Auditory Brain Training to Enhance Satisfaction and Usage of New Hearing Aids by Older Adults

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A Introduction

A1 Study Abstract

Auditory training as the potential to dramatically affect older persons' adjustment to a new hearing aid and to maximize the benefits they receive from wearing one. In turn, by wearing hearing aids, they experience easier and more successful communication patterns. They enhance their ability to engage in everyday conversations and will be able to become more socially involved with their family and friends. In this study we will try to determine the extent to which web-based clEAR auditory brain training, with concomitant support from a clEAR in-house audiologist, affects satisfaction with new hearing aids and increases daily use time. Thirty adults over the age of 60 years will receive new hearing aids for the first time. After an adjustment period, half will complete clEAR's auditory brain training program right away and the other half will complete it after a delay period, and both will complete a control condition. To establish the level of feasibility and clinical utility we will measure hearing aid satisfaction, benefit ratings, and hearing aid use time.

A2 Primary Hypothesis

Use of the web-based clEAR auditory brain training system with concomitant support from a clEAR in-house audiologist improves satisfaction with new hearing aids and increases daily use time.

A3 Purpose of the Study Protocol

Determine the extent to which web-based clEAR auditory brain training with concomitant support from a clEAR in-house audiologist affects satisfaction with new hearing aids and increases daily use time.

B Background

B1 Prior Literature and Studies

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.

B2 Rationale for this Study

clEAR auditory brain training has been shown to be effective and that patients like the contact with an audiologist during training. Barcroft et al. (2011; see also Tye-Murray et al., 2017) showed that computerized, game-like auditory training is beneficial for older adults (mean age=66 years, SD=16) who have hearing loss by conducting a 3-year large-scale study that addressed the effectiveness of computerized training for a talker trained with and for a talker not trained with. We also considered whether benefits were maintained three months later. A one-way ANOVA revealed a significant overall effect of training regardless of the talker. In a second study, Adults with hearing loss completed the clEAR program and were placed in a group that trained on either multiple talkers or a single talker (Barcroft et al., 2016). A control group also completed 12 hours of training in American Sign Language. The experimental group's training included a 4-choice discrimination task but not an open-set sentence test. The assessment phase included the same 4-Improvement on 4-choice discrimination was

observed in the experimental group as compared with the control group. Gains were (a) highest when the task and talker were the same between training and assessment; (b) second highest when the task was the same but the talker only partially so; and (c) third highest when task and talker were different. The findings support applications of transfer-appropriate processing to auditory training and favor tailoring programs toward the specific needs of the individuals being trained for tasks, talkers, and perhaps, for stimuli, in addition to other factors.

Auditory brain training has been shown to reduce perceptual effort. Sommers et al. (2015) assessed the extent to which engaging in gamified auditory training would reduce perceptual or listening effort. As the name implies, perceptual effort pertains to the cognitive resources that must be allocated to recognizing speech. Perceptual effort was assessed using an n-back memory task. Eighty-three participants heard lists of words presented without background noise and were asked to continually update their memory of the three most recently presented words. Perceptual effort was gauged by memory for items in the three-back position immediately before, immediately after, and 3 months after participants completed 12 sessions (approximately 8 hours) of the clEAR auditory brain training games. Immediate post-training measures of perceptual effort indicated that participants could remember approximately one additional word compared to pre-training. Moreover, some training gains were retained at the 3-month follow-up, as indicated by significantly greater recall for the three-back item at the 3-month measurement than at pretest. A significant correlation was found between gains in intelligibility and gains in perceptual effort.

Auditory brain training enhances recognition of familiar voices. Tye-Murray et al. (2016) conducted a study to determine whether auditory training with the speech of an adult's spouse would lead to enhanced recognition of that person's speech. Ten older participants (mean age=73 years, SD=6) completed 6 weeks (12 hours) of training. Their spouses recorded the stimuli and each participant (partner with hearing loss) completed auditory training that presented the recordings. Training led participants to better discriminate their spouse's speech, as indicated by the 4-AFC. Subjectively, responses on a questionnaire indicated that training reduced participants' communication difficulties. Couples had been married an average of 14 years showed that providing training with a formerly unfamiliar talker led to significant gains in participants' ability to recognize the speech of the talker, and that gains were seen for the speech of untrained talkers, although not to the same extent.

Patients want regular contact with an audiologist. In a study of 93 adults (mean age=66 years, SD=17), we asked the question, what did you like best about the auditory training (Tye-Murray et al., 2012). One of the three top answers was "regular contact with an audiologist". The other two were "the games were fun to play" and "training gave me empowerment over my hearing loss." By completing auditory brain training, participants also reported increased confidence to engage in everyday conversations.

C Study Objectives

C1 Primary Aim

It is the objective of this study to determine if the use of clEAR following a first-time hearing aid fitting will increase satisfaction and daily hearing aid use.

C2 Secondary Aim

N'A

C3 Rationale for the Selection of Outcome Measures

1. Primary outcome measures are questionnaires used in hearing clinics to assess hearing aid satisfaction.
2. Hearing aids log use time. This information will also be collected to determine the average daily use time for each participant.

D Investigational Agent

D1 Preclinical Data

N/A

D2 Clinical Data to Date

N/A

D3 Dose Rationale and Risk/Benefits

N/A

E Study Design

E1 Overview or Design Summary

All qualified participants will first be fitted with one hearing aid using manufacturer recommended settings. The settings will be verified using real-ear measurements and any initial adjustments to the hearing aid will be made at the time of fitting. The participants will return again in 2-3 weeks to complete any final adjustments needed before they continue with the protocol.
After fitting and final adjustments are complete, all participants will be receive aided speech perception testing using the Speech in Noise Test (SPIN) and the NU-6.
Half of the participants will be assigned to the Early Group and receive 8 hours of clEAR auditory brain training in 20 minute intervals spread over four weeks. The other half will be assigned to the Late Group and receive the clEAR training after

a four week control period. The Early Group will do the control period after their training period.
For the control period, participants will be given a choice of three audio books stored on Amazon Kindle (a mystery, a biography, or a popular fiction) to ensure that the book will engage a participant's interest and that they will be motivated to follow the training schedule. They will be provided with a formal schedule that parallels the training schedule for the clEAR training, and will receive 8 hours of training. We will confirm their compliance through weekly phone calls, email, and by asking them to report how far along they are in the book. If participants do not have a tablet for reading, they will provided with a loaner tablet which allow access to Kindle books. A final period will be four weeks after either type of intervention.
At the end of each period participants will receive the speech perception battery (SPIN and NU-6) and the subjective assessment battery. The subjective assessment battery includes questionnaires and scales commonly used to assess hearing aid satisfaction and changes in listening challenges. The battery will include three subjective measures, The SADL (Satisfaction with Amplification in Daily Life), the IOI-HA (The International Outcome Inventory for Hearing Aids, and the COSI (Client Oriented Scale of Improvement). Finally, at the end of the clEAR training period participants will complete a questionnaire designed to gain feedback about the games, participants will also complete a questionnaire about their clEAR experience, indicating what they did and did not like about the system.

E2 Subject Selection and Withdrawal

2.a Inclusion Criteria

All participants have the same inclusion/exclusion criteria but be assigned to one of two groups that differ only in the schedule, this will allow participants will act as their own control group.

All participants will:
1. Be over 60 years old
2. Have a bilateral sensorineural hearing loss mild-to-severe range
3. Vision will need to be corrected to at least 20/40 so participants can see the training games on the computer or tablet monitor.

2.a Exclusion Criteria

English must be the first language of the participant
Participants must pass a dementia screener (MMSE)
Must have the manual dexterity to manipulate and insert a hearing aid
Must have an email address and access to the internet

2.b Ethical Considerations

Nobody will be discriminated against based on conditions not noted in the inclusion/exclusion criteria.

2.c Subject Recruitment Plans and Consent Process

Lists of potential participants will be obtained from multiple sources including the Washington University's Volunteers for Health program and from an extensive database maintained in the Tye-Murray lab. Potential participants will hear about the study and complete a health and hearing screening questionnaire over the telephone. If they pass the telephone screening, they will be asked to come to the hearing lab for the hearing and vision assessment. The hearing screening will include pure-tone threshold testing and speech perception testing at comfortable levels.

To be enrolled in the study potential participants will have bilateral mild to severe sensori-neural hearing loss, and have never used hearing aids. They will also require the basic skills for wearing and maintaining a hearing aid including the manual dexterity to insert the aid and the anatomy required to wear the aid. They will also have corrected static visual acuity of 20/40 or better. They will be required to pass a dementia screener (MMSE). If they qualify for the study and wish to continue they will be consented after completing the assessments. Those that do not qualify will be paid for their time and any collected data destroyed.

2.d Randomization Method and Blinding

Because participants act as their own control per se, they will not be randomized and no blinding will occur.

2.e Risks and Benefits

There are no foreseeable risks to the participant beyond the basic risks associated with hearing aid fitting. These risks are rare but include possible skin irritation from the device or the occasional uncomfortably loud sound. Hearing aids are equipped with safety mechanisms that are supposed to reduce the possibility that a very uncomfortable level is produced.

The participant will participate in a study that provides amplification and auditory training. These devices and procedures are designed to be of benefit to individuals with hearing loss. The participants will also be providing feedback on their experiences. This feedback may improve the procedures and methods currently used in online auditory training practices, this may benefit society.

2.f Early Withdrawal of Subjects

Participants that have not completed the study but can no longer participate will be asked to return the hearing aid. They will be reimbursed for their time at 10$/hour.

2.g When and How to Withdraw Subjects

If it is deemed that they can no longer fulfill the needs of the study because they are not training or coming to the in-clinic assessments participants will be notified by phone or email if they are to be withdrawn from the study.

2.h Data Collection and Follow-up for Withdrawn Subjects

There will be no follow-up with withdrawn participants.

E3 Study Drug

3.a Description

N/A

3.b Treatment Regimen

N/A

3.c Method for Assigning Subjects to Treatment Groups

N/A

3.d Preparation and Administration of Study Drug

N/A

3.e Subject Compliance Monitoring

N/A

3.f Prior and Concomitant Therapy

N/A

3.g Packaging

N/A

3.h Blinding of Study Drug

N/A

3.i Receiving, Storage, Dispensing and Return

N/A

F Study Procedures

F1 Screening for Eligibility

A telephone survey will screen all potential participants that would not be eligible for reasons other than the hearing and vision screening. Hearing and vision testing will be conducted after the informed consent process.

F2 Schedule of Measurements

F3 Visit 1

F4 Visit 2 etc.

F5 Safety and Adverse Events

5.a Safety and Compliance Monitoring

5.b Medical Monitoring

i Investigator only

ii Independent expert to monitor

iii Institutional Data and Safety Monitoring Board

iv Independent Data and Safety Monitoring Board

5.c Definitions of Adverse Events

5.d Classification of Events

i Relationship

ii Severity

iii Expectedness

5.e Data Collection Procedures for Adverse Events

5.f Reporting Procedures

5.g Adverse Event Reporting Period

5.h Post-study Adverse Event

F6 Study Outcome Measurements and Ascertainment

G Statistical Plan

G1 Sample Size Determination and Power

We determined the power to detect an effect size for differences as large as or larger than in Tye-Murray et al. (mean = .733, SD = .783) with an alpha level of .05 will exceed .95 using a one-tailed test for the within-subjects comparisons in each group.

G2 Interim Monitoring and Early Stopping

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

G3 Analysis Plan

We will assess the effect of training on hearing aid use time, changes in speech perception, and subjective changes indicated by the questionnaire rating-scale responses. Three post-fitting times will be assessed to look at the effects of clEAR testing (Baseline/post-fitting, post-training, post control, and four weeks post intervention).

G4 Statistical Methods

Data will be analyzed with t-tests and repeated measures ANOVA.

G5 Missing Outcome Data

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

G6 Unblinding Procedures

N/A

H Data Handling and Record Keeping

H1 Confidentiality and Security

H2 Training

H3 Case Report Forms and Source Documents

H4 Records Retention

H5 Performance Monitoring

I Study Monitoring, Auditing, and Inspecting

I1 Study Monitoring Plan

I2 Auditing and Inspecting

J Study Administration

J1 Organization and Participating Centers

J2 Funding Source and Conflicts of Interest

INCLUDE INFO FROM CIRC? BUT WE ARE NOT THE PI, SO IT WOULDN'T MAKE SENSE HERE.

J3 Committees

J4 Subject Stipends or Payments

Participants will be paid $10/hour for the time spent in assessments and training.

Other - The project involves first time hearing aid users. We need to control for the level of technology and hearing aid quality across participants, so the hearing aid will be provided. The aid will be 'used' after the study so the participant will be allowed to keep the aid after the study is complete.

J5 Study Timetable

K Publication Plan

L Attachments

L1 Tables

L2 Informed consent documents

Adult SBIR HA and AT Informed consent.rtf	Consent & Assent Forms	1	407 k	E	08/20/19

L3 Patient education brochures

L4 Special procedures protocols

L5 Questionnaires or surveys

Attachment Name	Category	Ver	Size		Attached
JIT Letter.doc	Notice of Just in Time (JIT) Documentation	1	25 k	E	08/15/19
Telephone	Recruitment Script: Phone	1	59 k	E	08/19/19

Questionnaire.rtf					
AT and HA Flier.rtf	Recruitment Materials: Ads/Brochures/Posters/News Release/Fliers	1	115 k	E	08/19/19
COSI.pdf	Subject Data Collection Instruments	1	36 k	E	08/21/19
Demographic - Case History Form.rtf	Subject Data Collection Instruments	1	86 k	E	08/20/19
Email and Phone Script for Followups.doc	Subject Data Collection Instruments	1	23 k	E	08/20/19
IOI-HA.pdf	Subject Data Collection Instruments	1	37 k	E	08/21/19
SADL Form.pdf	Subject Data Collection Instruments	1	58 k	E	08/21/19
Assurance Form Signed.pdf	Assurance Document	1	226 k	E	08/21/19

M 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.

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