Speech Hero: a Rhythm-based Speech Therapy App for Individuals With Aphasia

ClinicalTrials.gov Identifier: NCT04471935

Date: 12/15/2021

The University of Texas at Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research Project: Feasibility of home-based aphasia intervention using mobile technology

Investigators:	**Contact Number**
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Key Information: This study involves behavioral assessments including surveys, and intervention to examine whether a home-based aphasia therapy using mobile technology can lead to improvement in speech and language function. This form is intended for review by the participant's primary caregiver. Your consent to participate (and the consent of the participant) is voluntary and can be withdrawn at any time with no repercussions for you on behalf of the Speech, Language, and Music (SLAM) Lab at the University of Texas Dallas (UTD). All study-related information we collect will be kept confidential. There are no known risks to participating in any component of this study. While it is possible that the participant may benefit from the therapy they receive, we cannot guarantee any benefit as this is an experimental therapy that requires validation.

Purpose: The purpose of this research study is to develop a home-based rehabilitation program using mobile technology for participants with chronic aphasia, a condition in which participants have lost the ability to understand and/or express speech. We hope that persons with aphasia will improve their speech and language abilities through this novel therapy program.

Description of Study: If you and the participant volunteer to participate in this study, we may ask you to do any, if not all, of the following activities:

Behavioral testing:

If the participant is deemed eligible for the study, you and the participant will be invited to one of two locations, based on the participant's convenience: either the Callier Center Richardson, or the Center for BrainHealth at UTD. We will perform in-person behavioral assessment at this location. You will be asked about the participant's music and language background. The participant's hearing acuity may be measured using pure tone audiometry. The participant's cognitive and music abilities will also be assessed. Then, the participant will be administered a standardized aphasia battery test for determining the severity of their symptoms and whether or not they are eligible to participate. When the participant completes the therapy program, these measurements will be taken again so that we may compare their post-therapy scores to those obtained before therapy. Some, if not all, of these behavioral testing sessions will be video recorded.

At the conclusion of the initial behavioral assessment, you and the participant will be introduced to an aphasia therapy app that will be used for home-based daily intervention. We will provide enough time for you and the participant to be acquainted with the computerized

therapy program as well as an opportunity to answer any questions you and the participant may have.

Aphasia Therapy:

The participant will participate in therapy for 4 weeks. This therapy program uses verbal guided speech therapy delivered via our computerized application called Speech Hero. All participants will be asked to use the app a minimum of 5 days per week and to complete one hour-long session. However, if the participant is willing, you are invited to use the application more each day, and even 7 days per week. Every week, we ask that you participate in a brief phone call to check in with us about any questions, concerns, or feedback you have on the therapy program.

Upon completion of the rehabilitation therapy, the same behavioral tests that we administered before the therapy will be administered as post-therapy assessments. Later, a survey will be sent to you asking about the general use of the therapy.

Questionnaires to Assess COVID-19 Symptoms and Exposure:

The investigators will be conducting pre-screening (before the in-person visit) and post-screening (after the in-person visit) questionnaires to assess your symptoms and exposure to COVID-19. The pre-screening questionnaire will be completed approximately 24 hours before the in-person visit and again when you arrive for your session, and the post-screening questionnaires will be completed approximately 5 days and 14 days after the in-person visit. If you experience any symptoms related to COVID-19 or receive positive test results after your participation in this research study, you are strongly encouraged to contact the investigators or the IRB Office.

Number of Participants: 10 participants will complete the experiment.

Length of Participation: The overall time commitment will last approximately 6 weeks. This includes 1 week of pre-therapy measurements, 4 weeks of therapy, and 1 week of post-therapy measurement. However, if you decide to stop participating in the study, we encourage you to tell the researchers.

Inclusion / Exclusion Criteria: This study focuses specifically on people who are experiencing language deficits as a result of brain damage from stroke, i.e. aphasia. To be included in the study, the participant's limb motor function, at least on the left side, should be relatively intact. The participant must be 6 or more months post-stroke.

Possible Risks:

COVID-19:

The novel coronavirus, COVID-19, has been declared a worldwide pandemic by the World Health Organization. COVID-19 is extremely contagious and is believed to spread by the kind of person-to-person contact that you may engage in by participating in this research study. Thus, as with any activity involving person-to-person contact, there is a risk that you might contract the virus and expose other individuals that you might come in contact with after participation in this study. Older adults and people of any age who have serious underlying

medical conditions like heart disease, diabetes, cancer, or a weakened immune system, are at a higher risk for getting very sick from COVID-19.

The University of Texas at Dallas continues to follow the CDC guidelines and recommendations related to COVID-19 prevention. While individuals are not required to wear face masks while on campus, they are encouraged to do so. If you do not have a facial covering and would like wear one during your experimental session, please let your investigator know and one will be provided to you.

COVID-19 Vaccine Disclosure:

The number of fully vaccinated individuals continues to grow, but there remains a portion of the population that has yet to be vaccinated. Studies indicate COVID-19 vaccines are effective at preventing disease and reduce the risk of people spreading the virus. However, some people who are fully vaccinated against COVID-19 will still get sick because no vaccine is 100% effective. Experts continue to monitor and evaluate how often this occurs, how severe their illness is, and how likely a vaccinated person is to spread COVID-19 to others.

The research personnel conducting this experiment have been fully vaccinated. However, while available COVID-19 vaccines have demonstrated high efficacy at preventing severe and/or symptomatic COVID-19, there is currently limited information on how much the vaccines might reduce transmission and how long protection lasts. In addition, the efficacy of the vaccines against emerging SARS-CoV-2 variants is not known.

Additional guidance from the Center for Disease Control (CDC) indicates there many things we are still learning about the vaccine, such as:

- How effective the vaccines are against variants of the virus that causes COVID-19. Early data show the vaccines may work against some variants but could be less effective against others.
- How well the vaccines protect people with weakened immune systems, including people who take immunosuppressive medications.
- How long COVID-19 vaccines can protect people.

Investigators are taking extra precautions based on CDC recommendations. If you have questions about the safety measures that are in place, the investigators can provide you with this information. These measures have been approved by the Institutional Review Board.

Behavioral Testing:

At this time, there are no known significant risks with any behavioral procedures. The participant may experience boredom or frustration with behavioral tasks. We understand that some of the questions in this study and some audio clips may lead to unpleasant feelings. At any time during this study, you and the participant can take a break, skip questions, or stop participating and both you and the participant will still receive full credit for your participation. If you or the participant feel uncomfortably distressed while filling out any questionnaires or completing laboratory tasks, please let us know.

Participants will be informed about new research that provides additional information about risks or that may influence their decision to continue participation in this research.

Possible Benefits to the Participant: It is possible that the therapy will assist the participant in their language skills, however the therapy is experimental and requires validation.

Removal from Study: We may decide to remove you and the participant from this study if you or the participant are unable to keep appointments or follow the researcher's instructions.

Alternatives to Participation: Individuals may choose not to participate without penalty or loss of benefits to which you and the participant are otherwise entitled.

Payments to Participate: By law, payments to subjects are considered taxable income. The pro-rated compensation will be $10/hour for the behavioral experiments. During the therapy component, the participant will be compensated $5 for each day that they use the tablet. Participants will receive payment via GalaxyPay, a pre-paid Mastercard gift card. You will be asked to provide your name, mailing address, date of birth, and gender in order to receive the card.

Voluntary Participation: All individuals have the right to agree or refuse to participate in this study. Individuals who consent to participate also have the right to change their minds while experiencing the experimental procedure. Participants may tell the investigator that they no longer wish to participate. Refusal or withdrawal of participation will not involve any penalty or loss of benefits to which non-participants are entitled. Refusal to participate will not affect participants' legal rights or the quality of education they may wish to receive at UTD.

Records of Participation in this Research: All of the information participants provide to investigators as part of this research will be protected and held in confidence within the limits of the law and institutional regulation. All identifiable data, such as name, date of birth, etc., will be coded with the participant's subject ID and stored separate from the participant's task performance and questionnaire data. When the results of the research are published or discussed in conferences, no information will be included that would reveal the participant's identity.

Identifiable Private Information: Private information that can be used to identify you will be removed from data collected in the course of this study. After such removal, the de-identified data could be used by Investigators for future research studies or distributed to another investigator for future research studies without additional informed consent.

If you or the participant test positive for COVID-19, investigators may be required to notify local health authorities that you and the participant have been on the UTD Campus. If investigators have to report this, they will only provide the minimum information necessary and will not provide any details about the reason(s) for the participant's visit. By signing this form, you and the participant are agreeing that the investigator may do so without an additional signed release.

To provide you with reimbursement for participating in this study, GalaxyPay requires that we collect your name, mailing address, date of birth, and gender. This specific information will be stored separately from the rest of the data collected over the course of the study and will be destroyed as soon as it is no longer required.

Information Available to Others: Members and associated staff of the Institutional Review Board (IRB) of The University of Texas at Dallas may review the records of you and the participant's participation in this research. An IRB is a group of people who are responsible for assuring the community that the rights of participants in research are respected. A representative of the UTD IRB may contact you or the participant to gather information about participation in this research. If you or the participant wish, you and the participant may refuse to answer questions the representative of the IRB may ask.

Publications Associated with this Research: The results of this research may appear in publications but individual participants will not be identified.

Research Results: Upon request, we will inform you and the participant of the outcome of the therapy program.

Contact People: Participants who want more information about this research may contact any of the investigators listed at the top of page 1 of this document. Participants who want more information about their rights as a participant or who want to report a research related injury may contact:

The University of Texas at Dallas Institutional Review Board UTD Office of Research	972-883-4579

Signatures

Your (the caretaker's) signature indicates that you and the participant have read, or listened to, the information provided above and that you have received answers to your questions. The signature also indicates that you and the participant have freely decided to participate in this research and that both you and the participant know you both have not given up any of their legal rights.

_____
Participant's Name (printed)

_____ _____
Participant's Caretaker Signature Date

_____
Name of Researcher Obtaining Consent

_____ _____
Signature of Researcher Obtaining Consent Date