in this study are low, we do not anticipate serious adverse events. In the case of an adverse event, the event will immediately be assessed and the IRB office will be contacted. Participant confidentiality will be maintained unless otherwise directed and approved by the IRB.

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