Customized auditory brain training for children with hearing loss

Principal Investigator:

Craig Buchman MD

Version Date/Number:

V2; 04/30/2020

TABLE OF CONTENTS

A Introduction

A1 Study Abstract

Almost 90% of children with hearing loss attend a regular public school classroom and 95% communicate with spoken language. Depending upon their degree of hearing loss, they miss between 30-60% of all spoken material in a classroom setting, even if they wear hearing aids. Research has shown that poor speech recognition leads to poor academic achievement. This project offers a potential solution to this problem. Our research team proposes to determine if web-based auditory training using an unfamiliar talker can result in better recognition of the person speech. Hand-held, game-like training programs will be used to present speech-in-noise training. Benefits will be compared after 4 weeks of required at-home training.

Using a Transfer-Appropriate Processing (TAP) theory of learning as theoretical motivation, we will determine the extent to which children benefit from talker-specific training. This research, which is based firmly on TAP theoretical underpinnings, will provide answers about how best to provide speech recognition training to children with hearing loss.

A2 Primary Hypothesis

Poor speech recognition leads to poor academic achievement.

A3 Purpose of the Study Protocol

To determine if web-based auditory training using an unfamiliar talker can result in better recognition of the person speech.

B Background

B1 Prior Literature and Studies

Our research team conducted a number of preliminary studies which give support for speech recognition training.

Study 1-We surveyed the 48 OPTION schools in the US (schools for children with hearing loss) and received responses from 8. The results of the survey found that these OPTION schools provided formal auditory training and these educators who are trained in aural rehabilitation and deaf education felt it was a critical part of the child's education. Teachers in public school settings who are not trained in deaf education might not be providing optimal intervention.

Study 2-We trained adults with game-like computerized auditory training and found that short term auditory only training is beneficial and by the use of questionnaires found that self confidence, and self impression of speech recognition skills improved. Eighty-seven percent of the participants indicated the training was worth their time.

Study 3-We had two children complete our adult version of the computerized auditory training and both children showed benefit.

Study 4-We conducted a TAP-style assessments on 36 adult participants with hearing loss who trained 20 hours with our computerized training program. The pre and post assessments included items spoken by the talker who was used during training and items spoken by an unfamiliar talker. The largest gains were seen by items spoken by the trained talker supporting the need for a TAP style of training.

Study 5-We have developed a number of tests to be used with children for both training and assessment purposes. The tests include: The Children's Audiovisual Enhancement Test, The Illustrated Sentence Test, The GIST test, and the Tri-Bas test.

Study 6-We brought back four of our adult participants who completed our auditory training. After the completion of the original AT, there scores at the 12 month test session had dropped compared to their post and 3-month scores. They received 6 hours of additional auditory training which we called "booster training" and their scores improved compared to their 12-mo scores.

Study 7-We currently have a "take-home" training component with our adult auditory training program. The participants are sent home with a hand held device with the training games. Of the participants who have completed this training, they are averaging approximately 6 hours of play over a 3-month period. If you removed the participants who did not play at all at home, the average is over 8 hours over the three month time period. These results are encouraging for our take-home portion of this current study for children.

B2 Rationale for this Study

This research, which is based firmly on TAP theoretical underpinnings, will provide answers about how best to provide speech recognition training to children with hearing loss.

C Study Objectives

C1 Primary Aim

Determine to what extent web-based auditory brain training with the speech of a here-to-fore unfamiliar communication partner results in better recognition of that person's speech.

D Study Design

D1 Overview or Design Summary

Hand-held, game-like training programs will be used to present speech-in-noise training. Benefits will be compared after 4 weeks of required at-home training.

D2 Subject Selection and Withdrawal

2.a Inclusion Criteria

All participants will be between the ages of 6-12 years with bilateral sensorineural hearing loss and will use either a hearing aid(s), cochlear

implant(s)(CI) or a combination of both.

2.a Exclusion Criteria

Individuals less than 6 years of age or greater than 12 years of age or with vision worse than 20/40 corrected will be excluded.

2.b Subject Recruitment Plans and Consent Process

A team member will recruit potential participants by telephone via recruitment list from REC, RPR, AudBase, and current lab database of previous participants. Potential participants who see a flier, advertisement, or who are referred from an outside source will call our lab. A team member will describe the study using the telephone script. If they pass the telephone screening (as in, their child passes the screening qualifications) and are interested participating then the study is described in detailduring the informed consent process over the telephone. The participant will have an opportunity to ask any questions about the study during the consent process. A participant can refuse to participate at any time during the recruitment process or any time during the study.

2.c Risks and Benefits

There are no forseeable risks.

Participants have the potential to hear better/function better in noisy listening environments. Participation in this study allows us to better understand how children with hearing loss function in different types of listening environments when listening to a variety of speakers. These findings can potentially lead to better clinical applications in the area of auditory training and aural rehabilitation.

D. Study Procedures

D1 Screening for Eligibility

We will need the individual's name, phone number, and hearing status to see if they meet the criteria.

D2 Schedule of Measurements

FOCUS GROUP (n=10):
Two focus groups will take place (approximately 5 children per focus group). The children will have completed the “Enhancing children’s everyday communication: Talker specific speech recognition training” program (IRB # 201602007).

Each focus group session will last approximately 1.5 hour. After providing consent participants will be grouped in a kid-friendly room at the Central Institute for the Deaf with the researcher and the other children. For the first 20-30 minutes the children will be discussing a hypothetical scenario about a child with hearing loss, and the last 40-50 minutes the children will answer specific questions about the training program, their experiences during the training program and questions about themselves. The sessions will be audio and/or videotaped for later transcription. The focus groups will take place at our labs at Washington University. The focus groups will be audio/videotaped for later

transcription and for use in educational settings (examples, conferences or presentations).

HOME TRAINING GROUP (n=25):
All home training and assessments will take place remotely with the assessments administered via the take home device. Responses will be monitored by the experimenter using a phone or online communication software when available. One pre-training assessment (baseline) will be administered. It will take approximately 1-1.5 hours over 1-2 days
-The parent will complete a case history for their child. The examiner will record their responses on the case history form.
-Participant will complete the COSI while the tester records the participant's responses on the form.
-The participant will complete a device/setting check. The tester will record the participants responses on the form. -The participant's aided hearing will be checked using an online hearing screener. -The Ling 6 will be administered. . For the Ling 6, each participant will hear six sounds at three different levels (sot, but audible, comfortable, and loud but comfortable). The participant will repeat the sound they hear at each level.

The following tests of speech perception ability will be administered at baseline:
-BKB-SIN
-Words in noise (training stimuli) (familiar talkers from training)
Sentences in noise(Illustrated sentence test stimuli (IST)) (unfamiliar talkers)
-Phrases in Quiet (bound morpheme stimuli) (familiar talkers from training)

The online training will consist of game-like activities developed for 6-12 year old children with hearing loss. Each child will complete 16 hours of online auditory training. They will be provided with a user name and password to the online training system that is not their real name to protect their identity. Training is spread over approximately 30 days. They will be asked to average about 36 minutes per day of training 7 days a week. They will have the opportunity to make up training if they miss any days. We will provide a hand-held tablet for them to use during the training. The training is computerized game-like auditory training. During game play they listen and make judgments about what was heard. Responses will be recorded and stored as potential secondary outcome measures.

Training Games:
1. DefendEAR- auditory discrimination and auditory attention
2. HoopstEAR- bound morpheme training game
3. Simon’s EAR- word memory, like the classic Simon’s game
4. Match EAR- Auditory concentration game, can play with 4, 8 or 12 cards
5. Time TravelEAR- word-level discrimination
6. EARplane- works on processing speed

After the completion of the 16 hours of training the participant will be scheduled for a post assessment which will include the Ling, device/setting questionnaire, all the same primary outcome measures taken at baseline, and a training satisfaction questionnaire.

D3 Safety and Adverse Events

No adverse events are anticipated however the study team will monitor through weekly phone calls.

E Statistical Plan

E1 Sample Size Determination and Power

Sample size (N=20) for the proposed study is calculated based on findings from previous studies using the same type of outcome measures. This effect size was selected for the power calculation because their training protocol is similar to the one proposed for the current study. Using this design, power to detect an effect size as great or greater than that reported our previous studies will exceed 0.8.

E2 Interim Monitoring and Early Stopping

We will monitor progress in the software to be sure participants are following protocol.

E3 Analysis Plan

Quantitative data from the main experiment will be analyzed with ANOVA to assess the effect of training on speech recognition for two talker conditions (familiar and unfamiliar) and to assess subjective changes indicated by the questionnaire rating-scale responses. Qualitative data from the focus groups will be analyzed using established procedures recommended by J. Eliot, (2005). Using narrative in social research: Qualitative and quantitative approaches. Thousand Oaks, CA: Sage.

E4 Missing Outcome Data

Participants with missing data will not be included in the analyses for that outcome measure.

F Data Handling and Record Keeping

F1 Confidentiality and Security

Study numbers will be assigned and used in place of names. Only the study team will have access to the corresponding study names and study numbers.

G Study Administration

G1 Subject Stipends or Payments

Participants will be paid $10/hour for the time spent training ($160). If the child completes the 16 hours of at-home training and all of the assessments a tablet and speaker will be given to the child.

H Attachments

H1 Informed consent documents

- Informed consent – Focus Group
- Informed consent – Home Training

H2 Questionnaires or surveys

- BKB-SIN List
- Bound Morpheme stimuli
- Device/Setting questionnaire
- COSI Child
- Training Satisfaction Questionnaire Post
- GIST (IST) stimuli
- Fast Word List
- Training Word List

I References

Barcroft, J., Sommers, M., Tye-Murray, N., Mauzé, E., Schroy, C., & Spehar, B. (2011). Tailoring auditory training to patient needs with single and multiple talkers: Transfer-appropriate gains on a four-choice discrimination test. International Journal of Audiology, 50(11), 1802–1808.

Barcroft, J., Spehar, B., Tye-Murray, N., & Sommers, M. (2016). Task-and talker-specific gains in auditory training. Journal of Speech, Language, and Hearing Research, 59(4), 862-870.

Sommers, M. S., Tye-Murray, N., Barcroft, J., & Spehar, B. (2015). The effects of meaning-based auditory training on behavioral measures of perceptual effort in individuals with impaired hearing. Seminars in Hearing, 36(4), 263-272.

Tye-Murray, N., Sommers, M., Mauzé, E., Schroy, C., Barcroft, J., & Spehar, B. (2012). Using patient perceptions of relative benefit ad enjoyment to assess auditory training. Journal of the American Academy of Audiology, 23(8), 623–634.

Tye-Murray, N., Spehar, B., Sommers, M., & Barcroft, J. (2016). Auditory training with frequent communication partners. Journal of Speech, Language, and Hearing Research, 59(4), 871-875.

Tye-Murray, N., Spehar, B., Barcroft, J., & Sommers, M. (2017). Auditory training for adults who have hearing loss: A comparison of spaced versus massed

practice schedules. Journal of Speech, Language, and Hearing Research, 60(8), 2337-2345.