Informed Consent

Official Title: Strategy Training for People with Aphasia After Stroke

ClinicalTrials.gov ID (NCT number): NCT03593876

Protocol Date: May 28, 2020

University of Pittsburgh

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Strategy Training for People with Aphasia after Stroke

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SOURCE OF SUPPORT: Eunice K. Shriver National Institute of Child Health and Development, National Center for Medical Rehabilitation Research (R01 HD074693)

Researchers at the University of Pittsburgh are conducting a **research study** to see whether new rehabilitation methods are effective for helping people with a stroke regain independence with important every day activities. You are being asked to take part in this research study because your stroke has affected your ability to communicate and you are receiving treatment on an

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inpatient rehabilitation unit. We will ask 25 people to be in this research study.

If you decide to take part in this research study, **first you will be asked to take 3 tests that measure your thinking and speaking abilities, and ask questions about your feelings**. These tests will tell us if you are eligible for this study, and together they will take about 1 hour. We will also review your medical record to determine if you meet study criteria.

If you are eligible, **we will ask you to complete additional tests of your thinking and moving abilities, and answer questions about your mood and your everyday activities.** These tests will take **2 hours total,** and will be **split into 2 sessions.**

After the tests, a **rehabilitation professional** will **meet with you every day** while you are in the rehabilitation unit for about 1 hour each day for a total of 10-15 sessions. The rehabilitation professional will ask you about every day activities that are important to you, and may have you practice these activities. These sessions will be videotaped. If you do not complete the 10-15 research sessions while you are in the rehabilitation unit, you will be asked to complete the remaining sessions at your home.

We will ask you to **repeat some tests 3 and 6 months later** during 2 hours sessions at your home. Finally, we will **call you at your home 12 months from now** to ask you questions about your everyday activities, which will take approximately 30 minutes.

If you decide to participate in this study, your attending physician and clinical care team at UPMC will be notified of your enrollment. As part of this study, we are **requesting your authorization or permission to review your medical records.** We will obtain past, current and future demographic (age, gender, race, ethnicity, education, vocation, pre-stroke residential status, social support), medical (stroke location and volume, stroke etiology and onset, co-morbidities, medications) and rehabilitation history (type and duration, documented impairments). This information will be used to help us learn about your stroke and rehabilitation. As part of this research study, some information that we obtain from you may be placed into your medical records held at UPMC, including progress notes and results from study testing sessions. This identifiable research data may be shared with your primary care physician or clinical care team. In addition, if we identify previously undiagnosed conditions that may benefit from treatment, we will notify you and request permission to notify your primary care physician and UPMC clinical team.

Identifiable medical record information will be made available to members of the research team for an indefinite period of time. Your de-identified medical information, as well as information obtained during this research study, may be shared with other researchers in the future. **We will protect your privacy and the confidentiality of your records**, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University. This authorization is valid for an indefinite period of time. However, **you can always withdraw your authorization to allow the research team to review your medical records** by contacting the investigators listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

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The possible risks and discomforts of this research study include the possibility that you may become frustrated, upset or tired during the testing and the daily sessions. If this happens, you will be allowed to take a break or stop the testing. There is also the risk that information about you may be seen by someone who is not part of the research team during the screening, testing or daily sessions. We will make every effort to ensure that your information is protected so only authorized persons can see your information. Finally, there is a possibility that you may experience a fall or injury during the daily sessions or during the motor performance testing at each time-point (Baseline, 3 and 6 month follow ups). A trained rehabilitation professional will be present during the testing and the daily sessions. If you do experience a fall or injury, you will receive treatment through UPMC.

You may benefit by participating in the daily sessions with the rehabilitation professional **but there is no guarantee that this will help you**. We hope to learn whether or not the program is useful to people like you while they receive inpatient rehabilitation.

If we learn about any new risks that may cause you to change your mind about continuing to participate, we will let you know.

Neither you, nor your insurance provider, will be charged for any of the procedures performed for the purpose of this research study. You will be charged, in the standard manner, for any procedures performed for your routine medical and rehabilitation care (i.e., doctor or medical visits, treatments, and all other tests and procedures including laboratory tests and imaging that you would normally have as part of your regular medical care).

You will be paid $20 for each completed testing session at every time-point (Baseline, 3, 6, and 12 month follow-ups) for a total of $80 over the course of the 12-month study.

Any information about you obtained from this research will be kept as confidential (private) as possible. Research records, including the videotapes, will be stored in a locked file cabinet or in password-protected computer databases, and you will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

In addition to the investigators listed on the first page of this consent form and their research staff, authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years and for as long as it may take to complete this research study.

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In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Center for Medical Rehabilitation Research within the National Institute of Health, which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law if the investigators learn that you or someone with whom you are involved is in serious danger or potential harm.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, including progress notes and results from study testing sessions that will be placed in your medical records at UPMC.

Your participation in this research study is completely voluntary. Whether or not you provide your consent for participation in this research study, or if you decide to withdraw your consent after you sign this consent form, will have no effect on your current or future relationship with the University of Pittsburgh, UPMC hospital or affiliated health care provider. You may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor. **If you decide not to take part in this research study, you will receive usual rehabilitation care as determined by the clinical team at UPMC.**

You may withdraw your consent for participation in this research study at any time. Any identifiable research or medical information obtained for this research study prior to the time you withdraw your consent may continue to be used and disclosed by investigators for the purposes described above. To formally withdraw your consent for participation in this research study, provide a written and dated notice of this decision to the Principal Investigator of this research study at the address listed on the first page of this form or call the number listed.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

It is important that you understand that participation in the study is above and beyond your usual rehabilitation care. **If you chose not to participate in the study, or chose to withdraw from the study at a later date, you will still receive rehabilitation care**.

You may be removed from the study if it is determined by the research team for any reason that you do not meet criteria for the study or if the research team believes that further participation in this study would place you at risk for injury.

One of your health care providers may be involved as an investigator in this research study. As both your provider and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another provider who is not associated with this research study. You are not under any obligation to participate in any research study offered by a member of your health care team.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____	_____
Participant's Signature	Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date

PROXY CONSENT

_____ _____
Participant's Name (Print) Date

The above-named individual is unable to provide direct consent for study participation because

_____

Therefore, by signing this form, I give my consent for his/her participation in this research study and provide my authorization to share his/her medical records with the research team.

_____ _____
Representative's Name (Print) Representative's Relationship to Participant

_____ _____
Representative's Signature Date

VOLUNTARY ASSENT:

This research has been explained to me, and I agree to participate.

_____ _____
Participant's Signature Date

VERIFICATION OF EXPLANATION:
I certify that I have carefully explained the purpose and nature of this research study to the participant in appropriate language. He/she has had an opportunity to discuss it with me in detail. I have answered all his/her questions and he/she has provided affirmative agreement (i.e., assent) to participate in this study.

_____ _____
Investigator's Signature Role in Research Study

_____ _____
Investigator's Printed Name Date

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CONSENT FOR CONTINUED PARTICIPATION

I understand that I am currently participating in a research study. I further understand that consent for my participation in this research study was initially obtained from my authorized representative as a result of my inability to provide direct consent at the time that this initial consent was requested. I have now recovered to the point where it is felt that I am able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form I agree to participate in this research study.

By signing below, I agree to continue my participation in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.

_____ _____

Participant's Signature Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

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