

Variability In Hearing Aid Outcomes In Older Adults
9.1.2019

NCT02448706

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Inclusion and Exclusion Criteria

All individuals will receive a hearing test to determine their current hearing status. Additionally cognitive testing may be administered to determine inclusion, as described below.

Inclusion criteria:

Experimental group: Adults aged 55 or older with sensorineural hearing loss.

Exclusion criteria:

Diagnosis of dementia; failure to pass the cognitive screening measures; conductive hearing loss; hearing loss exceeding the limits that can be successfully aided with hearing aids (i.e., profound hearing loss); hearing loss remediated with a cochlear implant (cannot wear hearing aids), and Non-English speaking participants. Additionally participants must be free from clinically significant unstable or progressive medical conditions, or conditions which, in the opinion of the investigator places the participant at unacceptable risk if he or she were to participate in the study.

Procedures Involved

Participants. We will include only older listeners with adult-onset hearing loss. Because this experiment requires that listeners be fit with binaural hearing aids, all participants' hearing loss will be mild to moderately severe and symmetrical (<15 dB average difference between ears, at .5, 1, 2, 3 kHz). normal-hearing adults will not be included. All participants will be in good health (self-report), have no significant history of otologic or neurologic disorders and speak English as their primary language. To ensure they can read computer displays, all participants will have good organic or corrected visual acuity. Only participants who are not actively wearing hearing aids during the past year will be included. This avoids any bias from previous hearing aid experience and ensures that the participant will be using only the study hearing aids. Participants will be divided into low and high working groups based upon the results of their working memory reading span tests. Once either high or low working memory group is filled (approximately 25 participants each) we will selectively enroll participants to fill the other category.

The following tests will be completed for all participants and will used to determine study eligibility as well as group assignment. Audiogram (PTA¹) will be considered in the analysis. The remaining tests are included to describe the subject cohort and as possible covariates.

1. Case history and otoscopic exam
2. Audiogram (pure-tone air and bone conduction thresholds).
3. Loudness discomfort levels. LDLs will be measured at .5 and 3 kHz and used in combination with subject report to ensure that stimulus levels are not uncomfortable.
4. Tympanometry. Subjects with conductive loss (air-bone gaps > 10 dB at any frequency and/or abnormal immittance will be excluded from participation.

¹ Pure-tone average. We expect to use standard PTA (.5, 1, 2 kHz) and high-frequency PTA (2, 3, 4 kHz) as possible covariates.

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5. Monosyllabic word recognition in quiet. Although of limited experimental use, this is included to facilitate comparisons to other published research
6. QuickSIN. This 5-minute recording contains female-talker sentences in a background of 4-talker babble. The speech is audible and the noise is gradually increased. The final score is based on number of words correct and expressed as a threshold in dB SNR. A larger SNR indicates poorer ability to hear in noise.
7. Cognitive testing. Working memory is a limited-capacity system that enables an individual to actively maintain task-related information while simultaneously performing other relevant processing. In contrast to short-term memory, which emphasizes pure storage capacity, working memory is conceptualized as an active system whose storage mechanisms operate in the service of complex goal-directed cognition (e.g., language comprehension, mental arithmetic). Numerous studies have shown that performance on working memory tasks can predict individual differences in complex cognitive activities better than pure-storage measures such as digit span. Recent data suggests that working memory capacity, as measured by the reading span test, can predict benefit of hearing-aid processing. We will use a complex verbal span task, a measure of working memory capacity developed to capture the individual variability in such capacity to coordinate simultaneous storage and processing requirements. Participants read a series of sentences presented a few words at a time on a computer monitor and then recall the last word of each sentence.

Hearing aid fitting

We will select two sets of signal processing parameters that either provide a high level of signal manipulation (with concomitant improved audibility) (Fitting A) or a low level of signal manipulation (Fitting B). We will select signal processing (combinations of WDRC, frequency compression) that produce either high levels of signal manipulation or low levels of signal manipulation; that is, that represents a situation of more or less signal manipulation, with corresponding variability in patient response. Note that our goal here is simply to select processing choices that suit the experimental hypothesis; we are not interested in making recommendations about specific algorithm parameters (e.g., frequency compression); rather, we are interested in testing the idea that listeners respond differently to the net effect of signal manipulation and that those responses are related to patient factors including cognition. All hearing aid parameters will be constrained such that the signal is audible, comfortable, and clinically realistic (based on the range of available fitting parameters).

We will obtain hearing aids for use in the trial. We will choose the specific hearing aids based on the technology available at the time of the trial. Commercial hearing aids universally offer noise suppression and WDRC. We anticipate that twelve individuals (fit binaurally = 24 aids, with 4 aids held for backup) will be enrolled at a time. Each individual will wear one processing condition for 6 weeks, followed by the other for 6 weeks, for a total 12-week trial. Order of the processing conditions will be counterbalanced across subjects. Allowing for transition time (to order earmolds, program hearing aids, etc.) we anticipate testing 36 individuals per year and completing the target sample of 45 subjects in <1.5 years. Fitting procedure will follow accepted clinical protocol. Briefly, we will program each hearing aid to NAL-NL frequency-gain response, plus the desired features (e.g., frequency lowering, noise reduction, WDRC release time). Real-ear aided response will be measured with a probe microphone system and frequency-gain response adjusted to meet prescribed NAL-NL targets. Each

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participant will be tested at the hearing aid fitting and again and 6 weeks post-fitting. During that time they will wear the hearing aids in their own environment.

Outcomes. Two important goals in hearing-aid processing are to improve speech intelligibility and quality.

Speech intelligibility. Speech intelligibility will be tested using low-context (IEEE⁵¹) sentences in quiet and in babble at a range of signal-to-noise ratios (SNRs). The processing will be provided by the settings of the wearable hearing aids; and the patient will be aided binaurally. Subjects will be tested in a double-walled sound booth with the test signal (conversational speech level) presented through a speaker. The speaker will be positioned at a typical conversational distance (approximately 1m) and azimuth (0°) and the subject will respond by repeating the sentence heard. The hearing aid will be programmed by the research audiologist. Both the research assistant (who will conduct the speech tests) and the patient will be blind to the processing condition. Based on our previous data and on desire to sample realistic listening conditions we expect to use SNRs ranging from 0 to +10 dB. Our protocol for measuring speech intelligibility is as follows. The listener is seated in a double-walled sound booth and speech is presented to the listener at conversational levels in free field. Speaker distance (~ 1 m) and azimuth (0°) mimic a conversational situation. A locally-developed Matlab interface allows the listener to signal for presentation of the next sentence and for scoring of correct repetition of key words by an experimenter seated outside the sound booth. To confirm reliable scoring, an audio file of the listener's response is digitally stored and rescored by a second tester who is blinded to the initial scoring.

Speech quality. There are many situations where speech intelligibility is high but sound quality is still rated as lacking. In addition, sound quality is a critical component to successful hearing aid outcomes. Quality ratings will therefore be obtained in addition to the intelligibility tests. Perceptual quality ratings will be obtained using a rating scale ranging from 1 (poor sound quality) to 10 (excellent sound quality). The rating scale will be implemented with a slider bar that registers responses in 0.05 increments. Listeners will make their selections from the slider bar displayed on the computer screen by using a customized interface that included a point-and-click method for recording and verifying rating scores. The timing of presentation will be controlled by the subject. This rating scale has been used successfully in quantifying the differential effects of hearing aid signal processing algorithms on sound quality ratings by both normal-hearing and hearing-impaired listeners.

Handicap reduction (subjective outcome). Objective measures provide insight into treatment efficacy, but effectiveness depends on the psychosocial adjustments to hearing loss that cannot be measured in a sound booth. Therefore self-administered scales are a critical component of assessing treatment effectiveness.

Three subjective measures will be used:

Effectiveness of Aural Rehabilitation (EAR). The EAR measures intrinsic issues of hearing loss (functional, physical, emotional, and social impairment), as well as extrinsic factors such as the comfort, convenience, and cosmetic appearance associated with hearing devices. Two modules, the "Inner EAR" (intrinsic) and the "Outer EAR" (extrinsic), were created. Both scales are brief (10 domain items, in

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addition to one or two global questions). The EAR scales were developed and validated by the PI and colleagues. Item reduction was based on inter-item correlation, internal consistency, and factor analysis. Final scales take an average of 5 minutes to complete, have well-distributed responses, and no ceiling or floor effects. The effect size of the Inner EAR is high (2.1). The Minimal Clinically Important Differences (MCID) of the EAR is 6.0 points (on a 0 to 100 scale).

Adherence. We will evaluate adherence using 2 questions: “Do you use your hearing aids?” and “How many hours a day do you use your hearing aid?” In our previous work, we used these questions and found responses to be well-distributed. While responses correlate with the Inner EAR ($r=.35$, $p<.001$) and satisfaction with amplification ($r=0.41$, $p<.001$), the moderate correlation coefficients suggest that adherence is an important construct that reflects more than mere function and satisfaction.

Speech and Spatial Qualities of Hearing (SSQ) questionnaire. The SSQ addresses static and dynamic listening environments, and includes situations with several types of background noise and where the target talker is unpredictable. The SSQ items are categorized as: understanding speech; judging sound location/distance; and sound clarity/naturalness. Patients rate how well they performed in the specified situation. The SSQ is included because we are interested in difficult listening situations which require cognitive resources, such as those involving background noise and multiple talkers. In a recent study²³ we collected SSQ data along with a variety of other objective measures, including ability to hear speech in complex noise. In those data, older listeners’ reports of listening in complex situations was much more variable than for younger listeners with comparable hearing thresholds.

Hearing aid use verification: Approximately one week after Fitting A, and one week after Fitting B participants will return to the lab to take the Practical Hearing Aid Skill Test (PHAST). This test requires participants to demonstrate hearing aid use tasks (e.g insertion/removal of hearing aid, changing batteries, and cleaning). This test insures participants are using and wearing their hearing aids appropriately.

Mid-fitting follow-up: Three weeks after hearing aid fitting participants will be contacted via telephone or email. The purpose of this follow-up is to insure participants are wearing their aids, and to assess any problems participants are having with the hearing aids.

Datalogging: During the one week post fitting verification and 6 weeks post fitting visit hearing aid data logs will be measured. This hearing aid feature allows the PI to identify how many hours the hearing aid has been in use.

Data Management

Each subject will receive a study code and that code will be used for all study data. The link between the subject name and code are password-protected and stored on a HIPAA-approved server with server security managed by Northwestern School of Communication computer support staff. All research staff will be trained in appropriate Human Subjects protection procedures, including confidentiality. Data is accessible only to study staff via password-protected files. Additionally subject data may be shared with collaborators at the University of Colorado Boulder. When sharing information will be exchanged via secure FTP. All (de-identified) data will be stored in a secure database accessible via password by study staff at either

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site. Weekly meetings across sites will include discussion of subject confidentiality. All personnel involved at either site will complete appropriate Human Subjects Protection training. Any unanticipated problems will be reviewed by the PI and reported as required.

Withdrawal of Subjects

Subjects are free to discontinue testing at any time at any point of the study, for any reason. All testing will be done in a manner to ensure safety of our subjects (e.g presenting sounds at a comfortable listening level) If a subject decides to withdraw from the research study only the data collected up to that point will be used with their permission. If they do not provide their permission their data will be withdrawn completely. A participant may be removed from the study if they lose or damage the study aids, do not wear the study aids for more than 6 hours a day, or are unable to adhere to the prescribed study schedule and tasks. In the event that a participant is removed from the study without their consent compensation will be pro-rated based upon the duration the participant remained compliant with study tasks and procedures. Once a participant is unable to continue with the study, compensation will end.

Statistical analysis plan

Outcome measures between the optimal and suboptimal conditions will be compared using a paired t-test. We expect customized processing settings, which will utilize our cognitive and peripheral test batteries, will result in statistically significant and clinically meaningful improvements when compared to traditional fittings. We will identify any acclimatization effects by monitoring changes in outcomes observed over time. All subjects are expected to fully acclimatize to the hearing aid device by the end of the six-week trial. We will use a paired t-test analysis to compare the outcomes between the “high modification” and “low modification” conditions. This experiment will be powered to detect mean differences of 0.5 standard deviations with a sample size of 45 at 90% power and $\alpha=0.05$.

Sharing of Results with Subjects

Results of standard clinical procedures (e.g auditory testing) will be made available to participants at their request. Participants often have questions about their hearing and hearing aids. Counseling and recommendations will be done by or under the supervision of Dr. Pamela Souza the study PI and clinical audiologist. If research participants request the results from the research testing or cognitive testing, these results will be provided to the participant with the explanation that they are for “research purposes only” and not meant as a diagnostic tool or clinically reliable.

Recruitment Methods

Individuals in our lab subject pool who have expressed an interest in future studies will be contacted by phone or email (whichever they have indicated as a preferred contact) by the PI or her research assistant. Additional subjects will be recruited as needed by: (a) Flyers posted in our clinic and on community bulletin boards (b) Letter to potential participants. These letters will be sent to potential participants in the Aging Research Registry and the Northwestern University Audiology Clinic (c) newspaper advertisements

Subjects will receive \$10 per hour for participation. Participants will receive a bonus payment of \$40 after 6 weeks of wearing Fitting A, and \$50 after 6 weeks of wearing Fitting B. Therefore in experiment 2, a subject will be paid \$250 if they complete all study visits/tasks. (8 study visits lasting 2 hours paid at \$10/hour: \$160 + bonus payments of \$40 and \$50 = \$250 total)The

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subject is paid by check or cash. Typically this is done at the end of each study visit (for multiple visits), but some subjects opt to receive a single payment at completion of the entire study. We follow the subject's preference in this matter. The subject will be asked to sign a receipt verifying that they have received payment. A subject who withdraws from the study retains the amount paid for the portions of the study that were completed, but forfeits pay for the uncompleted portions of the study. Potential subjects will not be paid for the hearing test which is done to determine whether criteria for participation has been met.

Provisions to Protect the Privacy Interests of Subjects

During the consent process a lab member will explain that their identifiable information will not be used. Each participant will receive a study code that will be used for all study data. The only link between identifiable data and a study code will be on a password protected HIPAA-approved server with server security managed by Northwestern School of Communication computer staff. Before starting a study procedure the lab member will explain the task and reiterate that they are free to stop at any point. During the administration of questionnaires or cognitive testing the tester will remind the subject they can decline to answer any question they feel uncomfortable answering without any negative consequences.

Consent Process

Prior to enrollment potential participants will have a hearing and cognitive test with authorization by a screening audiogram consent form. These tests will allow us to exclude potential participants from enrolling in the study who are ineligible based upon their hearing status or over-enrolling participants in a particular working memory group. If participant is eligible based upon their screening results, they will be enrolled in the study with separate consent. All subjects will provide their consent to study procedures to the investigator or her research assistants. This process will take place in the Hearing Aid Laboratory, prior to any research procedure taking place. All consent forms are stored in a locked file cabinet drawer within the Hearing Aid lab (a locked laboratory). An unlimited amount of time will be provided to the participant to ensure they have adequately reviewed the consent form and all questions have been addressed by study staff. Following the subject's opportunity to read the consent document, study staff will review each section with participant to clarify the study or any procedure, and ensure understanding. Additionally consent forms may be provided to a potential research participant before a study visit is scheduled so they may take extra time to review before committing to participation. All participants will receive a copy of their signed consent form.

Non-English Speaking Subjects

At this time we are unable to include non-English speaking subjects, because the study requires repetition of English-language materials.