CB3 Pilot (Communication Bridge: A Person-centered Internet-based Intervention for Individuals With Primary Progressive Aphasia)

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STUDY TITLE:

Communication Bridge: A multicomponent person-centered Internet-based intervention for individuals with primary progressive aphasia

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RELATED STUDIES:

- STU00206086: Communication Bridge: A person-centered Internet-based intervention for individuals with primary progressive aphasia.
    1) This study will extend the STU00206086 protocol for up to 30 participants and their communication partners who completed, were screened for, were placed on the waitlist for, or new persons meeting the eligibility criteria for the study. The objective is to evaluate the effectiveness of evidence-based interventions on individuals living with PPA and their ability to communicate after treatment, but for a longer duration of time (3 session blocks over ~18-months, see figure and detailed description below) in order to examine further stages of the disease.

Check any **applicable** boxes in the table below – you will be asked for further detail on these topics later in the protocol form:

Indicate Vulnerable Population(s) to be Enrolled	☐ Children (you must **complete Appendix A** in addition to this protocol document if you plan to enroll children) ☒ Cognitively Impaired Adults ☐ Pregnant Women (IF the research activities will affect the pregnancy or the fetus) ☐ Prisoners (or other detained/paroled individuals)
International Research (check this box if you will collect data from individuals located outside the United States)	☒
Research involving external collaborators (some research activities will be carried out by individuals not employed by Northwestern or NU affiliates)	☒
Research has U.S. Federal government funding via direct award or a sub-award (e.g., NIH, NSF, other federal agencies or departments)	☐

1.0 Purpose and rationale of the study:

The purpose of this study is to evaluate the effectiveness and feasibility of evidence-based interventions in individuals living with primary progressive aphasia (PPA) that address communication-focused outcomes. By extending the intervention to include social work our aim is to address psychosocial and communication concerns that may have emerged as a result of their progressive neurodegenerative condition, and/or potentially slow the inevitable decline of functional communication that occurs as a consequence of PPA. The study will enroll individuals who have completed, were screened for, were placed on the waitlist for, or new persons meeting the eligibility criteria for the related study, STU00206086, to understand the added benefit of adding social work to the intervention. The intervention will be provided remotely by speech-language pathologists and social workers using a HIPAA compliant Zoom license, provided by Northwestern University. This study will be a continuation of one of the largest non-pharmacologic intervention studies for individuals with PPA to date. It will add critical information regarding the effectiveness of telepractice interventions for communication disorders in adults with primary progressive aphasia specifically, and in

dementia more broadly. The information gained will be especially important for understanding the psychosocial needs of individuals and in different stages of the disease, a topic that is currently not covered in research.

Aim: Understand the added benefit and feasibility of multicomponent (speech-language therapy and social work) intervention for individuals who have completed, were screened for, were placed on the waitlist for, or new persons meeting the eligibility criteria for the related study, STU00206086

Background:

Primary Progressive Aphasia. The diagnosis of primary progressive aphasia (PPA) is made when a relatively isolated and progressive impairment of language that occurs as a result of a neurodegenerative disease process[1]. It is associated with Alzheimer's disease and/or a form of frontotemporal lobar degeneration. Adults with PPA can have deficits in word finding, word usage, word comprehension, and/or grammar, among other language impairments. Consensus research criteria recognize three variants of PPA based on the profile of language deficits: agrammatic (PPA-G), semantic (PPA-S) and logopenic (PPA-L)[2].

Speech and language intervention for language impairments associated with PPA. Promising case-reports and small group studies of non-pharmacological communication interventions in PPA show positive effects of impairment-based and participation-based interventions (i.e., script training to improve fluency, multi-syllabic word production training to improve articulation; for reviews see[9-11]). However, with few exceptions (our current RCT) there are no gold-standard randomized control trials, which limits the ability to move this research into mainstream clinical implementation. Importantly, few studies have extended intervention and data collection beyond a 6-to-12-month window or included social work, and none have done so at the group level. As such the longer-term benefits of extended multi-component interventions on maintaining communication abilities, preserving participation in functional communication activities, and slowing language impairment progression remain unexamined. We will address this concern by enrolling a subset of consenting participants into a multi-component intervention to examine whether we are able to address both functional and psychosocial needs of the individuals living with PPA.

Telepractice model. Access to services and the ability to conduct large evidence-based studies has been limited because individuals with PPA may not live near an SLP who has experience in treating individuals with neurodegenerative aphasia[15]. In fact, >40% of the participants in our preliminary Communication Bridge study lived in rural areas and >94% lived outside Chicago, IL, the home site for the study. Distance from a healthcare facility is one of many variables that can be alleviated using a telepractice model. The intervention in this protocol will be deployed via a telehealth service delivery approach. This is consistent with our in-progress Phase-2, 12-month, study and also our pilot study[16]. To date, 33 people have completed our 12-month study using our Communication Bridge web-based portal and a video-conferencing platform without any significant issues or concerns.

Social work component. In this protocol, we augment the intervention provided in our base 12-month protocol by adding a social work component alongside the speech-language pathology intervention. The combined, multi-disciplinary intervention approach is designed to address the psychosocial impairments that may interact with language impairments to negatively impact communication outcomes in individuals with PPA. Individuals with PPA tend to have preserved insight into their disease, which may contribute to increased risk for depression[3]. Onset of PPA tends to be before the age of 65, which is younger than those with amnestic Alzheimer's dementia[4]. This creates unique psychosocial and economic challenges since adults with PPA are commonly in the prime-earning phase of their careers and often have dependent children at home[5]. Social workers can help families navigate the difficult decisions related to their diagnosis. Here we will provide a multi-component intervention to examine whether we are able to address both functional and psychosocial needs of the individuals living with PPA.

2.0 Enrollment Criteria (who can be in your study and who would not be eligible to participate in your study):

Must have completed, were screened for, were placed on the waitlist for, or new persons meeting the eligibility criteria for the related study STU00206086 within the last 24 months and maintain eligibility criteria:

- Must speak English as their primary language and have sufficient proficiency in English for completing all assessment and treatment activities
- Hearing adequate to have a conversation in a crowded room (correction permitted)
- Reported vision adequate to read the newspaper (correction permitted)
- Must have a communication partner (spouse, family member, close friend) who is willing to participate in the study
- Adequate experience with computers
- Diagnosis of PPA must be made by a clinician
- Must be 18 years or older
- Must have the ability to consent

3.0 Sample Size:

Up to 30 individuals with PPA and their communication partners (spouse, family member, or close friend) will be enrolled. A formal sample size estimate and power analysis was not completed as this is a feasibility study to examine the added benefit of extended multi-component treatment for persons with PPA. Data from this Phase I expansion of our current Phase II trial will be used to establish feasibility of the protocol, to make protocol adjustments, and to collect preliminary effectiveness data for an upcoming grant submission.

4.0 Recruitment and Screening Methods:

This study will only recruit participants from four routes:

- Participants completed the related study (STU00206086). When they consented to that study, they selected "I agree" to be contacted for future studies.
- Participants were screened for the related study (STU00206086) and were not eligible to participate and voluntarily signed up for the Mesulam Center Research Registry (which could have occurred before or after they were screened). The Mesulam Center Recruitment Registry is housed within the Alzheimer's Disease Core Center IRB-approved protocol (STU00023196). Participants residing in the European Economic Area will not be contacted for this study. There will be no external recruitment strategies needed. Potential participants will be contacted by the study team, with whom they already have an established relationship. Participants will be emailed the initial recruitment script (see supporting document) and asked if they would like to enroll in this study.
- Participants were placed on the waitlist for the related study (STU00206086) due to the high volume of interest and limited enrollment capacity. All participants were added to the waitlist after voluntarily signing up for the Mesulam Center Research Registry. Individuals who were seen at NMH's Neurobehavior and Memory Clinic will have a HIPAA authorization in their consent form to grant approved study team members access to their medical records through an Enterprise Data Warehouse (EDW) exception. Individuals who were not seen at NMH will be asked to send in their own medical records and will not require a HIPAA authorization. We will verify these individuals as meeting eligibility criteria through medical records and a brief screening by our team.
- New persons meeting eligibility criteria for the related study (STU00206086) who contacted the study team after enrollment closed. Individuals who were seen at NMH's Neurobehavior and Memory Clinic will have a HIPAA authorization in their consent form to grant approved study team members access to their medical records through an Enterprise Data Warehouse (EDW) exception. Individuals who were not seen at NMH will be asked to send in their own medical records and will not require a HIPAA authorization. We will verify these individuals as meeting eligibility criteria through medical records and a brief screening by our team

If the participant is interested, a screening call will occur over phone or video-chat. During this interest call, a study team member will complete a brief screening discussion (see supporting document) to assess whether the participant has experienced any significant life or medical changes since being screened for or completing STU00206086 that affect eligibility. A summary of this conversation will be stored in the REDCap project.

5.0 Research Locations:

The research team will be located at the Mesulam Center for Cognitive Neurology and Alzheimer's Disease. Speech language pathologists and social workers that provide treatment for the study will come from Northwestern University and Oregon Health and Science University.

All research and data collection visits will take place online over a HIPAA-compliant Zoom software. This study does not require any in-person visits. The potential participants who will enroll in this study come from all over the United States or international countries, excluding the European Economic Area, and will connect to the study visits from their home.

6.0 Multi-site Research (research that involves external collaborating institutions and individuals):

The individuals from OHSU are clinicians on the current study. However, all hard copies of data and coordination for the study will take place at NU. Enrollment decisions will be made by the team at NU and participants will be assigned to one of the clinicians. All recruitment, enrollment, and consenting procedures take place at NU. We are using these clinicians because they are experts in treating individuals with primary progressive aphasia, which is rare.

The researchers joining us from OHSU are Aimee Mooney, M.S., CCC-SLP, speech-pathologist and Melanie Fried-Oken, PhD. Both researchers are listed as Co-Investigators. Aimee Mooney will be seeing participants as a treating clinician. Dr. Fried-Oken will not see participants for the study but will play an advisory role and have access to participant data. An IAA has been established between Northwestern University and OHSU. Northwestern University will serve as the IRB of Record.

7.0 International Research (where data collection will occur outside the United States and U.S. territories, including online activities)

International participants, excluding those from the European Economic Area, may be enrolled if they meet all eligibility criteria, including using English as their primary language. Similar to domestic participants, international participants will join all study visits using the iPad provided for them. All data collection will take place from Northwestern University and our approved collaborator at OHSU. An external IRB review will not be obtained since Northwestern will remain the primary study site. In accordance with Northwestern's policy, the Institution's human research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects, will be guided by an assurance of specific principles governing the institution in carrying out its responsibilities for protecting the rights and welfare of humans in research conducted at or sponsored by the institution.

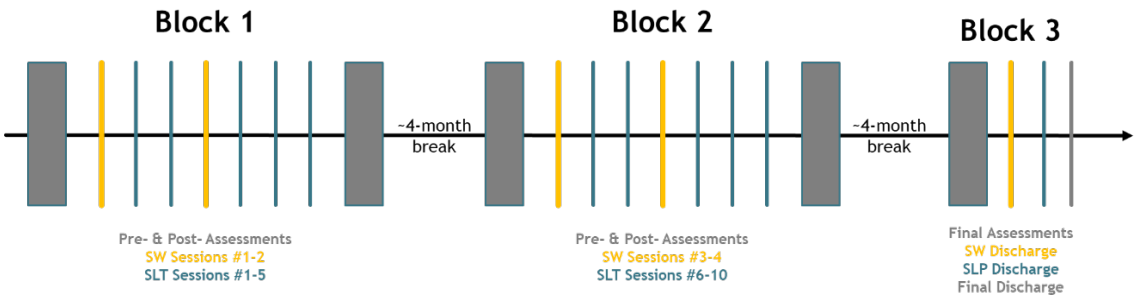
8.0 Procedures Involved:

Eligible participants will be enrolled in this study for up to 18 months. Blocks 1 and 2 will last about 3 months each, with an approximately 4-month break between each block. After Block 2, there will be an approximately 4-month break. Block 3 will last about 1 month.
Participants will be mailed an Apple iPad, Apple Smart Keyboard, and Apple Pencil to keep for the duration of the study. The study team will use secure tablet shipping boxes through FedEx to deliver and track shipments. The Apple equipment will be used to

connect for study visits and to complete home exercises assigned during the study. When the participant has completed the study, they will be a sent a FedEx shipping label to return the Apple equipment in the box they were originally shipped in.

Orientation and Training

Participants and communication partners will receive an orientation to the technological aspects of the study. During this session, both the participant and the communication partner will be consented to the study, provide updated demographic and health information, and learn the technological components of the iPad and study web application. This web-application is the main resource for the study and is where individuals access their therapy sessions, instructional videos and resources, and interactive web exercises.



After the orientation, participants and communication partners will go through a series of Blocks. In Blocks 1 and 2, there will be a pre- and post-evaluation, consisting of a series of neuropsychological measures and/or questionnaires. Blocks 1 and 2 will contain 5 therapy sessions and 2 social work sessions. Block 3 will consist of an evaluation with neuropsychological measures and questionnaires followed by three discharge sessions. The battery may be reduced at any timepoint based on the study team judgment of participant burden and ability. Neuropsychological measures will require at least a 6-month gap between administration.

1) Neuropsychological Testing. Participants with PPA will complete neuropsychological tests relevant for assessing cognition with a particular focus on language abilities for individuals with primary progressive aphasia. Administered by a research coordinator. *See appendix.*

2) Questionnaires. A research coordinator will administer the questionnaires to the participant at the neuropsychological testing session. The communication partner may assist the participant with PPA in completing the questionnaires if needed. The communication partner will also fill out self-report questionnaires including measures of communication/behavioral/cognitive abilities of the individual with a diagnosis and estimates of caregiver burden. Assistance will be provided from the study team as requested. *See appendix.*

3) Speech-Language Pathology (SLP) Evaluation. At this evaluation, the SLP will complete several assessments for assessing language abilities for individuals with primary progressive aphasia. They will also discuss personal goals (participant and communication partner), current challenges related to their diagnosis, and therapy expectations. *See appendix.*

4) *Speech-Language Pathology (SLP) Therapy Sessions.* Sessions are approximately 1 hour long. The sessions will be composed of impairment-based strategies (e.g., script training and training of target-words), compensatory-based strategies, and other related strategies and tasks as deemed appropriate by the SLP. The SLP, the participant with PPA, and the communication partner will collaboratively identify the most appropriate strategies to focus on based on other evidence-based therapy approaches (conversation strategies, impairment-based strategies, compensatory strategies). During therapy sessions, the communication partner is engaging as a co-participant in the intervention.

5) *Social Work Sessions.* Sessions are approximately 1 hour long. The first session will include an in-depth psychosocial assessment with the participant and their communication partner. Areas of discussion will include how the participant and family are coping with PPA symptoms and changing roles, their understanding of the diagnosis, the health of their family relationships along with emotional, social and financial resources, overall strengths and challenges and the need for community services. The participant, family and social worker will work collaboratively to identify needs and tailor plans for future sessions to address the most concerning identified needs.

9.0 Research with Vulnerable Populations

Vulnerable Populations: Individuals with Primary Progressive Aphasia are cognitively impaired. However, individuals in the mild stages of Primary Progressive Aphasia have deficits primarily in the use of language. Memory, attention, and other cognitive abilities are preserved. When the individuals enrolled or were screened in the related study, they were verified as being in the mild stages of the disease through medical records and a brief evaluation by our team. Although some disease progression is expected, we anticipate (based on more than 15 years of working with this population) participants will be able to understand and complete the consent process. We will gather medical records and conduct a screening for the individuals placed on the waitlist and new persons who contacted the study team after enrollment closed for the related study to determine eligibility. To aid with comprehension, participants with PPA will be consented with their communication partner. Their communication partner will also be consented into the study. This study provides an intervention for a population that has no pharmacological treatment for their disease, and thus a benefit for them to more effectively cope with their symptoms.

Individuals will be provided with the opportunity to speak with members of the study team, including speech-language pathologists, prior to consent and enrollment to ask any

questions they have. The study team members, including SLPs and social workers, are trained in communicating with individuals of this population.

To confirm that participants have the ability to provide their own consent, individuals with PPA will complete a consent assessment task with the research coordinator after reviewing the consent from. The task will prompt the participant to respond, either verbally or by pointing, to yes or no questions regarding information discussed in the consent form. If nonverbal answers are provided, the communication partner will aid in relaying the participant's gestural answers. During this task, the research coordinator may need to provide clarification on any areas of confusion. This assessment task will provide documentation of the participant's understanding and consent (see supporting documents). The assessment task template is based on a task used in the ACT NOW international clinical trial (NCT00831740).

During the first visit of Block 2 and Block 3, the research coordinator will confirm participants; understanding of their involvement in a research study. The research coordinator will complete the consent confirmation task (see supporting document) and document PT's decision. If the participant expresses confusion, the research coordinator will re-administer the consent assessment task and provide any clarification needed. The consent confirmation task and updated consent assessment task, if needed, will be stored in the participant's study file on FSMresfiles.

10.0 Incomplete Disclosure or Deception:

N/A

11.0 Consent Process:

Both participants (individuals with PPA and their communication partners) will be consented verbally over video-chat with a research coordinator. The consent forms will be housed within REDCap. There will be two separate consent forms for individuals with a PPA diagnosis. Participants who were seen at NMH's Neurobehavior and Memory Clinic will have a HIPAA authorization in their consent form to grant approved study team members access to their medical records through an Enterprise Data Warehouse (EDW) exception. Participants who were not seen at NMH will be asked to send in their own medical records and will not require a HIPAA authorization. Participant consent forms that contain HIPAA authorizations must be retained for at least 6 years after completion of the study.

During this video-chat consent, participants will have the study explained to them in detail and they will have ample time to ask for questions or clarifications. A research coordinator will go through the REDCap consent (sent via link to the participant) withthe participants. After reviewing the forms, the research coordinator will administer the consent assessment task to ensure the person with PPA's understanding and consent to participate. The participants will electronically sign the consent forms. Participants will be emailed their signed informed consent from REDCap after completion of the form.

Participants (individuals with PPA and their communication partners) will be asked to consent to an optional element on the consent form that asks if they would be willing to allow their audio and/or video recordings from sessions to be used in scholarly presentations or publications. These recordings could potentially be shown at disease-related conferences and speech-language pathology professional conferences in order to help professionals in the field understand the research and/or aid in training purposes. Because of the unique and rare presentation of PPA, speech samples and/or video recordings that display the effortful motor movements in producing words are often the best way to convey how the disease presents itself. In order to thoroughly explain our research methods and describe the speech therapy strategies used, it will be most beneficial to provide audio and/or video recordings during presentations to explain what written or verbal text cannot accomplish. If the participant answers "I agree," he or she is indicating they understand the risks associated with identification.

Participants (individuals with PPA and their communication partners) will complete an optional section on the consent forms that asks if they will allow their identifiable data to be shared with Mesulam Center faculty, staff, students, or approved collaborators for use in future studies. Participants will initial whether they agree or disagree on the REDCap form via the electronic signature function in REDCap.

Participants (individuals with PPA and their communication partners) will complete an optional section on the consent forms that asks if the PI can contact them in the future to see if they are interested in participating in other research studies by the PI. Participants will initial whether they agree or disagree on the REDCap form via the electronic signature function in REDCap.

12.0 Waiver of Participant Signature on Consent Form:

N/A

13.0 Waivers and Alterations of Consent Information:

N/A

14.0 Financial Compensation:

N/A

15.0 Audio/Video Recording/Photography

All study visits will take place online through a HIPAA-compliant Zoom license, provided by Northwestern for the Communication Bridge email account. All visits will be audio and video recorded for internal data collection purposes. The recordings are essential for data collection and analysis. Due to the language impairments present in PPA, participants and SLPs often communicate through nonverbal language (i.e., gestures, typed visual aids) during study visits. The therapy tasks being completed require us to watch visual indicators during data analysis. The data are used for intervention fidelity assessments that are conducted over the duration of the protocol. The

audio and video recordings are used to verify responses to uphold data rigor and integrity. Additionally, the recordings are used for continuous trainings of study personnel.

Participants and communication partners must consent to have their audio and video recorded for data collection purposes to participate in this study. There is an optional element in the consent form asking participants for permission to use audio and/or video recordings for use in scholarly presentations or publications.

All video files will be stored on FSMresfiles on locked computers and will be coded by study identity. Video recordings will not be saved to the Zoom cloud. The recordings themselves will not be deidentified. Portions of the recordings will be transcribed in order to complete therapy tasks and fulfill data collection (i.e., speech therapy strategies that incorporate script training and scoring). These transcriptions will be coded by study identity and stored on FSMresfiles. Only the PI and approved study personnel will be able to access these files. Recordings will be saved for as long as may be necessary to protect any intellectual property resulting from the work.

16.0 Potential Benefits of this Research:

By participating in this study, participants will learn new strategies for coping with their communication difficulties caused by the disease. These strategies may allow the individuals to engage more actively in their lives by facilitating communication. Due to the progressive nature of the disease, individual's communication will get worse over time and is known to impact psychosocial wellbeing of families. This current study is important in determining the duration of potential benefits of a multi-component intervention beyond the speech language therapy intervention studied in the related protocol.

Information learned in this research will provide valuable knowledge for the speech therapy community regarding treatment for moderate to late stages of PPA.

17.0 Potential Risks to Participants:

The risks for participation in the proposed research are minimal. Potential adverse events associated with this research include:

1. Loss of confidentiality
2. Fatigue and/or frustration in performing the online intervention
3. Depression and Anxiety: Caregivers of individuals with PPA and living with PPA can both be psychologically taxing experiences. It is not abnormal for individuals in these circumstances to express negative emotions, including hopelessness, sadness, anger, or frustration. It is important to recognize when these symptoms go beyond what is normally expected.

These risks will be minimized in the following ways:

1. Data will be stored securely, and any data sharing agreements will adhere to NU's strict policies on privacy protection.

2. This risk of fatigue is considered to be minimal and is addressed in the consent form. Fatigue will be minimized by advising the participant and caregiver that they should rest if they feel fatigued, before continuing with any component of the intervention. Participants will be working with licensed speech-language pathologists who are trained to identify fatigue and frustration and they will modify the plan accordingly. Participants will be informed of this risk when consenting to join the study.
3. The risk of depression and anxiety is considered to be minimal. Depression and Anxiety measures are completed with both the participant and communication partner at every evaluation. Specifically, the CAT-version of the PROMIS Depression and Anxiety Sub-tests are given to participants and communication partners (Cella et al., 2010). If the measures reveal a clinically relevant level of anxiety or depression (based on normative values), the research team will follow a risk-specific protocol outlined in the Risk Identification and Response Plan. The Risk Identification and Response Plan identifies unanticipated risks that go beyond what is expected in this study. However, if any verbal/behavioral indication of suicidal/homicidal thoughts are observed by the speech-language pathologists in the study, measures will be taken to alert the appropriate people. A licensed clinical social worker, Darby Morhardt, Ph.D., is a Co-Investigator on this study. She will be consulted according to the plan and will meet with our participants for a session. Since Dr. Morhardt is a member of the study team, this information will be kept with the participant records.

18.0 Provisions to Protect Participant Privacy and Data Confidentiality:

All of the data and materials collected are for research purposes only, and data will be kept in strict confidence. No information will be given to anyone without permission from the participants. The consent form includes the informed consent statement required by the IRB of NU for clinical studies of cognition. The consent form will explain that only the PI and approved study personnel will have access to medical records and personal identifiable information. Participants will be given the opportunity to ask questions and will be provided with a signed copy of their consent form. All data collection will occur over a HIPAA-compliant Zoom software. Participants will be given a unique meeting ID for each study visit that only study personnel will have access to.

Medical records will be sent to the study team by the participants, if they are not seen by a doctor affiliated with Northwestern Memorial Hospital. Participants who were seen at NMH will consent to have their medical records shared with the study team for review by completing the HIPAA Authorization on the consent form. No one outside the PI or study team will have access to the medical records.

Data will be collected, entered, and stored securely in REDCap (Research Electronic Data Capture) database using the subject ID number. REDCap is a secure, web-based application for building and managing online data capture for research studies. Data will be de-identified through the use of the assigned study ID number and entered into the

password protected REDCap database within 48 hours of collection. All participant data are checked for accuracy. Data are maintained in a format that is easily transferred to statistical software for analysis. The database will be password protected and accessible only to the principal investigator and study personnel. Paper copies of any measures will be kept in locked files in our research offices and will only be accessible to the PI and study personnel. Northwestern University is a member of the REDCap consortium and the services are made available for this project through our CTSA-funded NUCATS Institute.

Data from the web-application will be constructed using an industry-standard software platform (PostgresSQL, Ruby on Rails, Apache, Linux). Data obtained through the web-application infrastructure will be stored and managed by Table XI, a product development and software consultant firm, and will be protected via IP restriction and on a Virtual Private Network accessible only to study-authorized staff. Data from the web-application will be stored using the participant's study ID number. Performance data from the web-application (e.g., Picture Cards accuracy) can be downloaded according to the participant study ID by the PI or approved study personnel into files that are easily used for data analysis (e.g., .csv, .xls). All access to this application will be provided over encrypted-TLS communication and all servers are locked and managed in a physically secure facility with Marlok identity management.

19.0 Data Monitoring Plan to Ensure the Safety of Participants:

An adverse event (AE) is any untoward medical occurrence in a participant during participation in the clinical study that is attributed to the cognitive testing or the engagement in the online therapy intervention. An adverse finding can include a sign, symptom, abnormal assessment, or any combination of these. While all adverse events will be reported, some may be expected due to the participant's medical condition. Each adverse event will be classified as being attributable or not to participation in the study. A serious adverse event (SAE) is any AE that results in one or more of the following outcomes that are attributable to participation in the study:

- Death
- A life-threatening event
- Inpatient hospitalization or prolongation of existing hospitalization
- An important medical event based upon appropriate medical judgment

Grading Scale: AEs will be labeled according to severity, which is based on their impact on the participant. An AE will be termed "mild" if it does not have a major impact on the participant, "moderate" if it causes the participant some minor inconvenience, and "severe" if it causes a substantial disruption to the participant's well-being.

Study Relatedness Criteria: AEs will be categorized according to the likelihood that they are related to the study intervention. Specifically, they will be labeled definitely unrelated, definitely related, possibly related, or probably related to the study intervention.

Reporting and Follow Up: AEs will be reported by severity, relatedness to the intervention, action taken and outcome. Each adverse event will be reported separately. All AE reports and annual summaries will be de-identified and will not include participant-identifiable material. The PI will engage in continuous close monitoring of research participants with reporting of AEs to the Northwestern University Institutional Review Board.

SAEs that are unanticipated, serious, and possibly related to the study intervention will be reported to Northwestern University's IRB within 24 hours of notification of its occurrence.

20.0 Long-term Data and Specimen Storage and Sharing:

Data collected from this study will be stored for at least the minimum requirement of three-years after study completion. Per Northwestern's policy on Research Data: Ownership, Retention, and Access, research data from this study may be kept for as long as may be necessary to protect any intellectual property resulting from the work. Data will be stored in locked files in our research offices as well as on FSMresfiles.

21.0 Qualifications of Research Team to Conduct the Research:

All study team members are CITI trained.

Speech-Language Pathologists (SLPs): SLPs have completed a two-year Master's program in Speech-Language Pathology and hold a current Certificate of Clinical Competence (CCC) issued by the American Speech-Language-Hearing Association (ASHA).
Social Workers: Social workers must have completed a Master's program in Social Work and must be a Licensed Clinical Social Worker (LCSW) or Licensed Social Worker (LSW) in the State of Illinois.
Research Staff: All staff members go through a rigorous training protocol before performing study visits. This includes observing others team members perform data collection, studying the protocol and standards of procedures, and being observed by senior team members until approved to work solo.

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Appendix

This appendix contains a comprehensive list of all measures that may be used throughout the duration of the study. The battery may be reduced at any timepoint based on the study team judgment of participant burden and ability.

Neuropsychological Measures

1. Western Aphasia Battery
2. Rivermead Behavioral Memory Test – Version A
3. Mini-Mental Status Exam
4. Psycholinguistic Assessment of Language Processing in Aphasia – reading subtest
5. Screen for Dysarthria and Apraxia of Speech – increasing word length subtest
6. Boston Naming Test
7. Peabody Picture Vocabulary Test
8. Discourse Elicitation Tasks
9. Clinical Dementia Rating

Questionnaires for Participant

1. Communication Confidence Rating Scale for Aphasia
2. Communication Participation Item Bank
3. Assessment for Living with PPA (reviewed with SLP)
4. PROMIS Depression – computer adaptive test
5. PROMIS Anxiety – computer adaptive test

Questionnaires for Communication Partner

1. Neuropsychiatric Inventory Questionnaire
2. Montgomery Burden Interview
3. Health Utility Index
4. Revised Dyadic Adjustment Scale
5. Parent Adult-Child Relationship Questionnaire (Mother/Father)
6. Activities of Daily Living Questionnaire
7. Perception of Communication Index – Dementia of the Alzheimer's Type
8. Communication Effectiveness Index

9. PROMIS Depression – computer adaptive test
10. PROMIS Anxiety – computer adaptive test

SLP Measures

1. Assessment for Living with PPA
2. Social Network Inventory – revised questionnaire
3. Progressive Aphasia Severity Scale