Discourse Intervention in Aphasia
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Consent Form
Discourse Intervention in Aphasia

INTRODUCTION
As a person with aphasia, you are being invited to participate in a research study to helpus better understand the effects of treatment for conversation.

This research study will be conducted at Boston University, Sargent College of Healthand Rehabilitation Sciences with Elizabeth Hoover as the principal investigator. The study will also be conduced by Gayle DeDe at Temple University and Gretchen Szaboat the Adler Center. Up to 68 participants will be enrolled at each site across the 5 years of the grant.

You do not have to participate in this research study. Before you make a decision to participate, you should read the rest of this form. The main purpose of research is to benefit future patients and society in general. You might get personal benefit from participating in this study, but you should understand that the purpose of research is tocreate new knowledge.

PURPOSE
The purpose of this study is to gather data which will help us better understand the effects of a treatment to improve conversational skills for individuals with stroke-inducedAphasia. The study is being conducted at Boston University (BU), Temple University, and the Adler Aphasia Center. Coded data from all sites will be stored on a server at BU.

PROCEDURES
If you are eligible and decide to participate in this study, you will be randomly assigned to receive treatment immediately or following a delay of up to 6 months. Treatment, whether received immediately or following the delay, will take place in 60 minute sessions twice a week for 10 weeks (total of 20 hours). Treatment may be provided in large group (6 - 8 persons) or small group (2 persons) and will focus on conversations about topics designed to enhance participation in daily tasks using commonly accepted protocols. Treatment will be individualized to meet your individual needs. For example,you may want to work on naming, or producing complete sentences within the conversations. The goal of this research is to understand the effects of conversation treatment for persons with aphasia

You will also be asked to participate in 3 to 5 assessment periods. Each assessment will include 2-3 hours of testing divided across two sessions. Sessions will be scheduled at specificintervals at your convenience before and after treatment.
Specifically, you will be complete common, standard speech and language tests. Assessment sessions will be completed immediately before the program begins, immediately after treatment ends, and at 3, 6, or 12 months after treatment. The data will help us better understand your aphasia and establish your treatment goals. The results will also help us determine the effects of the program. Testing and treatment sessions will be video recorded, with your consent. We ask that you do not participatein other speech-language therapy focusing on conversation while participating in this study.

RISKS

There are no known risks or discomforts associated with this study. You may get tired,but you may take a break at any time. If you consent to video recording, it is possible that you will lose confidentiality of your health information, as your face will be visible inthe recording.

NEW FINDINGS STATEMENT

You will be informed if any significant new findings develop during the course of thestudy that may affect your willingness to participate in this study.

ALTERNATIVES

If you choose to withdraw from the study you would still be eligible to participate in other programs offered in Sargent College, Temple University, or the Adler Aphasia Center.

BENEFITS

You may benefit from participating in this study. This research program may result in improved language function, mobility, dietary habits or participation in cooking, shopping, etc., and leisure activities. While participants may experience these benefits,results cannot be guaranteed for all subjects.

It is hoped that additional information gained in this research study may be useful in thetreatment of other patients with aphasia.

We will share the results of your tests and the outcomes of your treatment with you verbally.

COSTS

There are no costs to you related to participation other than your transportation to thecenter.

PAYMENT TO SUBJECTS

You will receive $100 for completing the treatment and $35 for each assessment.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

Study records will be collected at BU, Temple University, and the Adler Aphasia Center. Records which identify research participants will be kept confidential as required by law. Researchers cannot guarantee absolute confidentiality. Efforts will be made to keep your personal information confidential. Your information will be de-identified and kept in a secure server at BU. The Institutional Review Board and study staff will have access to the data collected. If the results of this study are published or presented in public, information that identifies participants will be removed.

QUESTIONS

Before you sign this form, Elizabeth Hoover or her associates should answer your question(s) to your satisfaction. If you have any more questions, concerns, or complaints after signing this form, you may contact Elizabeth or one of her associates at(617) 353-8967. If you have any questions about the rights of research subjects, you may contact the Charles River Campus Institutional Review board at (617) 358-6115.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

You may skip any questions which you are not comfortable answering on anyquestionnaire or survey.

You may stop being in the study at any time without penalty. Your decision to stop willnot prevent you from enrolling in other treatment or services at the Sargent College of Health and Rehabilitation Sciences. The entire study may be discontinued for any reason without your consent by the investigator conducting the study. Participation canbe discontinued by the investigator if it is felt to be in the participant's best interest or ifthe participant does not follow the study requirements.

CONSENT

Elizabeth Hoover, Gayle DeDe, or Gretchen Szabo and their research associates have given you information about this research study. They have explained what will be doneand how long it will take. They explained any inconvenience, discomfort, or risks that may be experienced during this study.

I freely and voluntarily consent to participate in this research study. I have read the information in this form and have had an opportunity to ask questions and have them answered. **I will be given a signed copy of the consent form to keep for my records.**

☐ **I authorize video recording of my involvement in this study.**

_____
Type/Print Subject's Name

_____ _____ _____
Signature of Subject Time Date

_____
Type/Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date