OREGON HEALTH & SCIENCE UNIVERSITY

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The Listening Brain

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Audiobooks for Hearing Loss App as Auditory Training
Small Business Innovation Research (SBIR)
Grant 1R44 DC017403-01A1

NCT04231396

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Information Sheet

IRB#20161

CLINICAL RESEARCH CONSENT AND AUTHORIZATION SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

TITLE: Audiobooks for Hearing Loss

PRINCIPAL INVESTIGATOR: Jill Dolata, MS, CCC-SLP (503)346-3763

CO-INVESTIGATORS: Jan van Santen, PhD [(503) 346-3765 (BioSpeech)
Kirsty Lindaas, MS, CCC-SLP (503) 893-8637 (BioSpeech)
Brittany Wilson, AuD (503) 494-5171

WHO IS PAYING FOR THE STUDY? Funded by BioSpeech, Inc. with a grant from the National Institutes of Health.

DO ANY OF THE RESEARCHERS HAVE A CONFLICT OF INTEREST WITH THIS STUDY?
OHSU has a financial interest in BioSpeech, Inc. the company funding this study. Additionally, study team members J. van Santen and K. Lindaas are employees of BioSpeech, Inc. The nature of these financial interests and the design of the study have been reviewed and there is a plan to help ensure this research study is not affected by the financial interest. If you would like more information, please contact the OHSU Research Integrity Office at (503) 494-7887.

WHY IS THIS STUDY BEING DONE?
You have been invited to be in this research study "You" means you or your child in this consent form.

You have been invited to be in this research study because you have a hearing loss. This study will have subjects from the following groups: individuals with hearing aids and a moderate HL (41-55 dB HL); individuals with hearing aids and a moderately-severe to severe HL 56-90 dB HL); healthy aging individuals with a non-recent Cochlear Implant (CI), post-lingually deaf; children, ages 9+, with a non-recent CI, pre-lingually deaf; and adults and children, ages 9+, with a recent CI, post-lingually deaf.

The purpose of this study is to create an Audiobooks for Hearing Loss (HL) App. This audiobook App has a wide range of features designed to provide auditory training. The App is designed to help individuals with recent Cochlear Implants or Hearing Aids through the early stages. The App will adjust to each individual's own pace toward the goal of understanding "habitual speech" (speech spoken without special effort to be clear). Even if not used for auditory training, this App would provide access to audiobooks where standard audiobooks fail. Thus, the App may serve both auditory training and accessibility. Features include enhanced ("clear") speech modes, visual support by real-time display of text and a talking face, and other features. Features can be turned on or off to serve the individual's

unique needs.

This study will consist of either: (1) 1 remote visit via video conference, taking 1 – 2 hours per session; and/or (2) 12 weekly remote visits by a researcher via video conference over a 3-month period. Visits may last up to 1 hour. In addition to the remote visits, we also ask that you use your Audiobook for HL App at least two hours per week total. There will be 40 participants.

We are asking you to provide information for a data bank, also called a repository. Your information will be stored for up to 10 years to use in this research project and product development.

WHAT EXAMS, TESTS AND PROCEDURES ARE INVOLVED IN THIS STUDY?:
You will start by being given the Expressive One-Word Vocabulary Test, 4th edition. Failure to score at least in the 15th percentile will lead to the end of participation. Full payment of any Honoria will be given. Prior telephone screening will be designed to make such failure unlikely.

In the first part of the study (1 or 2 visits), you will interact with a computerized system, Audiobooks for HL App, and will do tasks that involve using audiobooks. The researcher will observe and take notes of any problems you encounter with the iPad. You can take breaks as needed by pausing the screen on the iPad. Then you will answer questions via a survey given by the researcher. This session will take 1- 2 hours and the subject will be paid $20 regardless of whether the session is completed.

In the second portion of the study (12 visits), the researcher will conduct 12 weekly virtual video visits. At each of the 12 visits, you will listen to two pre-recorded sentences with increasing noise in the background and repeat them back. During the last 6 weeks of the study, the following will be done:

- The researcher will observe you using the Audiobooks for Hearing Loss App for 20-30 minutes.
- You will be given a simple comprehension test which consists of being asked 4-6 questions from the observed reading. These questions will be presented in text form and answers will be recorded and scored virtually.
- The researcher will address any problems with the App that you may bring up
- The researcher will discuss the usage log and the comprehension test results with you. Then the researcher may: (a) suggest adjusting the speech mode (clear vs. habitual speech, noise level); (b) suggest switching off a visual support (face, synchronized text); suggest next milestone (e.g. completion of a story or book).
- The researcher will discuss real-world rewards with your parent/guardian if milestones are met.

The iPad will be mailed to you once you agree to be a part of the study. You will receive an Apple USB to Lightning connector charging cable, Apple power adapter charging "brick" and protective case provided with the iPad.

The iPad only contains the standard preloaded files and applications ("apps") needed for the Audiobooks for hearing loss research study and will be locked and no longer operate at the conclusion of the study. Do not save personal data to the iPad. Anything saved on the hard drive or to the iPad will be lost when you return the iPad. If the iPad is lost, damaged, or stolen during the lending period you must notify BioSpeech immediately.

Throughout the session the researcher will balance emotional support with emphasis that the App is for training, not just for recreation. You will receive an $80 payment at the end of your 12 weeks regardless of whether you complete the full 12 weeks or not.

At the conclusion of the study you will be sent a prepaid kit with a shipping label. Please use this to send the iPad and accessories (Apple USB to Lightning connector charging cable, Apple power adapter charging "brick" and protective case) directly to BioSpeech.

The medical records of participants will be reviewed from OHSU to determine eligibility for this study. Protected health information including age and HL diagnosis will be collected during the study. Data will be collected using: surveys and an iPad App. The hard copy responses to surveys and electronic data (audio, touchscreen responses, test scores, App usage statistics) will be retained for immediate and future analyses. Standard institutional practices will be followed as described by the OHSU Information Security Directives at the following link: https://www.ohsu.edu/information-technology/information-privacy-and-security. This will maintain the confidentiality and security of data collected in this study. Study staff will be trained with regard to these policies.

In the future, the results data from participating in the 12-week evaluation study may be given to BioSpeech for other research studies. The information will be labeled as described in the **WHO WILL SEE MY PERSONAL INFORMATION?** section.
If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact Jill Dolata at (503) 346-3763.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?:
Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality.

This is a minimal risk study since the procedures involve interacting with user-friendly software and undergoing listening tests and a simple language test. Audiobook contents will be carefully selected to be "safe" i.e. age-appropriate for children and non-offensive or fear inducing for adults. These procedures do not contain any elements that are fundamentally different from or riskier than assessments or remediation subjects already receive. This includes procedures as part of the participant's routine care or intake procedures, or at home, school, or other medical or non-medical environments. Conducting the procedure in an environment familiar to the participant should further reduce any physical or mental discomfort.

There is a risk of time burden the subject may incur from participating in the study.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?
You may or may not benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS STUDY?
You may choose not to be in this study.

WILL I RECEIVE RESULTS FROM THIS STUDY?
The results of research tests will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.

WHO WILL SEE MY PERSONAL INFORMATION?

We will create and collect health information about you as described in the Purpose and Procedures sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form.

The investigators, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this research study. All data will be stored up to ten years. All materials that may have identifying information will be kept secure in a locked filing cabinet. All data will be coded and electronic data will be stored on restricted drives on the OHSU network as well as on the cloud file storage solution provided by Box.com. Any analyses of information will be performed on password-protected computers; no copies will be made. All procedures for HIPAA compliance, where relevant, will be observed. The iPads used for data collection will be password protected. They will not contain any PHI. Specifically, they will not store any information used in the study derived from medical records for determining eligibility and for characterization of the sample, nor performance on the listening tests. Audio recordings will not be identifiable since they will not contain any identifiable information. Access to data is restricted to study personnel.

We may release this information to others outside of OHSU who are involved in conducting or overseeing research, including:

- The funder of this study, BioSpeech,Inc.
- National Institutes of Health
- The Office for Human Research Protections, a federal agency that oversees research involving humans

We will not release information about you to others not listed above, unless required or permitted by law. We will not use your name or your identity for publication or publicity purposes, unless we have your special permission.

When we send information outside of OHSU, it may no longer be protected under federal or Oregon law. In this case, your information could be used and re-released without your permission.

We may continue to use and disclose your information as described above for up to 10 years.

Some of the information collected and created in this study may be placed in your OHSU medical record. While the research is in progress, you may or may not have access to this information. After the study is complete, you will be able to access any study information that was added to your OHSU medical record. If you have questions about what study information you will be able to access, and when, ask the investigator.

You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. If you choose not to participate, or if you decide to stop at any time, that will not affect your ability to receive health care at OHSU or insurance coverage.

WILL ANY OF MY INFORMATION OR SAMPLES FROM THIS STUDY BE USED FOR ANY COMMERCIAL PROFIT? Study result information about you or obtained from you in this research may be used for commercial purposes, such as making a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and

its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?:
It will not cost you anything to participate in this study.
You will receive $20 per session for your participation in the design, usability and intelligibility parts of the study. You will be paid $80 total for your participation in the 12-week evaluation of the App portion of the study. You will receive payment regardless of whether you complete the study. You may receive payment via a debit card. There may be fees (for example, if the card is inactive for more than six months), which will be deducted from the balance on your card. Details on how to use the card and any fees are included in the separate card member agreement and FAQ sheet.
We may request your social security number in order to process any payments for participation.

WHERE CAN I GET MORE INFORMATION?:
This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day, 7 days a week).

DO I HAVE TO TAKE PART IN THIS STUDY?
You do not have to join this or any research study. You do not have to allow the use and disclosure of your health information in the study, but if you do not, you cannot be in the study. If you do join, and later change your mind, you may quit at any time. This includes the right to withdraw your authorization to use and disclose your health information. Talk to the investigator if you want to withdraw from the study. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled including being able to receive health care services or insurance coverage for services.

If you no longer want your health information to be used and disclosed as described in this form, you must send a written request or email stating that you are revoking your authorization to:

Dr. Jill Dolata
Oregon Health & Science University
3181 SW Sam Jackson Park Road, CDRC
Portland, OR 97239
dolataj@ohsu.edu

Your request will be effective as of the date we receive it. However, health information collected before your request is received may continue to be used and disclosed to the extent that we have already acted based on your authorization.

HOW DO I TELL YOU IF I WANT TO TAKE PART IN THIS STUDY?

Please indicate whether you provide your consent to participate in this study using the check boxes below:

(__) Yes, I would like to participate in the study.

(__) No, I would not like to participate in the study.