Adapting Acceptance and Commitment Therapy for Stroke Survivors With Aphasia
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institute

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY:
Adapting acceptance and mindfulness-based behavior therapy for aphasia
Text

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Sources of support: National Institutes of Health (NIH)

Key information:

You are being asked to take part in a research study. Research Studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision about participating.

The purpose of this study is to pilot and adapt Acceptance and Commitment Therapy (ACT) to help people with aphasia to better adapt and adjust to their aphasia. The typical involvement for this study is 2-4 months (no longer than 6 months), divided into the following phases:

- Pre-treatment assessments (e.g., speech, language, and psychological assessments).
- Treatment phase: Ten treatment sessions provided approximately one to two times per week, consisting of counseling and individualized communication strategy training.
- Post-treatment phase: second administration of assessments and an interview.

Risks related to the study include minimal risk of eyestrain, boredom, frustration, and emotional

distress from thinking about your aphasia. There is also a risk of breach of confidentiality. All safety precautions related to COVID-19 will be followed.

There may be some direct benefits from participating in the study, such as improving your ability to respond to your aphasia and your mental well-being. However, we cannot guarantee these benefits. This study will help researchers to develop more effective treatments for aphasia.

You can decide not to participate in this research without any consequences. Not participating in this study has no effect on your current or future relationship with the University of Pittsburgh or your health care provider.

Why is this research being done?

This research is being done to develop and pilot a treatment design to address mental health and successful communication in aphasia. We aim to adapt Acceptance and Commitment Therapy (ACT), an approach that can improve psychological flexibility in response to difficult circumstances. Our purpose is to help people with aphasia to better adapt and adjust to their aphasia in the presence of emotional distress.

Who is being asked to take part in this research study?

You are being invited to participate in this research study because you are over 18 years of age, a fluent speaker of English, and have an existing diagnosis of aphasia following a stroke. You have no prior history of neurodegenerative diseases (acquired or progressive), and do not have severe language comprehension or severe semantic memory impairments. You also do not have unmanaged drug /alcohol dependence or severe diagnosed mood or behavioral disorders that require specialized mental health interventions. A maximum of 21 people will participate in this study.

What procedures will be performed for research purposes?

Study procedures normally take place at the Language Rehabilitation and Cognition Laboratory in Forbes Tower at the University of Pittsburgh Oakland campus, in your own home, or in a public space (e.g. library, community center) with private rooms. However, given current recommendations regarding COVID-19, this protocol has been modified to have the option that some portions may be administered remotely via tele-conferencing.

> This study involves pre-treatment assessments, a treatment period, and a post-treatment phase:
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> **Pre-treatment assessments**: we will give you a series of speech, language, and psychological assessments, and some assessments that ask about your quality of life. These tests may involve tasks such as naming pictures, following brief instructions, and talking about your emotional responses to aphasia. Testing sessions will take approximately 1-3 hours each. This phase will take approximately 2-4 testing sessions spread out over 2 weeks. You will also be asked to provide personal copies of your medical records to confirm diagnostic information, if it is determined that you are eligible to participate in the study. **Based on the results of this testing, you may or may not be eligible to continue participating in the study.**

Treatment period: If you are eligible to continue the study, you will receive 10 individual treatment sessions given approximately one to two times per week consisting of counseling and individualized language and communication strategy training. This treatment is designed to improve psychological flexibility and to communicate successfully. This treatment is for you. However, it is known that educating caregivers about aphasia and involving them in treatment is helpful for aphasia recovery. For your treatment, you are therefore welcome to invite caregivers for to sit in during sessions and participate in home practice and other carryover activities. This is entirely optional, and you may decide to change their level of involvement at any point during the treatment.

Post-treatment phase: In this phase, we will give you the same series of assessments that you received in the pre-treatment phase. In addition, you will have an interview to provide feedback about the intervention and suggestions for improvement.

In sum, research activities will include speech, language, and cognitive testing, and counseling combined with compensatory speech-language therapy.

All of these procedures will be audio-recorded and/or video recorded.

What are the possible risks, side effects, and discomforts of this research study?

The possible risks of this research study are due to the behavioral tasks and breach of confidentiality.

Risks of the Behavioral Tasks: During the sessions, you will be performing assessment and treatment procedures in which there is **minimal risk of eyestrain, boredom, frustration, and emotional distress**. If eyestrain occurs, we recommend that you take the break, if needed. To alleviate eyestrain, you may look around the room for 30 seconds and allow your eyes to focus on objects further away than the computer screen. If you are getting tired or bored, you may take a break. Some tasks involved in this study may be frustrating, but you are in no way being judged by your performance, and you may take breaks as necessary. While you may experience emotional distress when thinking about your stroke or aphasia during assessment and treatment activities, this treatment is intentionally designed to address negative consequences of this distress. In addition, participants will be actively monitored in terms of mental health status by treating members of the study team in consultation with Dr. Meyer (a clinical psychologist), and will be referred to appropriate clinical mental health providers for additional support as necessary based on severity.

Risks of Breach of Subject Confidentiality: Every effort will be made to ensure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you. Any electronic or hard/paper copies of the information collected about you will be stored in a secured location in our lab or in the private office of the study PI. Only those individuals who are authorized to review your information will have access to it. Your research data may be shared with investigators conducting similar research; however, this information will be shared in a de-identified manner.

For data collection, we will follow all safety precautions related to COVID-19 and general universal precautions with the study providing all necessary PPE for the data collectors.

What are possible benefits from taking part in this study?

You may benefit from participating in this study. Direct benefits may include improvements in your ability to respond to your aphasia and your mental well-being, although we cannot guarantee these benefits. Your participation may help others by enabling medical research to develop more effective treatments for aphasia.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if, during the conduct of this research study, any new information develops, which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for the purpose of this research study.

Will I be paid if I take part in this research study?

You will receive payment of $50.00 for completing the pre-treatment assessments and $50 for completing the post-treatment interviews and assessments. In addition, any costs you incur for travel for coming to this study will be covered by this project, up to $150.00. Payment to participants is considered taxable income regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a "Form 1099 – Miscellaneous" with the IRS and provide a copy to the taxpayer. We are required to give your name and social security number to the Accounting Office. Participants who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet or secured servers. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. Only the researchers listed on the first page of this form and their staff will have access to your research records. You will not be identified in any publication of the research results unless you sign a separate consent form giving your permission (release).

Your de-identified data may be used for future research or may be shared with other researchers at a future date, either directly, or using online research data repositories such as Open Science Framework.

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.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

What will I learn about my own results in this research study?

If you wish, feel free to contact us (email: lrcl@groups.pitt.edu) in the future for a copy of any final published results of this study. These results include only de-identified group-level information, which means that you we will not provide you with identifiable individual results.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent form) and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

- Authorized representatives of the University of Pittsburgh Office of Research Protections. They 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.
- You will be permitted to audio record treatment sessions for your review, if you choose to do so. These audio recordings will contain identifiable information relating to your participation in this study, however the recordings are for your own personal use and study staff will not have access to them. You may use these recordings to reference between

sessions in order to review treatment concepts and to complete tasks outside of treatment sessions.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study no more than seven years from the date of study closure. Electronic recordings of research data could be kept indefinitely.

Is my participation in this research study voluntary?

Yes! Your participation in this research study **is completely voluntary**. This includes the use and disclosure of your identifiable information for the purposes described above. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide 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.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

- To formally withdraw your consent for participation in this research study, you should 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.
- Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. 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.

If I agree to take part in this research study, can I be removed from the study without my consent?

It is possible that you may be removed from the research study by the researchers if you no longer meet the criteria to participate in the study. You may also be withdrawn if you do not follow the instructions given to you by the Principal Investigator or his research staff.

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VOLUNTARY CONSENT

PARTICIPANT'S CERTIFICATION:

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction.
- I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that those questions will be answered by the researchers listed on the first page of this form.
- I understand that it is important that I not withhold any information regarding my past history, and that I may be asked to provide personal copies of my medical records to confirm diagnostic information
- 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.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future care at this institution.

_____	_____	_____
Participant's Printed Name	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.

_____
Printed Name of Person Obtaining Consent

_____	_____
Signature of Person Obtaining Consent	Role in Research Study

_____
Date