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Audiobooks for Hearing Loss App as Auditory Training
Small Business Innovation Research (SBIR)
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Minimal Risk Protocol

1) Protocol Title

Audiobooks for Hearing Loss

2) Objectives

The goal of the proposed project is to create an Audiobooks for Hearing Loss (HL) App – an audiobook App that has a wide array of user-selectable features designed to provide auditory training: Help individuals with recent Cochlear Implants/Hearing Aids through the difficult initial adjustment process, and help with transitioning at one's own pace toward the goal of understanding "habitual speech" (speech spoken without special effort to be intelligible). Even if not used for auditory training, this app would provide access to audiobooks where standard audiobooks fail. Thus, the App serves both auditory training and accessibility. Proposed features include enhanced ("clear") speech modes, visual support by simultaneous display of text and a talking face, and other features that can be enabled or disabled to serve the user's unique needs.

3) Background

Twenty percent or more Americans have a Hearing Loss (HL), a commonly used term that includes congenital deafness as well as aging-related hearing challenges, so severe that it may make communication difficult. Worldwide, this translates into 65 million people with English as a first language.

Hearing aids (HAs) and cochlear implants (CIs) are not enough to remedy this. The types of enhancement these devices can perform is inherently limited due to the requirement that they need to perform their task in real time, since otherwise they would not be lip-synchronized, which is essential in face-to-face communication. For example, they cannot change the temporal structure of incoming speech, even if that may help intelligibility. But there is a deeper shortcoming. When individuals wait too long with obtaining these devices, synaptic and pathway re-organization takes place in the auditory cortex that needs to be addressed, and mere device usage may not be up to this task. Cochlear implants provide a special challenge: Individuals may initially have great difficulty deciphering the unfamiliar sensory input generated by these devices.

There is a growing consensus that HL cannot be addressed with HAs or CIs alone: auditory training is also needed. While face-to-face auditory training is available, this intervention is generally not covered by insurance plans. Auditory training Apps have become available to fill this need in a cost-effective manner. Unfortunately, evidence for the efficacy of these products is weak; a recent large-scale randomized controlled trial found no effect on a wide range of outcome measures. A likely suspect for these results is that most aural rehab Apps are repetitive, even with gamification and rewards. A popular method used by individuals with HL to improve their listening skills is listening to audiobooks. Audiobooks have the strong advantage over many aural rehab Apps of being intrinsically motivating. However, existing audiobooks do not adequately accommodate individuals with more severe levels of HL unless they are fundamentally re-thought.

4) Study Design

We will build an Audiobooks for Hearing Loss App that serves both AT and accessibility. The following features all serve to transform the basic audiobook concept into a powerful tool for AT: (1) Multiple speech modes; (2) Visual supports; (3) Enhanced navigation; (4) Track and train; (5) Usage logging; and (6) Gamification. The App will then be used by individuals with HL, both children and adults with a variety of HL diagnoses using both CIs and HAs. The AT efficacy of the Audiobook for Hearing Loss system will be evaluated from the results of this study.

5) Study Population

a) Number of Subjects

40 subjects will participate in total, including children and adults with HL comprised in 5 distinct HL subgroups.

b) Inclusion and Exclusion Criteria

To establish that the system is widely usable and to examine the AT efficacy of the App we will be comparing five distinct HL subgroups: (1) Adults with HA, moderate HL (41-55 dB HL); (2) Adults with HA, moderately-severe to severe HL 56-90 dB HL); (3) Adults with non-recent traditional CI, post-lingually deaf (4) Children, ages 9+, non-recent-traditional CI, pre-lingually deaf; and (5) Adults and children, ages 9+, recent traditional CI, post-lingually deaf.

These five subgroups span broad ranges in terms of: (1) age (adults vs. children); (2) severity of hearing loss; (3) device used (HAs vs. Cis); (4) familiarity with device (recent vs. longer-term); and (5) onset of HL (pre-lingual vs. post-lingual. The team expects the highest efficacy for children and adults with recent CI who are post-lingually deaf; the lowest efficacy for adults with HA with either moderate or severe HL; and intermediate efficacy for children with non-recent CI who are pre-lingually deaf. While Phase I does not assess AT efficacy of the system, Phase II will, and Phase I needs to establish acceptability of the various aspects of the proposed system for these groups.

Inclusion criteria for all 40 participants will be: speaking English as first language, no suspicions of cognitive deficits or vision impairments that would interfere with system usage or invalidate usability assessment, no signs of external ear disease, being able to read at least a third-grade level and having access to a device that allows them to access a webcam for a video conference call. If participants do not have Bluetooth capability in their hearing aids or CI processors, they will need to be willing to wear either their own headphones or study-provided headphones while using the audiobooks app. All participants will be tested with the Expressive One-Word Picture Vocabulary Test, 4th Edition (EOWPVT-4; Brownell 2000), normed for ages of 2 and older, and are required to score in the 15th percentile or better. Responses to this test, whether correct or incorrect, will also be analyzed for intelligibility. Reading ability will be based on caregiver or teacher reports. Non-traditional/non-standard hearing aids (example: bone anchored hearing aids) or cochlear implants (examples: hybrid or electric acoustic stimulation (EAS)-type) will be excluded.

c) Vulnerable Populations

This study will include children. The inclusion of children is important to the research because the disease being studied affects children, and little is known about the available treatment options in the pediatric population. This study is minimal risk and holds out prospect of direct benefit so one parent/guardian must provide parent permission for the child to be enrolled in

the study. In addition, written permission will be obtained from children who, in the assessment of the investigator, have that capacity.t. If a child subject reaches the age of majority during the study, he or she will be asked to indicate their willingness for further participation.

d) Setting

The subjects will be seen remotely via video conference call for design, usability, and intelligibility sessions. The Hello clinic is a space that provides speech-language services to children and adults. The subjects will use the Audiobooks for HL App at home and then be seen at their home for weekly sessions by a Researcher.

e) Recruitment Methods

Subjects will be recruited from flyers posted at multiple sources, including local healthcare specialists (Audiologist and Otolaryngologist offices), schools, and hearing loss support group meetings. Most prominently we will be recruiting through the OHSU Institute on Development and Disability (IDD) Rehabilitation Center, and the OHSU Cochlear Implant Division. Individuals will be paid $20 per session for their participation in the design, usability and intelligibility parts of the study. Individuals will be paid $80 total for their participation in the evaluation portion of the study. They will receive this payment (up to $100 total) regardless of whether they complete the study.

Participants will also be identified using the EPIC cohort discovery tool, allowing the study team to identify possibly eligible patients who are seen in the OHSU Cochlear Implant Division and the OHSU Institute on Development and Disability (IDD) Rehabilitation Center. Participants will also be recruited via a Facebook advertisement on the OHSU and OHSU Doernbecher Children's Hospital Facebook Pages. We will rely on OHSU electronic health records to identify eligible individuals who have received a clinical diagnosis of HL based on standard research diagnostic criteria and that they currently wear HAs or CIs.

f) Consent Process

Participants and/or their parent/guardian will receive paper or electronic copies of the appropriate information sheet prior to the first session, to enable them to study the sheet. They will then participate in a telephone or email screening to establish the eligibility of themselves or their child. The telephone or email screen will be performed by OHSU OCTRI personnel that are not involved with either BioSpeech or CSLU. If the participant or parent/guardian is interested then willingness to participate will be obtained verbally over the phone or via video conference call. The information sheet itself as well as any accompanying instructions will make it clear that non-participation has no consequences of any type.

Non-English Speaking Subjects

This study does not involve non-English speaking subjects. Non-English speakers are excluded since the materials will all be English-only. In addition, by excluding participants that have learned English as a second language it will help ensure that any potential language comprehension problems do not interfere with system usage or invalidate usability assessment.

Assent of Children and Parent Permission

One parent/guardian must provide parent permission for the child to be enrolled in the study. In addition, written willingness to participate will be obtained from children who, in the assessment of the investigator, have that capacity. If a child subject reaches the age of maturity during the study, he or she will be asked their willingness for further participation.

6) Procedures

Our study includes a total of 40 participants; 8 individuals from each of these five distinct HL subgroups. The product design/development process (Aim I.2.), usability (Aim I.2.b) and intelligibility (Aim I.3) studies involve one session (N=40). Sessions are expected to take one hour. The evaluation (Aim I.4) requires twelve video sessions. The adult and child groups (N=20 each) are mixtures of the five subgroups that were previous participants. All sessions will be conducted via video conference. Subjects will be sent an iPad with the prototype of the App preloaded.

Participants will start by being administered the Expressive One-Word Vocabulary Test normed for ages 2 and older. Failure to score at least in the 15th percentile will lead to termination of participation, but with full payment of any honoraria. Preceding telephone or email screening will be designed to make such failure extremely unlikely. Special language and procedures will be designed and incorporated in the OHSU IRB information sheet to prevent any negative feelings due to termination.

In the design, usability and intelligibility portions of the study participants will interact with a computerized system, Audiobooks for HL App, in tasks that involve using audiobooks. The researcher will observe and take notes of any problems the subject encounters with the iPad. The subject can take breaks as needed by pausing the screen on the iPad. Then they 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 evaluation portion of the study participants will be given the BKB-SIN test for the first 6 weeks. Then, the study participants will also use the Audiobooks for HL App for the remaining 6 weeks using the App at least two hours per week total. The researcher will conduct 12 weekly remote visits via video conference where the following will be done:

- Throughout the 12 week study, the BKB-SIN will be administered using 2 new word list pairs in each session rotating through all 18 list pairs. The BKB-SIN is a speech-in-noise test that uses BKB (Bamford-Kowal-Bench) sentences, recorded in four-talker babble.
- During the last 6 weeks of the study the following will be done, in addition to the administration of the BKB-SIN.
- Observe the subject use the audiobook for 20-30 minutes.
- Conduct a comprehension test. Questions will be developed with the Sentence Verification Technique (SVT; Royer, 2001), in which alternative versions of passages in the materials are written and participants are to decide which version matches what was read. These questions (up to 5 per hour of read materials) will be presented in text form and answers will be recorded and scored during the session.
- Address any usability issues the participant brings up.

- Based on discussion with participant (and parent/guardian if available), the usage log, and the comprehension test results: (a) suggest adjusting the speech mode (clear vs. habitual speech, noise level); (b) suggest switching off a visual support (face, synchronized text); discuss next milestone (e.g. completion of a story or book).
- Discuss real-world rewards with parent/guardian if milestones are met.

Throughout the session the researcher will balance emotional support with emphasis that the App is for training, not just for recreation. These individuals will receive an $80 payment at the end of their 12 weeks regardless of whether they complete the full 12 weeks or not. At the end of 12 weeks, they will be sent instructions and materials to package their iPad device and ship it back with a pre-paid return label.

7) Data

a) Handling of Data

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 survey/questionnaires 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 to maintain the confidentiality and security of data collected in this study. Study staff will be trained with regard to these policies.

Paper files with restricted information in transit will be kept out of sight. Once the restricted information has arrived at BioSpeech, it will be secured in a locked filing cabinet. 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.

Access to data is restricted to study personnel.

Upon enrollment, subjects will be assigned a code that will be used instead of their name, medical record number or other personally identifying information. Electronic files for data analysis will contain only the subject code. Codes will not contain any part of the 18 HIPAA identifiers (initials, DOB, MRN). The key associating the codes and the subject's personally identifying information will be restricted to the PI and the study staff. The key will be kept secure on a restricted OHSU network drive in a limited access folder.

b) Sharing of Results with Subjects

The data will not be shared with the subjects because the research is still in an early phase and the reliability of the results is unknown.

c) Data Banking

All data will be stored for up to ten years for future analyses in this study. Access to data is restricted to study personnel. All of BioSpeech's study personnel are required to participate in a mandatory, ongoing training program on human subject protection. Hard copy data will be secured in a locked filing cabinet. 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.

8) Data Analysis

We will use a multiple baseline method. We will administer the BKB-SIN in 12 weekly sessions, using 2 new word list pairs in each session rotating through all 18 list pairs. In the training phase, starting in week #7, participants are asked to use the App at least 2 hours per week. To evaluate auditory training efficacy of the App we will measure the change in slope of the curve relating test performance to session number. This will be evaluated by computing for each subject, S, a normalized slope difference, ZS=(bs1-bs2)/sqrt(SEbs1**2 = SEbs2**2); here, j=1,2 refers to pre- and in-training phase, and, for each subject S, bsj's are the associated slopes and SEbsj's the standard errors of the slopes.

The design of the study allows for multiple statistical analyses. We will conduct analysis within-subjects, as noted above. We will also conduct planned comparisons between selected groups, using *t*-tests, comparing score changes between a pre-post change.

Since ZS is approximately normal, we apply a one-tailed single-sample t-test to the 40 ZS's, yielding a power of 0.80 at p=0.05 (one-tailed) for small-medium effect sizes (d=0.4).

9) Privacy, Confidentiality and Data Security

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.

Coded research records may be reviewed and/or copied by the OHSU Institutional Review Board and the Office for Human Research Protections (OHRP).

10) Risks and Benefits

a) Risks to Subjects

This is a minimal risk study since the procedures involve interacting with user-friendly software and undergoing listening tests and a simple language test (Expressive One-Word Picture Vocabulary 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 already received 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. And there is a risk of breach of confidentiality, which is common to almost all research studies.

b) Potential Benefits to Subjects

The key benefit to the subjects is the possibility of improved listening ability. They will be paid $20 per session for usability/design/intelligibility sessions and $80 for the 12-week evaluation portion of the study, for a total of $100 if they participate in both portions. Given the extremely low-risk nature of the study, these benefits outweigh the risks. The information sheet will indicate the purpose of the study.