Title: Assessing an Animal-Assisted Treatment Program for Adults With Aphasia: The Persons With Aphasia Training Dogs Program

Document Date: October 28, 2024

Protocol

Study Title: **Assessing an animal-assisted treatment program for adults with aphasia: the Persons with Aphasia Training Dogs (PATD) Program**

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Principal Investigator: Sharon M. Antonucci, PhD CCC-SLP

PROTOCOL SYNOPSIS

This study is an investigation of the feasibility of administering, and quantifying the effects of a canine-assisted aphasia treatment entitled, the Persons with Aphasia Training Dogs Program. Individuals with aphasia are trained in using positive reinforcement techniques to train dogs in basic obedience skills. On program completion, participants are evaluated on their ability to use the techniques and are assessed for the effects of program participation on psychosocial aspects of living with aphasia and on cognitive-linguistic factors. It is hypothesized that 1) persons with aphasia will be able to independently cue a dog to perform basic obedience skills and that 2) participants will demonstrate increases in self-confidence and social engagement.

Participants self-select into groups based on interest and dog-status: a) PATD participants working with family dog or b) PATD participants working with PSPCA (Pennsylvania Society for the Prevention of Cruelty to Animals) shelter dogs. Guidance is provided relative to the fact that some interested participants may have a family dog that is not eligible to participate (e.g., bite history), in which case the participant would be invited to participate with PSPCA dogs. All PATD and behavioral assessment sessions are conducted individually, i.e., between an individual participant and members of the study team.

The program was previously run as an activity offered by the MossRehab Aphasia Center. The current study will enroll a minimum of 20 PATD participants and is informed by the PI's experience of administering the program and commensurate to the timeline and resources of the funding mechanism. For this feasibility study, data analysis will be performed using criterion-referenced benchmarks to assess within- subject effects and, for secondary analyses between-group (immediate vs. waitlist) differences where possible**.**

SIGNIFICANCE

Aphasia is an acquired language impairment, most commonly resulting from stroke, that affects more than 2 million Americans. The hallmark impairment associated with aphasia is difficulty with word retrieval, which can sometimes be so severe that persons with aphasia (PWA) are able to produce only one or two words in an utterance. By definition, the language impairment in aphasia exists in the context of relative preservation of cognitive functioning, leaving PWA having retained their personality, their intellect, and their drive to engage with those around them trapped inside a brain that "knows what it wants to say, but just can't get it out". Whereas the definition of aphasia highlights the linguistic impairments associated with aphasia, those living with aphasia often highlight its psychosocial consequences that include loss of identity (Musser et al., 2015; Shadden, 2004), loss of confidence (Babbitt, 2010), and social isolation (Davison et al., 2008; Vickers, 2010). Aphasia rehabilitation aligned with the principles of the life participation approach to aphasia (LPAA, Chapey et al., 2000) bridges the gap between rehabilitation of language skills and the use of those skills to engage in meaningful communication and activities. As first described by the "LPAA Working Group" in 2000, the LPAA emphasizes not only the need to facilitate communication for and with PWA, but to situate the use of communication skills in the context of the "real life" goals that PWA have for themselves relative to engaging with and participating in their communities (Chapey et al., 2000). To realize these goals, clinicians facilitate not only development of linguistic skills and strategies, but also reduction of barriers to community participation for PWA, both internal (e.g., reduced communicative confidence) and external barriers (e.g., community members reluctant to communicate with people with aphasia) (Simmons-Mackie & Damico, 2001; Simmons-Mackie & Kagan, 2007).

From the perspective of community (re-)engagement, canine-assisted treatment is perfectly suited to aphasia rehabilitation. People with aphasia often are 'punished' for their communication attempts, being ignored or actively rejected, when they have difficulty. In their role as social catalysts, dogs can promote social interaction

by enticing potential communication partners and promoting communication partners' trust in the PWA accompanied by the dog (Beetz, 2017).   In addition to providing an engaging presence to talk to and about, as non-judgmental recipients of care-taking and attention, dogs can increase positive mood, and feelings of self-efficacy and self-confidence, and contribute to improvements in self-perceived quality of life and ability to cope with stressful events (Beetz, 2017; Gee et al., 2018). The limited available evidence specific to PWA indicates PWA who participate in canine-assisted treatment report increased feelings of motivation to participate in and benefit from traditional language treatment offered in the presence of a dog, as well as experiencing more opportunities to practice communication when they are with the dog (Adams, 1997; LaFrance, 2007; Macauley, 2006). While compelling, the promise for benefit suggested by extant AAT studies with PWA is compromised by the same challenge noted in the wider AAT evidence base, a lack of replicable and manualizable methods (Gee, 2018; Morrison, 2007; O'Haire, 2015), such that there is little to no information specifying the procedures used during treatment and even less regarding the role of the dog, beyond being present, in facilitating any observed gains.

The gap in the AAT evidence base particularly with respect to PWA is striking also in light of the fact that PWA may be ideal candidates for canine-assisted treatment owing to a fundamental tenet of aphasiology that, "people with aphasia communicate better than they talk" (Holland, 1977). They achieve this "better" communication by capitalizing on their strengths. When their words fail them, a strength many PWA use to support communication is preserved pragmatic skill, including the ability to use and interpret tone of voice, facial expression, gesture or other 'body language' in the sharing of meaningful communication (Dronkers et al., 1998; Holland, 1977; Wulfeck et al., 1989). It is these types of skills that are critical in understanding and responding to dogs (Andics et al., 2016; Miklosi et al., 2003; Reid, 2009; Teglas et al., 2012). In this way, canine-assisted treatment for PWA provides for rehabilitation from a perspective of strength, capitalizing on what PWA can do and how that can be brought to bear in accomplishing what is most important to them. Our *Persons with Aphasia Training Dogs* program represents a convergence of 'what are strengths' and 'what is important', through creation of an animal-assisted treatment in which the strengths of PWA are brought to bear in a rehabilitation program designed to target what they report is important to them.

We hypothesize that 1) PWA can learn the skills of positive reinforcement dog training, and 2) that new skill learning in the context of working with dogs will provide psychosocial benefits including increased self-confidence and social participation. These hypotheses are supported by our preliminary data, and by evidence in the human-canine interaction and animal-assisted treatment literatures. The fact that the annual incidence of aphasia is anticipated to reach 180,000 by 2020, coupled with recent evidence that twenty percent of newly aphasic individuals report having no friends six months post-stroke (Simmons-Mackie, 2018), brings into sharp relief the need for rehabilitation that addresses the psychosocial consequences of aphasia. Animal-assisted treatment (AAT) is an ideal service delivery model, providing PWA the physical and psychological benefits of animal companionship along with dogs' ability to act as 'social catalysts' (Beetz, 2017) for engagement with others in the community. As such, there is a compelling need to fill the striking gap in the evidence-base regarding the efficacy of AAT in the rehabilitation of PWA. Our team is well-positioned to contribute to filling this gap, with the PI, an experienced aphasiologist with years of experience using positive reinforcement techniques to train dogs, working with experts in clinical aphasiology, cognitive neuropsychological rehabilitation, and canine behavior. The results of this study are expected to demonstrate the feasibility of administering, and quantifying the effects of, a canine-assisted aphasia treatment. Considering the large number of American households that include dogs (estimated 48.3 - 63.4 million), the growing interest in incorporating AAT into rehabilitation with clinical populations across service delivery settings (HABRI Central Brief, 2016; Hediger et al., 2019; Hediger & Hund-Georgiadis, 2017; Linder et al., 2017; Matuszek, 2010; McCullough et al., 2016; Munoz Lasa et al., 2015; Thodberg, Berget, & Lidfors, 2014), and the accessibility of this treatment to a wide variety of PWA, this treatment has the potential to have a substantive **positive impact** on a large number of Americans living with aphasia. This project is a crucial first step toward our **long-term goal** to augment the evidence base with what O'Haire and colleagues (2015) deem, "research [that is] essential to establish feasibility, efficacy, and manualizable protocols" (p. 1) for AAT and that target the psychosocial consequences of aphasia.

Innovation: The PATD program represents a novel understanding of what constitutes health care, engaging participants in an animal-assisted treatment program to address the communication and psychosocial needs of PWA through engagement in rehabilitation that occurs within the community itself. We are aware of no

program of this kind for persons with aphasia, nationally or internationally, in which dog training is conceptualized as AAT in service of psychosocial outcomes and participants' own community engagement goals. That said, we are encouraged by evidence of the success of similar programs for other clinical populations (Yeager & Irwin, 2012). This project represents the first systematic investigation of the effectiveness of AAT for rehabilitation with PWA. This work will provide a critical first step toward filling this gap as well as providing a much-needed model for operationalizing AAT.

APPROACH
Accomplishment of the <u>*overall objective*</u> of this application will be achieved through this small-scale, feasibility study aimed to garner preliminary support for our <u>*hypotheses*</u> and to provide the foundation for a future, large-scale clinical trial.

   Specific Aim 1: Determine whether PWA, through participation in the PATD program, can learn and implement positive reinforcement techniques to train dogs in basic obedience skills. *Hypothesis 1*: On program completion, PWA will be competent in using positive reinforcement techniques, to independently cue a dog to complete a minimum of 4 (of 5) trained obedience skills. To test this hypothesis, we will assess program participants using a PI-adapted version of the *Pet Partners© Animal-Handler Evaluation*.

<u>Rationale:</u> Our first hypothesis is supported by the fact that positive reinforcement dog training capitalizes on the pragmatic skills that may be accessed by individuals with aphasia even in the presence of severe language production impairment. Positive reinforcement training is based on the principle of reward-based associative learning, in which the dog learns to associate her performance of certain actions with a reward (e.g., food, praise in a happy tone of voice, toy, etc.) (Hiby et al., 2004; Perry & Conza, 2012; Pryor, 2006). Two of the most important components of the training are shaping of behavior and timing. *Shaping* (or successive approximation) might be described as helping the dog understand what you want her to do and is often achieved through the use of gestural cues. For example, when training SIT, a treat lure might be held above the dog's nose and slowly moved backward over her head, which, as the dog follows the treat with her eyes and nose, facilitates her putting her bottom on the ground. Similarly, when training TOUCH, i.e., the dog touches your open palm with her nose, you might first hold your 'hot-dog-smelling' hand quite close to her nose to make it 'obvious' to her. As she becomes faster with responding to the open palm cue, you move your hand farther back to make it more difficult. In this way, you proceed in a stepwise, sequential manner from the easiest iteration of the command to the more difficult, such that the dog learns to respond to each hand cue with the associated behavior. Because the dog is being trained through the use of cues to learn to associate her behavior with attainment of a reward, *timing* is critical. The trainer's attention must be focused on sometimes minute changes in the dog's posture or gaze so that the desired behavior can be captured or marked as soon as it occurs. A common marker is the 'click' of hand-held clicker device, which provides a brief but immediate, salient, and consistent signal to the dog that can then be followed by the slower process of providing the treat. These techniques are well-suited to use by PWA. The training itself can be easily depicted or modeled, if necessary, the person with the language impairment may learn through demonstration rather than lengthy verbal explanation. The use of hand signal cues and a clicker to mark the desired behavior remove the need for even single word production, but do not *restrict* use of verbal cues and other vocabulary if a goal for the PWA is to improve retrieval or production of this vocabulary. As such, the principles and techniques used in positive-reinforcement training are accessible to PWA. The procedures employed in training can also be adapted for those with the right-sided hemiplegia that often accompanies stroke. In addition to the fact that PWA retain the skills to work with dogs, evidence suggests that the presence of the dog "promotes the pre-conditions for learning" (Beetz, 2017, p. 7), reducing distraction and stress, while increasing intrinsic motivation (Beetz, 2017).

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Skills Training: In consultation with a certified professional dog trainer, the PATD program was developed by the PI, a trained speech language-pathologist with more than eighteen years of experience working with people with aphasia, who has spent more than ten years working with shelter animals using positive reinforcement techniques. Participants enrolled in the PATD program will engage in five once-weekly individual training sessions with the PI, either with a family dog (PATD) or by volunteering at a local shelter, the Pennsylvania SPCA (PATD-PSPCA). PATD-PSPCA participants will work only with dogs that have been evaluated by PSPCA staff as appropriate for interaction with new volunteers. Each session will be dedicated to one of five pre-determined, sequentially-presented, obedience skills (i.e., LOOK, TOUCH, SIT, STAY, COME). Training sessions will last approximately 75 minutes, with an additional half hour allotted to the beginning of the first training session to review principles of positive-reinforcement training. Subsequent sessions will begin with a brief probe of the participant's skill in cueing the dog to perform the behavior trained the previous week. Following the probe, sessions will continue with a review of that week's lesson plan (Figure 1), after which the PI will model the first training step three times. After the model has been provided, the participant will attempt the procedure, receiving instructive feedback or reinforcement from the trainer. Instruction will proceed to the subsequent step when the participant and dog have attained 5 successful trials at the current step. The same demonstration procedure will be used at each subsequent step. Commands will be trained using one hand gesture for each behavior. To mark behaviors, participants will use a clicker attached to a wrist band, which can be hand-held or allowed to dangle for ease of use for those with hemiplegia. Participants will have the option of introducing the verbal command, but will not be required to do so. All participants will be asked to provide their dog with a walk before training sessions to support the dog in being ready to participate.

Skills Practice: Participants will not be required to complete all steps for an obedience skill in a single session, and will be encouraged to practice the skill with the dog for at least 3 practice sessions over the course of the week. Practice will be used as a measure of participant compliance. Each participant will be provided with a copy of the lesson plan and, if interested, a video demonstrating the PI performing the target skill with her own dog. Participants will also be provided with a training log to complete after each time they practice over the course of the week. Using a nine-point visual analog scale adapted from the *Assessment of Living with Aphasia* (ALA) (Simmons-Mackie et al., 2014), participants will rate their own and the dog's performance during each practice session (see *PATD Practice Log*, in Appendix). To facilitate responses on the log, participants will practice self-reflection with the PI during training sessions (e.g., "How many times did I have to cue the dog", "Did I 'click' as soon as the dog did what I asked?".

Skills Evaluation: In consultation with a CPDT who is a practitioner of positive reinforcement training, the PI-adapted *Pet Partners© Animal-Handler Evaluation (PPAHE)* will be used to evaluate handler competence, on parameters associated with shaping and timing, on a scale of 0 ("not ready") to 2 ("best") (see blank *PPAHE* in Appendix). Weekly single-skill probes will be conducted by the PI/trainer but will be scored via video-recording by a certified professional dog trainer (CPDT). Summative assessment of all skills will occur twice, within one week of training completion and at a 3-month follow-up. Summative assessments will be completed in person by a CPDT who will also score the weekly formative evaluations via video-recording. To maintain scientific rigor, the CPTD will score probe evaluations via video after the follow-up in person summative evaluation has been completed. As reflected in the adapted *PPAHE*, scores will be based solely on participants' competence

using the positive reinforcement techniques, not on the performance of the dog. Dogs' behaviors in response to cuing are noted to provide for qualitative assessment of the participant's responsivity to the dog and so that relief (e.g., break for walk or play) may be immediately provided to the dog if signs of stress, fatigue, etc. are observed.

Statistical Considerations: Scores from weekly probes will allow for analysis of change in level of 'competence' over time, as determined using the *PPAHE* for that skill. For the purpose of statistical analyses of weekly evaluations, three scores (0= "not ready", 1= "ok", 2= best") will be dichotomized as competent (1 or 2) vs. not competent (0). In addition to the weekly evaluations, at the end of the training period, each participant will receive a summative score on the adapted *PPAHE.* This score may range from 0 to 10. In keeping with our a priori hypothesis that participants will be able to independently cue a dog to perform a minimum of 4 out of 5 obedience behaviors, a score of 5/10 points corresponds with achieving a minimum of a 1 ("ok") on all five targeted obedience behaviors or achieving a 2 ("best") on at least one behavior and 1 on three others. For the primary analysis, the proportion of subjects that successfully completed the training will be quantified with the corresponding two-sided 90% exact binomial confidence interval. For the secondary analysis, (i) the median cumulative score will be computed with the corresponding two-sided 90% distribution-free confidence interval (Hahn & Meeker, 2011) and (ii) the weekly competence scores will be analyzed using the repeated measures logistic regression model. With the total sample size of 20 subjects, the width of the two-sided 90% exact binomial confidence interval is at most 0.38 if the observed proportion of subjects successfully completed the training is 0.5. The interval is narrower if the observed proportion of successes is higher (or lower) than 0.5.

Expected results: It is expected that participants will be able to independently cue a dog to perform a minimum of 4 out of 5 obedience behaviors. It is also expected that the median cumulative score will be at least 5, which corresponds with achieving a minimum of a 1 ("ok") on all five targeted obedience behaviors or achieving a 2 ("best") on at least one behavior and 1 on three others.

Scientific rigor: To maintain treatment fidelity, all PATD training will be conducted by the PI. PATD training sessions will be digitally video recorded. Control for experimenter bias will be achieved by having skill probes scored via video-recording by one CPDT, and having summative evaluation conducted and scored by a second CPDT. The PI will not be present for the summative evaluations. For the purposes of establishing inter-rater reliability, summative evaluations will be digitally video recorded so that a third CPDT can independently evaluate participant performance. PSPCA participants may work with a different dog each week to accommodate for the fact that the same dog may not be available for training from week to week. All CPDTs will be practitioners of positive reinforcement training, the cuing and shaping techniques for which are relatively standard and are familiar to practitioners of the technique.

Preliminary Data:
The training procedures and lesson plans have been validated through use with four individuals with post-stroke aphasia (one with right-sided hemiplegia) who completed training and immediate post-treatment evaluation. Three participants worked with a family dog and the fourth participated in the program at the PSPCA. Consistent with our hypothesis, on program completion all four participants demonstrated ability to cue their dog(s) to perform a minimum of four out of five obedience skills commensurate with a handler skill level at or above a '1' on the *PPAHE.*

Specific Aim 2: Define participant characteristics associated with recruitment, retention, compliance and program acceptability/satisfaction relevant for determining PATD candidacy. *Hypothesis 2:* PWA will demonstrate high (above 80%) retention and compliance rates, and high program satisfaction, including increases in self-reported ratings of psychosocial well-being. To test this hypothesis, our primary outcome measure will be the *Assessment of Living with Aphasia* (Kagan et al., 2010), complemented by self-report of participants' PATD experience gathered through an *ALA*-modeled qualitative spoken interview and a written, aphasia-friendly, satisfaction survey.

Rationale: Our second hypothesis is supported by a growing literature regarding the physiological and psychosocial benefits of human-dog interaction (Friedmann & Son, 2009; Lundqvist et al., 2017; Odendaal & Meintjies, 2003) and the likely mechanisms of action for AAT, which include as Beetz (2017) described, "promoting the preconditions of learning" (p. 7) by increasing intrinsic motivation, attention, and positive mood and decreasing fear and stress (Beetz, 2017; Blakemore & Frith, 2005; Wholfarth et al., 2013), The direct and

regular interaction with dogs provided in the PATD program also provides for 'active engagement' with the animal, which may support greater potential for deriving these benefits than simply having the dog present (Dietz et al., 2012).

Feasibility Metrics: We will track *recruitment rates* appropriate to the creation of a CONSORT flow diagram (e.g., Horton et al., 2016) including: # contacted, # screened, # eligible (vs. ineligible), # consented/enrolled (vs. declined).. Similarly, participant *retention rates* will be tracked including: # completing baseline assessment, # completing immediate post-treatment assessment, and # completing follow-up assessment. Participant withdrawals will be tracked for whether initiated by researcher or participant. Participant *compliance rates* will be tracked including # assessment and training sessions (relative to total possible) completed, and # self-reported home practice sessions.

Outcome Measurement: The primary quantitative outcome measure of acceptability, the *ALA*, is a pictographic self-report measure of quality of life developed to assess the impact of aphasia on daily life. Questions address participants' perceptions of aphasia, their environment, their relationships, their community engagement, experiences of self-confidence and respect, and their progress toward "living well with aphasia". Participants respond by pointing to a visual analog scale, providing for quantification of responses, and rendering the tool accessible to those with language impairment. Overall score and subdomain scores have demonstrated acceptable-to-high test-retest reliability and internal consistency (Simmons-Mackie et al., 2014).   To augment standardized evaluation, the PI has developed a complementary interview, consistent with the format of the *ALA*, to more specifically probe PATD participants' perceptions of the impact of the training program. Participant narratives produced during the administration will be supported using interviewing strategies appropriate for persons with aphasia (Luck & Rose, 2007). A written, visual analog scale satisfaction survey designed to adhere to guidelines of 'aphasia-friendly' written materials will also be administered. We anticipate the assessment battery will take approximately 3 hours to complete.

Outcome Measurement/Participation Timeline: Participants will be randomized into immediate and waitlist treatment groups using permuted block randomization with stratification. Analysis between these two arms will be exploratory only in nature, and will inform us regarding the feasibility of the waitlist control design for use in a larger clinical trial. All participants will be evaluated before training begins, immediately following training, and at a 3-month follow-up. Participants in the delayed arm will participate in two pre-training evaluations, one immediately upon enrollment and one at the end of the delay period immediately before beginning training.

Week	1	2	3	4	5	6	7	8	9	10	11	12	13	
Immediate	Pre-training eval.	Skill 1	Skill 2	Skill 3	Skill 4	Skill 5	Post-training eval.							Follow-up eval. (week 19)
Waitlist	Pre-training eval.						Pre-training eval.	Skill 1	Skill 2	Skill 3	Skill 4	Skill 5	Post Training Eval.	Follow-up eval. (week 25)

Statistical Considerations: Primary outcome evaluation will be done with the entire sample of twenty. The mean pre-to-post-training change in each ALA domain score will be computed with the corresponding 90% confidence interval. With the total sample size of 20 subjects, the width of the two-sided 90% confidence interval is equal to 0.39 standard deviations of the pre-to-post-training changes.   For the secondary analysis, we will evaluate the mean difference in each ALA domain scores between the immediate and delayed treatment arms at week 7 using the two-sided 90% confidence interval and two-sided two-sample t-test with alpha 0.1 (reflective of the small size pilot study). The results of comparison between the immediate and delayed treatment arms will be used to inform a future larger clinical trial._Qualitative data derived from narratives produced by PWA during administration of the PATD *ALA*-supplement will be orthographically-transcribed for offline analysis consistent with procedures detailed by Luck & Rose, 2007.

Scientific rigor: Participants will be assessed by a certified speech-language pathologist (SLP) who is not involved in PATD training. All assessment sessions will be video-recorded. A portion (approximately 20%) of the data will be selected for evaluation of intra- and inter-rater reliability. Inter-rater reliability will be conducted

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with a second SLP not involved in PATD training. All individuals who collect and code data are trained by the PI.

Preliminary data: The four participants who have completed the program responded to the PATD Satisfaction Survey (see appendix). Average ratings were: 'better dog training skills'= 4.25 (range 2-5), 'more opportunities to socialize'= 4 (range 2-5), 'more opportunities to communicate'= 3.25 (range 1-5), 'more confidence'= 3.75 (range 2-5). Consistent with the hypothesized mechanisms of action for AAT, all participants responded 'Yes' that they 'had more confidence' and were 'communicating more frequently'.

PARTICIPANTS
The study population is persons who have aphasia consequent to cerebro-vascular accident CVA) who are a minimum of six months post-onset.

Eligibility/Inclusion criteria:
To participate individuals must have aphasia resulting from CVA, those who have had multiple strokes, subcortical strokes, or who have crossed aphasia, are not explicitly excluded. . All participants must meet the following criteria: 1) be aged 21 years or older, 2) have English as a native or primary language, 3) evidence of having the linguistic and cognitive capacity to understand the research requirements, 4) demonstrate the willingness and stamina to participate in the protocol, 5) be negative for diagnosis of neurological injury or disease other than CVA. 6) reside within approximately 1 hour drive from MRRI (50 Township Line Rd, Elkins Park, PA) and/or PSPCA (350 E. Erie Avenue, Philadelphia, PA). Participants may have concomitant medical conditions such as heart disease, or diabetes, but at the time of participation they will be medically and neurologically stable, such that they can participate in this multiple session protocol. Participants will be characterized relative to demographic (e.g., age, education-level) and stroke-related (e.g., time post onset, presence of hemiplegia) variables. To determine aphasia type and severity, participants will complete the *Western Aphasia Battery-Revised* (Kertesz, 2006) in week 1.

Participants will be included without respect to gender, race or ethnic background. Pregnant women and Einstein employees/students will be neither targeted nor specifically excluded. Children (persons under the age of 21) are excluded from this study as the aims of this project are relevant to the study of acquired aphasia in adults.

Recruitment
A minimum of twenty participants with chronic (> 6 months post) stroke-aphasia will be enrolled. Participants will be recruited from the MRRI Research Participant Registry and through additional venues. The MRRI Research Participant Registry is a database of individuals who have previously consented to being contacted regarding research opportunities (Schwartz et al., 2005). The database includes approximately 302 individuals with stroke-aphasia, with an average of 43 enrollees each year, who have self-selected for interest in research participation. Additional recruitment strategies will include use of IRB approved fliers, which may be posted on websites, social media (e.g., ARCH, Aphasia Recovery Connection, or Poems in Speech Facebook pages) included in newsletters (e.g., the Aphasia Resource Collaboration Hub), shared with individuals who have previously expressed interest in the PATD program, and provided to internal (Jefferson Moss-Magee Rehabilitation) and local community-based speech-language pathologists who work with people with stroke-to share with their clients. The study may also be posted on the Thomas Jefferson University Clinical Trials Finder and study staff may present information about the study at internal (Jefferson Moss-Magee Rehabilitation) and local community aphasia-groups and events. Recruitment will also occur using the Recruitment Enhancement Services provided by the Jefferson Clinical Research Institute at Thomas Jefferson University. Recruitment Enhancement Service (RES) provides assistance to the principal investigator in developing the study's recruitment plan and may assist in identifying and contacting potential participants using the Informatics group, internal communication resources, community contacts, and other available resources as outlined in the study team's protocol. MyChart may also be used to identify and generate lists of potential participants. Individuals identified by the RES as meeting eligibility criteria will be contacted by either postal mail or email.

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Participants will be informed that they may withdraw from the study at any time, without penalty, and contact personnel are provided on the consent form. Participants will be informed that they can contact the PI at a later time if they would like to spend time reviewing the information in order to avoid them feeling pressured to participate. They will also be informed that pre- or post-consent screening or behavioral test results may indicate that they are not eligible to continue with the study. Pre-consent, research candidates from outside of the MRRI Research Registry will be screened to confirm diagnosis and related medical information and for geographic eligibility.

Assignment into each arm will be done using block randomization with stratification. Interested participants will be screened for one of two strata: 1) participation with a family dog or 2) participation through the Pennsylvania SPCA (PSPCA). Interested participants will be automatically assigned to the PSPCA condition if a) they do not have a family dog or b) their family dog is not eligible to participate. There will be no minimum requirement for assignment into either stratum.. As participants are enrolled in either the PATD or PATD-PSPCA condition, they will be block randomized into either immediate or waitlist treatment groups. Recruitment will be ongoing, until a minimum of ten PATD immediate and ten PATD waitlist participants have been enrolled.

Retention plan: Strategies to encourage retention will include: 1) The timeline of the study will be detailed in recruitment and consent materials to indicate that multiple sessions are required for the study and that there will be a lag period between some phases of the study. 2) Scheduling of assessment and training sessions will be done, to the maximum extent possible, at the convenience of study participants. Assistance with travel arrangements to attend assessment sessions may be offered, Moss Rehabilitation Research Institute contracts with third-party vendors for this purpose. 3) Participants will be informed that they may continue or enroll in standard of care rehabilitation or therapy during the duration of their participation, but will be asked to inform study staff of any changes. 4) Participants will be asked to not enroll in any other research activities through completion of the immediate post training evaluations (with the speech-language pathologist and with the dog trainer). and will be asked to not enroll or participate in any other dog training activities for the duration of the study through the follow-up evaluations. 5) Participants will be informed at enrollment of the timeline for participation.

Study Timeline: Lesson plans consistent with the example in figure 1 have been written for all target obedience behaviors and validated with four participants with aphasia. Additional training and evaluation materials have been developed and piloted with these participants by the PI. Certified SLPs will have prior experience with PWA such that any training required on battery instruments will be minimal and will not delay data collection. CPDTs are positive reinforcement practitioners and have consulted with the PI on the lesson plans and adapted *PPAHE*. From the study start date (date of first enrolled participant) recruitment, enrollment will continue through week 72 of the study to provide sufficient time for later enrolled participants to complete either protocol. Data collection and analysis will be ongoing, with preliminary dissemination of findings anticipated to begin once enrollment has ended.

RESEARCH DESIGN AND METHODS

Study Procedures and Materials
Cognitive-linguistic and psychosocial assessment sessions for all groups will take place at the Moss Rehabilitation Research Institute. Participants will complete either 3 (immediate arms) or 4 (delayed arms) assessment (dx) sessions over the course of either 19 or 25 weeks, respectively (Table 1); we anticipate that each assessment session will take approximately three hours to complete. The instruments included in these assessments will be the *Assessment of Living with Aphasia* (Simmons-Mackie et al., 2014), the PATD-program ALA supplement (developed by the PI for this study, not administered in pretraining evaluation(s)) the *Confidence after Stroke Measure* (Horne et al., 2017), and the *Behavioural Assessment of Dysexecutive Syndrome* (Wilson et al., 1996). Participants will also complete at baseline the *Western Aphasia Battery-Revised* (*WAB-R*, Kertesz, 2006) to provide a profile of their aphasia. The *WAB-R* will not be repeated.

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All participants will be evaluated before training begins, immediately following training, and at a 3-month follow-up. Participants in the delayed arm will participate in two pre-training evaluations, one immediately upon enrollment and one at the end of the delay period immediately before beginning training.

Week	1	2	3	4	5	6	7	8	9	10	11	12	13	
Immediate	Pre-training eval.	Skill 1	Skill 2	Skill 3	Skill 4	Skill 5	Post-training eval.							Follow-up eval. (week 19)
Waitlist	Pre-training eval.						Pre-training eval.	Skill 1	Skill 2	Skill 3	Skill 4	Skill 5	Post Training eval.	Follow-up eval. (week 25)

Table 1: Sequence of participation

PATD training sessions will take place either at participants' homes, for those working with a family dog, or at the PSPCA. Training sessions that take place at the PSPCA will occur in an enclosed room, in an open indoor space in which the dog is tethered or on-leash, or in a fenced-in outdoor yard.

Participants enrolled in the PATD program will engage in five approximately once-weekly individual training sessions with the PI, either with a family dog (PATD) or by volunteering at a local shelter, the Pennsylvania SPCA (PATD-PSPCA). Each session will be dedicated to one of five pre-determined, sequentially-presented, obedience skills (i.e., LOOK, TOUCH, SIT, STAY, COME). Training sessions will last a maximum of 75 minutes, with an additional half hour allotted to the beginning of the first training session (before the dog begins participation) to review principles of positive-reinforcement training. Sessions may last for fewer than 75 minutes if a) criterion is achieved, b) human or dog participant demonstrates fatigue, loss of attention, etc. Subsequent sessions will begin with a brief probe of the participant's skill in cueing the dog to perform the behavior trained the previous week. Following the probe, sessions will continue with a review of that week's lesson plan, after which the PI will model the first training step three times. After the model has been provided, the participant will attempt the procedure, receiving instructive feedback or reinforcement from the trainer. Instruction will proceed to the subsequent step when the participant and dog have attained 5 successful trials at the current step. The same demonstration procedure will be used at each subsequent step. Commands will be trained using one hand gesture for each behavior. To mark behaviors, participants will use a clicker attached to a wrist band, which can be hand-held or allowed to dangle for ease of use for those with hemiplegia. Participants will have the option of introducing the verbal command, but will not be required to do so. All participants will be asked to provide their dog with a walk before training sessions to support the dog in being ready to participate. The PI will demonstrate the steps of the obedience training and will be present for the entire training session to observe, assist, and provide feedback to participants. Within the framework above, treatment will be individualized for each participant-handler/dog pairing based on real-time clinical decision-making. One goal of positive reinforcement training is relationship building between the particular handler/dog pairing. Reinforcement, redirection, and feedback will be provided by the PI, who will complete all training sessions, based on the individual needs of the human and dog participants. Participant handlers will be provided with feedback regarding their use of shaping, timing of cues and rewards in real time and lesson plans will be modified as needed for each individual. Examples of lesson plan modifications include training in use of one hand for those with hemiplegia or increased white space or font size or additional pictographs for those with reading difficulty.

Participants will be encouraged to practice the skill in 3 practice sessions over the course of the week. Participants will be instructed that each practice session should not last longer than approximately 30 minutes and that breaks for play, drinking water, sniffing-walks, should be provided as needed. Practice sessions may also be broken up into shorter increments (e.g., three 10-minute sessions, six 5-minute sessions). Practice will be used as a measure of participant compliance. PATD-participants will be provided with aphasia-friendly written materials including: 1) lessons plans, 2) practice log sheets, and 3) practice reminders. They may also be provided with example videos of the PI performing the obedience skills with her own dog. PATD-participants will be informed that at the beginning of the subsequent training session, the PI will be evaluating their ability to cue the behavior introduced the previous week using a PI-adapted *Pet Partners*© *Animal-Handler Evaluation*

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(adapted PPAHE) will be used to rate handler cueing on a scale of 0 ("not ready") to 2 ("best"). Procession to training of each behavioral skill will not be contingent on evaluation of the previous skill.

After each training session, the participant will be provided with a copy of the appropriate lesson plan, three participant practice logs, and, if interested, a video demonstrating the PI performing the target skill with her own dog. As study staff will not be present for practice sessions, participants will be instructed on behaviors to watch for that indicate the dog might need/want a break or to stop practice for the day, e.g., signs of fatigue (e.g., inattention, disinterest in interaction) or distress (e.g., tail tuck, ears flat/back, avoidance). PSPCA participants will be instructed to practice with the same dog with whom they trained on each skill. If that dog is not available, they will be instructed to work with another dog who has been labeled by PSPCA staff to be at (or easier than) their current level of proficiency as determined by the PSPCA (e.g., beginner volunteers may only work with beginner-appropriate dogs).

All sessions will be video-recorded. A section of the informed consent is dedicated to explaining the use & storage of recordings. An optional sharing of recorded information for educational purposes is also included in the consent.

Due to the variable nature of the timeline for PSPCA volunteer onboarding and to preserve the timeline of study activities, participants who choose to participate as PSPCA volunteers will be asked to complete volunteer training/onboarding before beginning other study activities. Once onboarding is completed, the participants' first assessment session will be scheduled and study activities will proceed accordingly.

Risks to Participants and Adequacy of Protection against Risks
<u>Informed Consent</u>
Once individuals express interest in learning more about the study, they will be invited to meet with members of the study team. The general purpose and procedures of this research will be explained to participants, and they will then be given the informed consent document, which will be read aloud; explanations and answers to questions will be given before any testing is undertaken. Along with the official consent form, a supplemental document that utilizes pictures has been developed by the PI to facilitate comprehension of the project procedures and risks for individuals with comprehension impairments secondary to aphasia. Per the criterion listed above, individuals must give evidence of having the linguistic and cognitive capacity to understand the consent form and give informed consent. An Informed Consent Comprehension Screen, adapted from the UCSD Geropsychiatry Research Center, is used with all participants during the consent discussion. Persons with aphasia will be invited to bring to the consent discussion a family member or an individual known to them who is not affiliated with the project. This witness will be encouraged to ask clarifying questions on the individual's behalf. Given the degree of independence of these community-dwelling stroke survivors, we will not require co-consent from a family member. Consent discussions will take place in a private room and as much time as needed will be alloted to thoroughly explain the study procedures, risks, benefits, confidentiality, and data collection/storage, as well as provide time for the participant to ask questions and have them adequately answered. (Approximately 30-60 minutes).

All PATD-participants will be informed that if evidence of dog abuse (e.g., hitting) or neglect (e.g., severe malnourishment) is observed, they will be withdrawn from the study and reported to Humane Law Enforcement for investigation.

<u>Behavioral assessments</u>
Anticipated risks are minimal and include fatigue or frustration during the behavioral sessions. To protect against fatigue, participants will be informed they may stop or take a break at any time without penalty. Participants will be invited to take breaks as necessary and reminded that they may cease participation at any time. It is recognized that some participants may demonstrate discomfort while completing the assessments of quality of life. They are informed that some of the questions they will be asked will deal with their personal experiences and emotions related to living with aphasia, and reminded that they may choose not to answer specific questions or may forego this assessment entirely. Participants may also be offered referral information

for psychological care, if interested. Risks associated with travel to and from behavioral assessment sessions are anticipated to be not more than those associated with urban daily life.

Dog-training
Risks associated with interaction with dogs include the possibility of physical injury and the risks associated with coming into contact with fur, saliva, waste, or zoonotic disease associated with dogs. Before beginning work with dogs, participants will be provided with guidance on universal precautions. PSPCA participants will receive a pictographic information sheet.

Dogs are screened through either owner-report (for family dogs) or PSPCA behavior staff-report for eligibility. Participants are informed that the program is directed toward training basic obedience skills, not remediation of behavior 'problems', and that the PI conducting the training is not a certified-professional dog trainer. Dogs with a reported history of bites, reactivity (e.g., barking, growling) toward strangers, or resource guarding are excluded. It is anticipated that for participants working with a family dog, risks will not be more than those otherwise experienced in regular interaction with the dog.

Participants interested in working with PSPCA dogs are required to successfully complete the official PSPCA volunteer orientation before beginning the PATD program, hence they must be independently approved by a representative of the PSPCA to be able to work with shelter dogs. Much of the orientation involves hands-on demonstration and practice, making it accessible to individuals with aphasia. Participants interested in volunteering at the PSPCA must demonstrate sufficient mobility and strength to handle a dog. Risks associated with travel to and from the PSPCA are anticipated to be not more than those associated with urban daily life.

Confidentiality
In any research study, there is the risk that personal data will become inappropriately known (risk of loss of confidentiality). Data will be coded with a participant ID number that has no connection with the participant's name or other identifying information. The master list containing the link between the data and the identity will be password protected and accessible only to study personnel. All physical information will be stored in locked drawers in the locked office of the PI or the PI's locked testing room at Moss Rehabilitation Research Institute to which other study staff will have access. Electronic data will be stored on AEHN/TJU networks and/or OneDrive, password-protected computers, , or encrypted external memory devices as appropriate. Data will be removed from the memory storage of the video-recording device as soon as it is practicably possible to transfer it to these systems. Iimmediately after transfer the videos will be removed from the video-camera storage.
Participants volunteering at the PSPCA will be informed that they are participating in the study in a public venue. PSPCA staff will not be involved in training sessions, and the PI will not identify study participants to PSPCA staff or share participant-specific study information with PSPCA staff. Study staff dog trainers are also PSPCA volunteers and do perform a variety of volunteer work for the PSPCA. They, as are all study staff, are trained in confidentiality via CITI training and review of study documents. There are no completely private spaces within the PSPCA. PATD participants participating at the PSPCA will be informed that it is possible that PSPCA staff or volunteers who see them with the PI or other study staff may surmise that they are PATD program participants, which identifies them as having stroke-aphasia. As participants are also free to discuss their own participation with whomever they choose, they will be informed that the PI cannot guarantee the degree to which their confidentiality will be maintained by third parties. Participants will also be informed that the PI may report to PSPCA staff the identity of the dogs who have worked on each obedience skill.
Unedited videos of participants collected during this study may be used for educational purposes (e.g., conference presentations). For video sharing necessary to obtain useful input from others (i.e., to assist the project team in interpreting research information), participant faces will be blurred to maintain participant privacy. The video editing software Davinci Resolve 19 will be used for this purpose.

Potential Benefits of the Proposed Research to Research Participants and Others

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We have found that participants appreciate the time and effort that study personnel take to talk with, as well as the opportunity to discuss, in a supportive environment, the effects of stroke and aphasia on their lives. It is also our experience that many people with aphasia are enthusiastic about the opportunity to contribute to the research evidence-base that could help others with aphasia. All participants will have the possibility of experiencing these benefits. For PATD participants, there is evidence to suggest there are physical and psychosocial benefits of interaction with dogs, and we anticipate there may also be psychosocial benefits to building self-confidence through learning the new skill of dog training. PATD participants may also derive benefit from the knowledge that they are providing enrichment and support to their own dog or to shelter dogs in need. The potential benefits of participation outweigh the possible risks that may be experienced by the individuals who participate.

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Data and Safety Monitoring Plan
The PI will serve as the Data and Safety Monitor. Study data are accessible to the PI at all times. The PI will maintain regular contact with the CPDTs and SLPs conducting and scoring behavioral assessments. As provided either through narrative interview or extemporaneously by participants, the PI will evaluate participant feedback related to their satisfaction with the program. Participants are free to stop their participation at any time throughout the course of the program. On an ongoing basis, safety associated with working with dogs will be evaluated by the PI, who will revise procedures as needed. Adverse events, including Serious Adverse Events and Unanticipated Problems, will be reported consistent with AEHN IRB procedures,

Overall Structure of the Study Team
The study team will consist of the PI, the study research assistant (RA), the certified professional dog trainers (CPDT) and the study speech-language pathologists (SLP). The PI will conduct PATD dog probe and training sessions. CPDTs will conduct and review video recordings of the probe and in-person cumulative evaluation sessions, during which the PI will not be present. A second staff member may be present during all PATD sessions to video-record the sessions. The RA may assist with recruitment, scheduling, and data collection (including video recording) and analysis. One SLP will conduct behavioral assessment sessions and a second SLP will score study instruments and code video-recordings of narrative interviews.

Statistical Design and Power
For this feasibility study, we anticipate enrolling a minimum of twenty participants with stroke-aphasia.

Scores from weekly probes will allow for analysis of change in level of 'competence' over time, as determined using the *PPAHE* for that skill. For the purpose of statistical analyses of weekly evaluations, three scores (0="not ready", 1="ok",2="best") will be dichotomized as competent (1 or 2) vs. not competent (0). In addition to the weekly evaluations, at the end of the training period, each participant will receive a summative score on the adapted *PPAHE.* This score may range from 0 to 10. For the primary analysis, the proportion of subjects that successfully completed the training will be quantified with the corresponding two-sided 90% exact binomial confidence interval. For the secondary analysis, (i) the median cumulative score will be computed with the corresponding two-sided 90% distribution-free confidence interval (Hahn & Meeker, 2011) and (ii) the weekly competence scores will be analyzed using the repeated measures logistic regression model. With the total sample size of 20 subjects, the width of the two-sided 90% exact binomial confidence interval is at most 0.38 if the observed proportion of subjects successfully completed the training is 0.5. The interval is narrower if the observed proportion of successes is higher (or lower) than 0.5.

The mean pre-to-post-training change in each ALA domain scores will be computed with the corresponding 90% confidence interval. With the total sample size of 20 subjects, the width of the two-sided 90% confidence interval is equal to 0.39 standard deviations of the pre-to-post-training changes. For the secondary analysis, we will evaluate the mean difference in each ALA domain scores between the immediate and delayed treatment arms at week 7 using the two-sided 90% confidence interval and two-sided two-sample t-test with alpha 0.1 (reflective of the small size pilot study). The results of comparison between the immediate and delayed treatment arms will be used to inform future larger studies. Qualitative data derived from narratives produced by PWA during administration of the PATD *ALA*-supplement will be orthographically-transcribed for offline analysis of themes discussed consistent with procedures detailed by Luck & Rose, 2007.

To the extent that variation across the sample allows, we will explore the effects on performance of demographic (age, education) and aphasia-related (time post-onset, *WAB-R AQ*) variables. Due to the nature of the differences between PATD participation with a family dog and with shelter dogs, we will not run between-group analyses of PATD versus PATD-PSPCA participant groups.

Dissemination Plan
The PI will ensure that the clinical trial information, including descriptive information, recruitment information, location and contact information, and administrative data is registered with ClinicalTrials.gov within 21 days of

enrollment of the first participant and that summary results information, including participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information is submitted to ClinicalTrials.gov within 12 months of the primary completion date. Informed consent documents will include a specific statement that de-identified study information and results will be posted to ClinicalTrials.gov. The Albert Einstein Health Network has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

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