Aging and Speech Perception in Complex Listening Environments
NCT03704142

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Study objectives

The goal of this study was to assess the effectiveness of, and benefits provided by, several over-the-counter, direct-to-consumer hearing devices. Specifically we were interested in assessing the benefits of these devices for middle-age people with no more than mild hearing loss. While some literature already exists on the effectiveness of devices of this type (Reed et al 2017, Cho et al 2019, Seol et al 2021, among others), these are primarily studies of individuals with greater degrees of hearing loss. Additionally, the goal of this study was to assess both the objective benefit of the devices, in terms of performance on a speech perception task, and to quantify subjective benefit in terms of self-rated listening effort while using the devices.

The study assesses four specific devices: Sound World Solutions CS50+, Nuheara IQ Buds, Tweak Focus, and Bose Hearphones. These four devices are all specifically classified as Personal Amplification Products, or PSAPs. Participants were randomly assigned to use one of these four devices during the study.

Study methods and procedures

The study consisted of three parts: intake procedures, where participants were given consent forms, performed cognitive and hearing assessments, and were fitted for the PSAP to which they were assigned; a speech perception task; and a brief post-test survey.

As part of the intake procedures, subjects completed the Montreal Cognitive Assessment (Nasreddine et al., 2005), after which audiometry and tympanometry were completed, and the subjects were fitted with a PSAP. Subjects were fitted binaurally, with suitable dome sizes and wire length selected to ensure an appropriate physical fit. Subjects assigned to the IQ Buds or CS50+ then performed an in-situ hearing test using the device's smartphone app. All devices were set to directional microphone mode (called 'focus', 'noisy', 'restaurant', and 'focused' for the IQ Buds, Tweak Focus, CS50+ and Hearphones, respectively) for the remainder of the time they were worn.

Verification of each PSAP was performed with the Audioscan Verifit 2 Speechmap system using an on-ear probe microphone to measure output. The International Speech Test Signal (ISTS) was used to obtain real-ear unaided responses (REUR) for 50 dB SPL input, followed by aided responses at 50 dB SPL and 65 dB SPL. The output of each device was adjusted so that the long-term average speech spectrum of the ISTS would approximate National Acoustic Laboratories Non-Linear 2 (NAL-NL2) targets within +/- 5 dB SPL where possible. For devices with limited fine-tuning ability, targets in the 1 kHz – 2 kHz range were given preference. To confirm loudness comfort, swept tones were presented from 0.25 – 8 kHz at 85 dB SPL, followed by pink noise at 80 dB SPL. Participants rated the above stimuli on a 7-point loudness scale (7 = uncomfortably loud). If participants rated either loudness test as a 7, gain was reduced and the loudness test was repeated until a comfortable loudness level was reached. In cases where gain was reduced following the loudness comfort test, aided responses to ISTS were re-measured with the final device settings to be used in the speech perception task.

In the speech perception task, subjects were played a series of sentences and instructed to repeat them back verbatim. The sentences were all taken from the same corpus, developed by Helfer, Merchant, and Freyman (2016). Sentences in this corpus all have the same syntactic structure: *Name found the color noun and the adjective noun here* (with the five underlined words denoting the target words which varied across sentences). A sample sentence is *Theo found the pink menu and the true item here*. All sentences were recorded from a female speaker. The subjects performed the task once while using a PSAP (aided) and once without (unaided), with different sets of sentences. Half of the

participants in each device group began with the unaided test block, and half with the aided; this factor was randomized within each device group. Their responses were audio-recorded and analyzed and scored off-line.

Subjects performed the task in a sound booth with three loudspeakers. Target sentences were played from a loudspeaker located directly in front of the participant and maskers were played from loudspeakers located 60 degrees to the right and left. Maskers were either speech-shaped steady-state noise (SSN), speech-shaped envelope-modulated noise (SEM), or sentences from the same corpus as the stimuli, also spoken by other female talkers. Masking sentences began at a random point in the sentence, with the beginning of the sentence appended to the end, in order to assist participants in segregating the target sentence (which always began with Theo, Victor, or Michael) from the masking sentences. Target presentation level and signal-to-noise ratio (SNR) were both varied as well: target sentences were presented at either 50 decibels A or 65 decibels A, and maskers were presented at levels corresponding to 0 decibels SNR and -6 decibels SNR.

Nine sentences (45 target scoring words) occurred in each of twelve auditory conditions (3 masker types by 2 presentation levels by 2 SNRs), all randomized within each block (aided vs. unaided), making 216 sentences across 24 total conditions. In addition, before each block, subjects were given 12 practice trials (four with each masker type) to become accustomed to doing the task with or without the device. Subjects were scored on the speech perception task in terms of percentage of correct target words accurately repeated in each condition.

At the end of each of the two blocks, subjects were asked to indicate how much effort they needed to expend to complete the task on a scale of 1 (very little effort) to 10 (a great deal of effort).

Participants also completed a brief survey after the speech perception task. This survey asked them to indicate the extent to which participants thought the device would be helpful in the real world; how willing they would be to use the device in the real world; whether they would recommend the device to others; and how comfortable they found wearing the device.

Statistical Analysis Plan

Dependent variables to be analyzed are performance on the speech perception task, benefit of use of the device, and self-rated listening effort. Performance will be measured as percent of target words accurately repeated; benefit will be measured as percent correct with device minus percent correct without device. Listening effort will be measured on ten-point scale (10 being the greatest effort, 1 the least).

Between-subjects variables to be measured are device (ie., which of the four devices the participant used), age, and hearing loss (better-ear Pure Tone Average). Within-subject independent variables to be analyzed are device condition (i.e., with vs. without device) and acoustic properties of the stimuli: presentation level of target sentences (soft vs. loud), type of masking noise (SEM noise, SSN noise, or competing speech maskers), and signal-to-noise ratio (-6 dB or 0 dB).

Statistical analysis will be done with separate Repeated Measures ANOVAs for Performance, Benefit, and Self-Rated Effort. Responses to the post-experiment questionnaire will be analyzed qualitatively.

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Consent Form for Participation in a Research Study
University of Massachusetts Amherst

Researcher(s):	Karen S. Helfer, Ph.D.
Study Title:	**Aging and Speech Perception in Complex Listening Environments: Personal Sound Amplifiers**
Funding Agency:	NIH--NIDCD

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1. WHAT IS THIS FORM?

This form is called a Consent Form. It will give you information about the study so you can make an informed decision about participation in this research.

This consent form will give you the information you will need to understand why this study is being done and why you are being invited to participate. It will also describe what you will need to do to participate and any known risks, inconveniences or discomforts that you may have while participating. We encourage you to take some time to think this over and ask questions now and at any other time. If you decide to participate, you will be asked to sign this form and you will be given a copy for your records.

2. WHO IS ELIGIBLE TO PARTICIPATE?

Adults between the ages of 45 years and 64 years may be eligible to participate in this study. Participants also must also have learned English as his/her first language; must not use hearing aids; must have no more than a mild-to-moderate hearing loss; and must have no major neurological conditions.

3. WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to identify how Personal Sound Amplifiers (PSAPs) affect speech understanding in adults who have early age-related hearing problems. PSAPs are over-the-counter hearing devices that provide a small amount of amplification, designed to help people who have mild hearing loss hear better in certain situations. The results may be published in a scientific journal and/or presented at a scientific conference.

4. WHERE WILL THE STUDY TAKE PLACE AND HOW LONG WILL IT LAST?

The study will take place in the Hearing Research Laboratory in Arnold House at the University of Massachusetts. You will be required to come for one or two visits of approximately 2 hours.

5. WHAT WILL I BE ASKED TO DO?

You will first have your hearing tested and then you will be counseled about the results. Based on the hearing test results, you may be excluded from the study. If this is the case, you will receive a $10 stipend. Next, you will complete two questionnaires asking about your health and your hearing, as well as a brief cognitive screening test. During the remainder of your participation you will complete tests of speech understanding in which you must listen for one message when there are distracting sounds playing

in the background. You will be wearing Personal Sound Amplification Devices (PSAPs) during the experiment. PSAPs are worn in the ear, similar to conventional hearing aids. The PSAPs will be adjusted so that they are never uncomfortably loud. Your vocal responses may be recorded in order for us to be able to analyze them at a later time. Breaks will be offered approximately every 30 minutes, although you can request a break at any time. The recordings will be stored on a password-protected computer that is only accessible to the research assistants. Your name or other identifying information will not be stored on the same computer. If your vocal responses are recorded, the recordings will be destroyed after the data are analyzed (generally within 1 week of your visit).

6. WHAT ARE MY BENEFITS OF BEING IN THIS STUDY?

There will be no direct benefit to participants except learning about their hearing status.

7. WHAT ARE MY RISKS OF BEING IN THIS STUDY?

We believe there are no known risks associated with this research study; however, a possible inconvenience may be the time it takes to complete the study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

The following procedures will be used to protect the confidentiality of your study records. All information that identifies you personally will be recorded with a code number, and the key that links this number to your information will be kept in a locked file on a password-protected computer. When the study is finished, this key will be destroyed. All electronic files containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health (NIH) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

9. WILL I RECEIVE ANY PAYMENT FOR TAKING PART IN THE STUDY?

You will be paid $30 for participating in this study. If you decide to withdraw early from the study, your payment will be pro-rated by the amount of time you have participated. The minimum you will be paid for participating is $10.

10. WHAT IF I HAVE QUESTIONS?

Take as long as you like before you make a decision. We will be happy to answer any question you have about this study. If you have further questions about this project or if you have a research-related problem, you may contact the researcher (Karen Helfer) at khelfer@comdis.umass.edu or at 413-545-4014. If you have any questions concerning your rights as a research subject, you may contact the University of Massachusetts Amherst Human Research Protection Office (HRPO) at (413) 545-3428 or humansubjects@ora.umass.edu.

11. CAN I STOP BEING IN THE STUDY?

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate.

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The University of Massachusetts does not have a program for compensating subjects for injury or complications related to human subjects research, but the study personnel will assist you in getting treatment.

13. SUBJECT STATEMENT OF VOLUNTARY CONSENT

When signing this form I am agreeing to voluntarily enter this study. I have had a chance to read this consent form, and it was explained to me in a language which I use and understand. I have had the opportunity to ask questions and have received satisfactory answers. I understand that I can withdraw at any time. A copy of this signed Informed Consent Form has been given to me.

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Participant Signature:	Print Name:	Date:

By signing below I indicate that the participant has read and, to the best of my knowledge, understands the details contained in this document and has been given a copy.

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Signature of Person Obtaining Consent	Print Name:	Date:

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Researcher(s): Karen S. Helfer, Ph.D.
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This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

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