Title: Description of the Baseline Audiologic Characteristics of the Participants Enrolled in the ACHIEVE Study

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ABSTRACT (250/250 words)

Purpose: The Aging and Cognitive Health Evaluation in Elders (ACHIEVE) Study is a randomized clinical trial designed to determine the effects of a best-practice hearing intervention versus a successful aging health education control intervention on cognitive decline among community-dwelling older adults with untreated mild-to-moderate hearing loss. We describe the baseline audiologic characteristics of the ACHIEVE participants.

Method: Participants aged 70-84 years (N= 977; median age = 76.8) were enrolled at four U.S. sites through two recruitment routes: (1) an ongoing longitudinal study; and (2) *de novo* through the community. Participants underwent diagnostic evaluation including otoscopy, tympanometry, pure-tone and speech audiometry, speech-in-noise testing, and provided self-reported hearing abilities. Baseline characteristics are reported as frequencies (percentages) for categorical variables or medians [interquartiles, Q1-Q3] for continuous variables. Between-group comparisons were conducted using chi-square tests for categorical variables or Kruskal-Wallis test for continuous variables. Spearman correlations assessed relationships between measured hearing function and self-reported hearing handicap.

Results: The median 4-frequency pure-tone average of the better ear was 39-dB HL and the median speech-in-noise performance was a 6 dB SNR Loss, indicating mild speech-in-noise difficulty. No clinically meaningful differences were found across sites. Significant differences in subjective measures were found for recruitment route. Expected correlations between hearing measurements and self-reported handicap were found.

Conclusions: The extensive baseline audiologic characteristics reported here will inform future analyses examining associations between hearing loss and cognitive decline. The final ACHIEVE dataset will be publicly available for use among the scientific community.

Introduction

Epidemiologic studies indicate that hearing loss is independently associated with accelerated cognitive decline and dementia. A recent Lancet global commission on dementia analysis found hearing loss potentially accounts for the largest population attributable risk among modifiable risk factors for dementia. Specifically, the report suggests nearly 8% of dementia cases across the globe could be attributable to hearing loss (Livingston et al., 2020). Evidence linking hearing loss and cognition has been obtained from self-reported and measured cognition (e.g., standardized neurocognitive test batteries designed to assess domains of attention, memory, language, processing speed, visuospatial, and executive functions), as well as self-reported and measured hearing (e.g., pure-tone thresholds) loss. A meta-analysis including three studies examining the relationships between measured hearing loss and standardized cognitive measures estimated a pooled relative risk ratio of 1.94 (95% confidence interval [CI; 1.38, 2.73]), indicating an increased likelihood developing dementia among included persons with measured peripheral hearing loss (Livingston et al., 2017).

A number of mechanisms seek to explain the association between hearing loss and cognitive decline (Baltes & Lindenberger, 1997; Lin & Albert, 2014; Powell et al., 2021; Wayne & Johnsrude, 2015). These hypothesized mechanisms include: 1) increased cognitive load; 2) structural changes in the brain as a result of the degraded auditory signal; and 3) impaired verbal communication leading to reduced social engagement and increases in loneliness. Importantly, these mechanistic pathways may be modifiable with comprehensive hearing loss treatment, the cornerstone of which is the use of hearing aids. Determining the efficacy of hearing loss intervention on cognitive decline is of high importance given the aging of the population and the personal, socioeconomic, and public health implications of both hearing loss and cognitive impairment in older adults (Livingston et al., 2020). Findings from

studies investigating the relationships between hearing device use and cognition are mixed, with some individual studies demonstrating positive results (e.g., Dawes et al. 2015; Maharani et al. 2018)) and some showing no relationship (Atef et al., 2023). Recently reported results of a meta-analysis pooling data across 19 observational studies and 4 trials found the use of hearing restorative devices (hearing aids; cochlear implants) was associated with a decreased risk of cognitive decline. Despite this finding, the authors highlighted the need to examine cognitive and other proximal benefits in randomized trials to better understand this relationship (Denham et al., 2022; Yeo et al., 2022).

A recently completed clinical trial, referred to as the "Aging and Cognitive Health Evaluation in Elders" (ACHIEVE Study) is investigating the effect of best practice hearing intervention on cognitive decline, dementia, and other health outcomes. The ACHIEVE Study was designed to determine the effects of a best practices hearing intervention compared to a health education control intervention. The hearing intervention included four 1-hour sessions with a study audiologist where participants received systematic, yet personalized, hearing counseling and self-management support in addition to bilateral prescriptive-fit hearing aids and other hearing assistive technologies (Sanchez et al., 2020). Participants assigned to the health education active control also completed four 1-hour intervention sessions with a certified health educator who discussed healthy aging, chronic disease, and disability prevention, per the standardized administration of the 10 Keys to Healthy Aging program (Newman et al., 2010).

The ACHIEVE protocol details are reported elsewhere (Jennifer A. Deal et al., 2018) and included on the ClinicalTrials.gov website (ClinicalTrials.gov Identifier: NCT03243422), but, briefly, the trial recruited community-dwelling older adults with untreated mild-to-moderate hearing loss between 2018-2019 from four study sites located in the United States. Participants were recruited either from the ongoing Atherosclerosis Risk in Communities (ARIC) longitudinal observational study (ClinicalTrials.gov Identifier: NCT00005131), which begin in 1987, or *de novo* from the local study site

communities. The ARIC study is a prospective cohort study that enrolled 15,792 participants aged 45-64 years between 1987-1989 (ARIC, 1989; Wright et al., 2021) who have been continuously followed with study visits to the present. Participants recruited to the ACHIEVE Study were English speaking adults between 70 and 84 years old and measured to be free from substantial cognitive impairment with a Mini-Mental State Exam [MMSE (Arevalo-Rodriguez et al., 2021)] ≥23 for high school degree or less ≥25 for some college or more. Participants reported adult-onset hearing loss that was measured (four-frequency pure tone average [PTA; 500, 1000, 2000, 4000 Hz]) in the better-hearing ear to be ≥ 30 decibels (dB HL) and < 70 dB HL with word recognition in quiet performance ≥ 60%. The degree and configuration of hearing loss was selected to allow for recruitment of individuals most likely to benefit from the use of conventional hearing aids (Humes, 2019; Stevens et al., 2011). Participants were randomized to receive either a best-practices hearing intervention (Sanchez et al., 2020), or a successful aging health education control intervention (Newman et al., 2010), and followed with semiannual visits for 3 years. The primary outcome of the study evaluated rates of cognitive decline (measured global cognitive function) (Lin et al., 2023). Additional analyses and dissemination of the results are forthcoming, with secondary cognitive outcomes including domain-specific cognitive declines (memory, executive function, and language) and incident cognitive impairment, and other outcomes including brain structure on magnetic resonance imaging (MRI), health-related quality of life, physical and social function, and physical activity.

The purpose of this work is to provide a comprehensive description of the baseline audiological characteristics of the ACHIEVE participants. Baseline characteristic reports are important to thoroughly describe the patient population enrolled in a clinical trial, especially in multidisciplinary and large-scale trials that cannot allow for such details to be reported in their outcome reports. Examples of similar baseline characteristics reports are commonly reported in the literature of large-scaled multi-site trials,

such as for treatments for cardiovascular disease, neurological disorders, and diabetes (Mentz et al., 2017; Pfeffer et al., 2009). Included in this report of the enrolled ACHIEVE participants are hearing function and performance data (e.g., audiometry, word recognition in quiet performance, speech perception in noise) and self-reported hearing difficulty and hearing handicap. We review differences among audiologic results based on geographical location (e.g., study sites) and related to recruitment route (e.g., ARIC vs. *de novo*). Through our goal of thoroughly reporting the baseline hearing characteristics we have a complete understanding of the cohort's hearing, and we will comment on the baseline characteristics with respect to the hearing intervention that was designed for the trial. This report thoroughly characterizing the audiological results will serve as one of several descriptive, genre-specific baseline papers, intended to offer deep complementary information for interpreting the main trial results and all outcome papers forthcoming. The work presented here will enrich future analyses evaluating the association between hearing loss and cognitive decline, and these data, as well as the broader ACHIEVE dataset, will become publicly available to the scientific community once the main ACHIEVE study results are published in 2023-2024.

Methods

Study Design, Setting, Recruitment, Participant Demographics

The ACHIEVE Study is a randomized phase III clinical trial to determine the effects of a best practice hearing intervention versus a successful aging health education control intervention on cognitive decline among community-dwelling older adults with untreated mild-to-moderate sensorineural hearing loss (SNHL). Full details of the ACHIEVE study design were described elsewhere (Deal et al., 2018). The study is supported by seven institutions: Johns Hopkins University, University of North Carolina – Chapel Hill, University of South Florida, University of Pittsburgh,

University of Minnesota, Wake Forest University, University of Mississippi Medical Center; with the four university-affiliated study sites located in: Washington County, Maryland (MD); Jackson, Mississippi (MS); Forsyth County, North Carolina (NC); and Minneapolis, Minnesota (MN). The Institutional Review Boards at all centers reviewed and approved the study protocol. There were no participant costs for the interventions provided as part of the protocol and paid transportation to and from the study center was provided for participants if needed. Participants received monetized compensation for each study visit completed.

At the study sites, participants were recruited either from the ongoing ARIC study, or *de novo* from the local study site communities. Local study site recruitment methods included clinic referrals and advertisements posted throughout the community and via online forums. Recruitment through the ARIC study was targeted, with previous hearing loss data available for review. ARIC participants were directly contacted about the opportunity to join the ACHIEVE study either through mail, telephone, or at their next pre-planned ARIC study visit [i.e., ARIC visit 7, which was ongoing at the time of ACHIEVE study enrollment (ARIC, 1989)]. Participants completed a screening and baseline visit, four intervention visits and then were seen semi- and annually for the next three years.

At the screening visit, participants completed questionnaires that captured health history, demographics, education, and other social determinants of health. Sex and race/ethnicity were self-reported using federal guidelines in existence at that time. Participants self-reported sex, as either male or female, rather than gender. Questionnaire items related to hearing history included the presence/absence of tinnitus, noise exposure, and history of otologic disorders.

Audiological Evaluation

High-level overviews of the ACHIEVE comprehensive audiological evaluation, including audiometric-related inclusion/exclusion criteria, are available in the literature (J.A. Deal et al., 2018; Sanchez et al., 2020). The objective of the audiological evaluation was to quantify the type and magnitude of hearing loss and confirm participant candidacy for the hearing intervention designed for the ACHIEVE Study. The intervention, described in detail by Sanchez, Arnold et al., 2020, is evidence-based and utilizes conventional hearing aids as a key component, along with goal setting, hearing assistive technologies, counseling, education and self-support management, and hearing-related outcomes assessment. If the results of the audiological evaluation were suggestive of a possible conductive or retrocochlear condition, medical assessment and clearance for use of conventional hearing aids was required. All audiological assessments were conducted in single-walled, 7x7 sound attenuating WhisperRooms at each site using Interacoustics Equinox 2.0 AC440 diagnostic, two channel audiometers. Guidelines were followed for routine equipment calibration, maintenance, and sound field specifications (American National Standards Institute, 1999, 2018) at each site.

Assessment of the Outer & Middle Ear Status. Otoscopy was completed to view the structure of the ear canal and tympanic membrane. The audiologist determined the potential for a collapsing ear canal, evaluated the presence of cerumen and need for self-management or professional removal of cerumen, or other problems (e.g., perforation, drainage, blood) that may interfere with audiometric testing. Additionally, tympanometry with a 226 Hz probe frequency was obtained with an Interacoustics Titan middle-ear analyzer (version 1). Tympanometry was completed to evaluate the physiological function of the middle ear. Site audiologists determined and reported the tympanogram tracings as normal (type A) or abnormal (types: A_S, A_D, B or C).

Assessment of Pure-tone Sensitivity. Pure-tone air- and bone-conduction thresholds were obtained using a modified Hughson-Westlake (1944) psychophysical bracketing method (Carhart & Jerger, 1959). Air-conduction thresholds were measured at octaves from 250 to 8000 Hz, including the inter-octave frequencies of 3000 and 6000 Hz. Pulsed tones were used with E-A-R 3A insert earphones, unless otherwise indicated. Bone-conduction thresholds were measured at 500, 1000, 2000, and 4000 Hz. Masking, using plateau method (Hood, 1960), for both air- and bone- conduction thresholds was completed if needed based on transducer specific interaural attenuation levels. If the audiologist indicated there was "no response" at a given frequency (i.e., a measurable threshold could not be obtained due to limits of the audiometer) the audiologists indicated they could not measure that threshold and noted the limits of the audiometer that was attempted.

Assessment of Speech Recognition. As a criterion for the potential to successfully utilize hearing aids, participants were required to have word recognition performance in quiet greater than 60% in at least one ear for inclusion (based on criteria from Humes et al. (2019). Word recognition in quiet testing was performed using recorded speech stimuli to determine the participant's optimal performance under controlled, standardized conditions and to reveal any asymmetry in performance not uncovered by pure-tone audiometry. Word recognition in quiet stimuli were NU-6 ordered-by-difficulty monosyllables (Hurley & Sells, 2003) presented monaurally at a sensation level referenced to the 2000 Hz threshold that is a presumed optimal listening level (Guthrie & Mackersie, 2009). Based on recognition performance of the first 10 administered words and following the ordered-by-difficulty procedures, either just 10 words or 25 words were presented to each ear. Masking of the non-test ear was used, as needed, presented at 20 dB below the presentation level of the speech stimuli (Hood, 1960; Studebaker, 1967). E-A-R 3A insert earphones were used unless otherwise indicated. Scoring was determined by

tallying the participant's correctly repeated words and was recorded as percentage correct scores. Speech recognition threshold (SRT) measurement with spondaic words was completed at the discretion of the audiologist, specifically to confirm reliability of pure-tone thresholds.

Speech recognition in noise performance was assessed in sound field using the Quick Speech-in-Noise Test (QuickSIN; Etymotic Research, 2001, Killion et al. (2003)). The QuickSIN consists of a series of lists of 6 sentences, with 5 target words per sentence, spoken by a woman talker, mixed with multi-talker speech babble that increases in 5-dB increments with each consecutive sentence presentation, for a signal-to-noise ratio (SNR) varying from 25 dB to 0 dB. The QuickSIN test was administered with channel 1 and channel 2 routed to separate RadioEar SP90 speakers. The sound field environment was calibrated daily in dB SPL using the substitution method (Walker et al., 1984). Sentences were presented on channel 1 at 0^0 azimuth using a fixed level of 70-dB SPL. Multi-talker babble was presented on channel 2 at 180^0 azimuth, manually adjusting the SNR from 25 dB to 0 dB in 5-dB increments. The most homogeneous QuickSIN lists were used in the ACHIEVE study (McArdle & Wilson, 2006). Participants were presented a practice list and then two test lists (list 1 and 2) for a total of 60 possible target words to recognize. Scoring was determined by tallying the participant's correctly repeated target words for each test list. The total correctly recognized words were summed to determine number of target words correctly recognized across both lists and all SNRs, allowing for a percentage correct calculation (e.g., number correct out of 60 possible target words). In addition, using the normalized threshold calculation based on the Spearman-Kärber equation (Killion et al., 2004), the 'dB SNR Loss' was calculated using the average performance from the two test lists.

Self-Report Hearing Ability

Two self-report measures were used to assess subjective hearing ability, and both were completed in a face-to-face format. First, participants answered the single 6-item Likert-type question from the National Health and Nutrition Examination Survey (NHANES) conducted by the National Center for Health Statistics (question AUQ054; CDC, 2023). This NHANES-developed question is often adopted by others (e.g.,(Dillard et al., 2022; Marrone et al., 2019)) and asks, *"Which statement best describes your hearing? Would you say your hearing is:"* with response options of: *"Excellent; Good; A Little Trouble; Moderate Trouble; A Lot of Trouble, and Deaf".* The second approach involved the use of a standardized measure of hearing handicap, the Hearing Handicap Inventory for the Elderly – Screening Version [HHIE-S; (Ventry & Weinstein, 1983)], The HHIE-S is a validated and highly reliable (r = .97) 10-item questionnaire that measures perceived hearing handicap. HHIE-S scores range from 0 to 40 with higher scores indicating greater self-perceived handicap, and the total scores can be categorized into No Handicap (0-8), Mild-Moderate Handicap (10-24), and Severe Handicap (26-40). A total score of 10 or greater is suggestive of significant self-perceived hearing handicap (American Speech-Language-Hearing Association, 1997).

Quality Control of Data, Database Management, & Statistical Analysis

An extensive quality assurance and quality control protocol was designed for the ACHIEVE Study. As described in detail elsewhere (Arnold et al., 2021), the comprehensive audiological evaluation was completed by licensed, nationally certified audiologists who completed training in ACHIEVE hearing related protocol administration. Audiological procedures were monitored through direct observation and validating data entry, ensuring fidelity across the study sites. After the baseline data were captured in the electronic database, the data coordinating center, located at the University of North Carolina at Chapel Hill, completed a database review followed by a database lock. During the

304 database review process, data were assessed using visual inspection of plots as well as influence
305 statistics and residuals from generalized additive models. Observations were flagged for review based on
306 leverage and Cook's distance to identify unusual patterns among the variables. The verified and
307 validated data were used for all analyses. Missing data were not imputed for analysis in the current
308 study. Less than 2% of the data were missing with all missingness reported. For air-conduction pure-
309 tone audiometry, if the audiologist indicated there was "no response" at a given frequency (i.e., a
310 measurable threshold could not be obtained due to limits of the audiometer) the threshold was set to
311 110-dB HL for inclusion in the descriptive statistics reported. There were 156 participants with one or
312 more 'no response(s)' and a total of 324 thresholds set to 110-dB HL in the final dataset. Using the pure-
313 tone audiometric results, the 'better ear' was determined by selecting the ear with lowest audiometric
314 thresholds; however, if the ears were identical, then the right ear was defined as the better ear.
315 All statistical analyses were completed using R version 4.2.0 (R Foundation for Statistical
316 Computing, Vienna, Austria), using the agicolae (1.3-5), boot (1.3-28.1), GLMMadaptive (0.8-8),
317 multcomp (1.4-23), splines (4.2.3), and VGAM (1.1-8) packages. Descriptive statistics were used to
318 present the audiologic characteristics and are provided as frequencies (percentages) for categorical
319 variables or medians [interquartile range] for continuous variables. To visualize QuickSIN results, data
320 were fit to generalized linear mixed models (GLMMs) to evaluate subject-specific associations between
321 presentation level and speech-in-noise performance, accounting for the repeated measures (i.e., the two
322 test lists administered) within individuals using subject-specific intercepts and slopes (i.e., random
323 effects). Population-average associations were obtained by marginalizing (i.e., integrating) over the
324 subject-specific effects, allowing visualization of the data through a psychometric function. Spearman-
325 Rho correlational analyses were conducted to examine the bivariate relationships between 4-frequency
326 PTA, QuickSIN performance, word recognition in quiet, and self-reported handicap (i.e., HHIE-S).

Confidence intervals for these correlations were obtained using 10,000 non-parametric bootstrap replicates. Differences between study sites and recruitment methods (*de novo* vs. ARIC) for objectively measured and subjectively measured baseline data were evaluated using a Kruskal-Wallis test for continuous variables (Kruskal & Wallis, 1952). Associations with categorical outcomes were assessed using proportional odds and multinomial logistic regression models. The proportional odds assumption was assessed using a likelihood ratio test. When the proportional odds assumption was violated, the multinomial model was used instead. Multiple comparisons were addressed using Holm's correction (Holm, 1979).

Results & Preliminary Discussion

Recruitment, Enrollment, Participant Demographics and Hearing History Characteristics

Recruitment and enrollment occurred between 2018-2019. Additional information about recruitment results is published elsewhere (see Reed et al., under review). Of the 977 participants enrolled, 24.4% were recruited through the ARIC study, while 75.6% were recruited *de novo* from the surrounding communities of the four university-affiliated clinical study sites. Recruitment allocation across the study sites included 262 (26.8%) from Washington County, Maryland (MD); 243 (24.9%) from Jackson, Mississippi (MS); 236 (24.2%) from Forsyth County, North Carolina (NC); and 236 (24.2%) from Minneapolis, Minnesota (MN).

Supplemental Table ST1 provides demographic results by study site and recruitment route. Participants were community-dwelling adults aged 70-84 years (median = 76.8 years, IQR: 6) and 53.5% female. Most participants were White (87.6%; 11.5% Black; 0.9% of another race). The median number of people living in their household was two (IQR: 1) with 62% reporting being currently

married. Approximately half of participants (53.4%) had a bachelor's degree or higher, 42.8% had a high school diploma or had completed some college, and 3.8% did not complete high school.

ST1 also provides additional information about hearing history variables including self-reported tinnitus perception, noise exposure, and otologic medical history. Approximately half of the participants (52%) reported no history of tinnitus in either ear, with 37% indicating bilateral tinnitus. Occupational noise exposure was reported by 27% of the participants and 11% reported other noise exposure. Nearly all participants denied any medical otologic history, with 97% indicating no ear surgery and 99% indicating neither a diagnosis of sudden idiopathic nor Meniere's Disease related. The distributions of the hearing history characteristics reported are consistent with our goal of recruiting adults with primarily age-related SNHL. Visual inspection of the data in **ST1** indicate that these hearing history characteristics appear comparable across study sites and recruitment routes.

Outer & Middle Ear Function

Shown in **Supplemental Table ST2** are the data for the results from otoscopy and tympanometry examinations. Of the 977 participants, 95% of the monaural otoscopic examinations were within normal limits. The ears indicated as abnormal otoscopy were noted as either required cerumen management (75 ears), or noted as abnormal (28 ears) for other reasons (e.g., foreign object in ear, blood visualized). As summarized in **Supplemental Table S3,** there were no difference in otoscopy by recruitment route, but differences across sites (Right Ear $p = <0.001$; Left Ear $p = 0.005$). Despite a significant difference overall in otoscopy across sites, the only pairwise difference that reached statistical significance was between MD and NC sites for both the right and left ears, but the largest difference in the number of abnormal otoscopic exams differed by only 8 ears.

Most participants had normal middle ear function, with 85% and 84% of the participants having normal tympanograms (type A) for the left (n = 830) and right (n = 824) ears, as classified for data entry by the site audiologist, respectively. There were missing data due to inability to maintain a hermetic seal to perform the measurement in 18 left ears and 13 right ears. As summarized in **Supplemental Table S3,** there were no differences in tympanometry by recruitment route, but differences across sites (Right Ear $\chi 2$ (3) = 18.97, $p < .001$); Left Ear $\chi 2$ (3) = 26.917, $p < .001$). There were pairwise differences in the proportions of participants with abnormal tympanometry as a function of study site. There were significant pair-wise differences with NC being different from MS for both the right and left ears and different from MD for the right ear only. Across both right and left ears, the greatest proportion of abnormal results was found for the MS site (20.6% and 21.8%, respectively) while relatively few participants at the NC site had abnormal tympanograms (7.6% and 7.2% for right and left ears, respectively). While these site differences were observed, overall, there was a small proportion of participants who exhibited abnormal otoscopic or tympanometric results, medical examination confirmed that no participants at any sites had outer or middle ear disorders or dysfunctions that were a contraindication for hearing aids.

Pure-Tone Audiometry Results

To determine the type of hearing loss in each ear, air-conduction and bone-conduction thresholds, with appropriate masking, were evaluated. As shown in **Supplemental Table ST2,** hearing losses were classified as sensorineural (SNHL), conductive hearing loss (CHL), mixed hearing loss (MHL), or unable to determine (UD) based on pure-tone audiometry alone. For each frequency tested by air- and bone-conduction an air-bone gap of 15 dB or greater resulted in a classification of a frequency-specific conductive component. There were 1,378 ears with no conductive component, and these ears

were classified as SNHL. For the remaining ears a present air-bone gap (576 ears or 288 participants), the type of hearing loss was vetted through an adjudication process for which two independent audiologists reviewed the audiogram to determine the overall type of hearing loss. Of 288 patients reviewed, 22 required a third reviewer and adjudication. The final classification of ears included 16 MHLs, 5 UD, 0 CHLs, with the remaining typed as SNHL (1,933 ears). Therefore 98.1% of participants had bilateral SNHL, 0.2% bilateral MHL, 1.7% had a SNHL ear and either a MHL or UD loss in other ear; thus, overall, most participants had bilateral SNHL. Visual inspection of the hearing loss types did not differ across sites nor recruitment route. Along with most losses being sensorineural, most participants had symmetrical hearing (83.1%) as defined by no greater than a 10-dB difference in thresholds at 3 consecutive frequencies or no greater than a 20-dB difference at two consecutive octave frequencies between ears. Right- and left-ear specific details of four-frequency and three-frequency PTAs are provided in **Supplemental Table ST2** and the ear-specific audiogram is displayed in **Supplemental Figure SF1**.

Better ear and poorer ear air-conduction threshold results are illustrated in **Figure 1** and summarized in **Table 1**. **Figure 1** shows the pure-tone thresholds in violin plots which depict the distributions of data using density curves, where the width of the curve corresponds with the approximate frequency of data points in each region. Our density curves are overlaid on box plots that depict numerical summaries of the data, with a central line marking the median value, the box denoting the 75^{th} and 25^{th} percentiles, lines extending showing the upper and lower fences of the data, and all observations outside the upper and lower fences are plotted individually. The median audiogram in **Figure 1** shows a pattern of hearing loss which is consistent with gradually sloping, symmetrical SNHL.

Table 1 shows that the median four-frequency PTA for the better ear was 39-dB HL (IQR 33-43), and the median for the poorer ear was 42-dB HL (IQR 38-48). As summarized in **Supplemental**

Table S3, there were some differences across sites. Despite a significant difference overall in four-frequency PTA across sites (overall $\chi 2$ (3) = 8.109, p = .044), no pairwise differences reached statistical significance, with the largest difference in medians between sites being 2 dB HL. No difference in PTA was observed by recruitment route ($\chi 2$ (1) = 0.461, p = .497), with the difference in medians between recruitment routes being 1 dB HL.

We also examined the better-ear four-frequency PTAs with respect to the World Health Organization (WHO) categorizations (World Health Organization, 2021), for which a better-ear four-frequency PTA ≤ 19 dB HL corresponds to "*normal*"; 20-34.9 dB HL to "*mild*"; 35-49 dB HL to "*moderate*"; 50-64.9 dB HL to "*moderately severe*"; 65-79 dB HL to "*severe*"; and, 80+ dB HL to "*profound*" hearing impairment. Based on this WHO grading criteria, 61% of our total number of participants had moderate hearing loss (PTA between 35-49.9 dB HL) and 29% had a mild loss (PTA between 20-34.9 dB HL), with very little variation in proportions across the two WHO categories as a function of study site or recruitment route. Although participants presented with a mild-to-moderate hearing loss, there was a large spread of the thresholds across the test frequencies as displayed in **Figure 1**.

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Speech Audiometry Performance

Table 1 also shows median recognition performance in quiet for the better and poorer ears as determined by four-frequency PTA. Word recognition performance greater than 60% in at least one ear was part of the inclusion criteria; thus, the range of scores was restricted to 60-100% for the higher

performing ear. The median word recognition in quiet performance was 90% in both the better and poorer ears (IQRs 90-100 and 88-96, respectively), with comparable findings shown for both ears as a function of recruitment route and a statistically significant difference was not observed (see **Supplemental Table S3**). Somewhat surprisingly, yet with a small effect size implicating the significant p-value is likely due to our large sample size, word recognition in quiet in the better ear was statistically significantly different across sites ($\chi^2(3) = 16.411$, $p < .001$). However, the largest pair-wise significant difference for Word Recognition in Quiet (better ear) between the participants from the Jackson, MS and Washington, MD sites was only 2.7 percentage points, and thus, would not be considered clinically meaningful (Thornton & Raffin, 1978). Overall, word recognition in quiet results are consistent with pure-tone audiometric results with respect to type, degree, and configuration of hearing loss.

In contrast to word recognition in quiet, participants' speech recognition in noise performance as measured binaurally in sound field showed a larger spread of performance abilities. The median number of words correctly recognized was 20 out of 60 (IQR 16-22), indicating that across the various SNRs participants recognized about 33% of the target words (see **Table 1**). Also shown in **Table 1** are the mean normalized threshold calculations based off the Spearman-Kärber equation [dB SNR Loss; (Killion et al., 2003)], with median of 6-dB SNR Loss (IQR 4-9), indicating that most participants needed between 4-9 dB SNR to correctly recognize 50% of the target words.

Figure 2 displays psychometric functions plotting speech recognition performance as a function of SNR from 25- to 0-dB. The left-side panel shows data from all participants while the right-side panel shows data stratified by study site. The median number of words correct varied by only 1 across study sites and recruitment routes. With no difference in median SNR-values across recruitment routes, it is not surprising that there were no statistically significant differences (see **Supplemental Table S3**). As with Word Recognition in Quiet, there was a statistically significant relation to study site ($\chi^2(1) =$

12.554, p = .006) and, again, the largest pair-wise significant difference in SNR Loss was between the participants from the Jackson, MS and Washington, MD sites. The magnitude of the difference was again relatively small at only 1.4 dB and unclear if clinically meaningful (Killion et al., 2003; McShefferty et al., 2015). The critical difference while using two QuickSIN lists is +/- 2.7-dB SNR (95% confidence interval; Killion et al., 2003), but it is appreciated that small changes in SNR can be perceived as large differences by individual listeners (McShefferty et al., 2015).

--- Enter Figure 2 about here----

Self-reported Hearing Handicap

Table 1 displays the results for the single-item self-reported hearing difficulty question and total HHIE-S scores. Examining of the data for the single-item self-report question, most participants reported either 'A Little Trouble' (42%) or 'Moderate Trouble' (36%) on the 6-point Likert scale, while only 12% reported 'Excellent/Good' hearing and 10% reported 'A Lot of Trouble/Deaf". Given these data, perhaps the results of the HHIE-S are not surprising, in that scores for 31% of the participants resulted in a classification of "No Handicap", while 50% had a "Mild-Moderate Handicap, and 18% were categorized as having a "Severe Handicap". Further, the median HHIE scores increased systematically as greater degrees of difficulty hearing were reported on the single question item (**Supplemental Figure SF2**).

The median HHIE-S score was 14 [IQR: 8-22], indicating that the average participant was classified as having a mild-moderate handicap. The median total score across sites ranged from 12 to 18

and the recruitment route medians differed by 6 points. Since self-reported hearing across sites (χ^2 (9) = 24.843, p < .001) and recruitment route (χ^2 (3) = 24.843, p < .001) reached statistical significance, logistic regression was used to assess differences by site and recruitment method. To further examine the data comparisons of frequencies were done using contrasts of the coefficients which revealed a significant difference between the Jackson, MS site which had the highest proportion of participants reporting "A Lot of Trouble/Deaf" (16%) and the Minneapolis MN site in which only 4% of the participants reported this level of difficulty. Similarly, the Kruskal-Wallis analysis revealed that study site was significantly associated with HHIE-S scores (χ^2 (3) = 14.844, p =.002). Several pair-wise comparisons were found to be statistically different for the HHIE-S scores, with the greatest hearing handicap observed for the Jackson, MS participants and the least for the Minneapolis, MN participants, consistent with the results for the single item question about hearing difficulty.

Finally, in contrast to the objective audiological results presented above for recruitment route comparisons, the results of statistical analyses were significantly associated with both the single item question of hearing difficulty (χ^2 (3) = 24.843, p < .001) and the HHIE-S score (χ^2 (1 = 37.881, p < .001). A larger proportion of the *de novo* participants indicated greater hearing difficulty and were categorized as having greater hearing handicap than the ARIC recruited participants. For example, only 27% of the *de novo* participants were classified as having "no hearing handicap" while 45% of ARIC participants' HHIE-S scores were classified as having "no hearing handicap". Similarly, a greater proportion of *de novo* participants reported having "A Lot of Trouble/Deaf" (11.5%) than did those recruited from ARIC (5.9%). In contrast, only 9% recruited *de novo* reported "Good/Excellent" hearing as compared to 20% of those recruited via ARIC.

Relationships among Audiological Variables

Relationships between the audiological variables (i.e., PTA-Better Ear, PTA-Poorer Ear, Word Recognition-Better Ear, Word Recognition-Poorer Ear, HHIE-S, and SNR-Loss) were examined using Spearman-Rho analyses**.** **Figure 3** displays scatter plots of the data and the results of the correlations. Not surprisingly, given our relatively large sample size, all relationships reached statistical significance ($p < 0.001$). Thus we focus on the strength of the relationships, with reference to Cohen's effect size descriptors (Cohen, 2013), where $r \geq .50$ is considered large, $\geq .20$, is medium, and $\geq .10$ is a small effect, and with consideration of the confidence intervals for each statistic and the direction of the relationships (also displayed on Figure 3).

Given that most of the hearing losses, as measured via pure tone audiometry, were noted to be symmetrical, it is not surprising that the strongest relationship between variables was between the PTAs for the better and poorer ears [$r = .83$, 95% CI, .79, .86]. The only other large effect size with PTA-Better Ear was with SNR-Loss [$r = .56$, 95% CI, .51, .60] with, as expected, the greater the hearing loss (i.e., the higher PTA) the poorer speech understanding in noise (i.e., the greater SNR Loss). Effect sizes are considered medium for the relationships between all other variables and PTA-Better Ear with 95% confidence intervals supporting a conclusion of a medium effect, with the direction of all relationships as expected. The correlation between poorer-ear PTA and SNR loss was medium to large ($r = .51$, 95% CI: .46, .56). The direction of the relationship however is as expected with those with greater PTA losses in the poorer ear having poorer speech recognition in noise performance. The correlation between poorer-ear PTA and word recognition in the poorer-ear was medium to large ($r = -.45$, 95% CI: -.50, -.39). Point estimates and confidence intervals for the relationships between PTA-Poorer Ear, Word Recognition-Better and HHIE-S scores revealed medium effect sizes.

The relationship between Word Recognition-Better and Poorer Ear was also found to have a medium effect size [$r = .34$, 95% CI, .28, .39]. Similarly, the relationships between Word Recognition-

Better Ear and SNR-Loss [r = -.33, 95% CI, -.38, -.26] and Word Recognition-Poorer Ear and SNR-Loss [r = -.33, 95% CI, -.39, -.27] reflect medium effects with poorer monaural speech recognition in quiet reflective of poorer binaural speech recognition in noise. Interestingly, but perhaps not surprising given clinical experience the weakest relationships were found between word recognition in quiet for better and poorer ears and self-report of hearing handicap with HHIE-S (r = -.12, r = -19, respectively). In fact, the 95% confidence interval (-0.18, -.05) for Word Recognition-Better Ear and HHIE-S suggest that the true effect size may be negligible. While the point estimate for the relationship between HHIE-S and SNR-Loss was classified also as a medium effect, the confidence intervals suggest a stronger association [r = .25, 95% CI, .19, .31] than the relationships between the self-report measure and objective speech recognition performance in quiet.

----Enter Figure 3 About here ---

Discussion

A growing amount of evidence describes the association between hearing and cognition (Dawes et al., 2015; Golub et al., 2020; Liang et al., 2021; Lin, 2011; Livingston et al., 2020; Livingston et al., 2017; Merten et al., 2020; West et al., 2022). Some of this evidence has included subjective hearing measurements and/or objective hearing measurements, yet very few have reported on a thorough comprehensive hearing evaluations in conjunction with measures of cognition. Although we report here a study population that was restricted by our selected inclusion exclusion criteria, we provide extensive detail on how our data were collected as such detail is often lacking in studies examining the relationship between hearing loss and cognition (Loughrey, 2022; Marinelli et al., 2022).

Baseline data from large-scale clinical trials such as the ACHIEVE Study are crucial for evaluating the validity and outcomes of a trial. Findings from systematic reviews of studies examining the relationship between hearing intervention and cognition call for increased rigor in the collection and reporting of hearing-related data. For example, Loughry, Kelly et al (2018) found only 36 studies in which hearing loss was objectively assessed, and these studies used varying definitions of the objectively measured hearing loss such as a single-frequency threshold, monaural or binaural calculations of loss, and reports of thresholds for either the better or poorer ear. Sanders et al (2021) identified 17 longitudinal studies, including 3526 participants which spanned over 30 years of research in which both audiometrically defined hearing loss and cognition were measured. The degree of hearing losses reported in included studies was similar to those in the ACHIEVE study (mild to moderate SNHL), but there was a lack of rigorous reporting regarding how hearing measurements were completed and how the audiological data were presented. Finally, the authors concluded that the effect of hearing intervention on cognition was equivocal, with the need for well-conducted, rigorous clinical trials, such as the ACHIEVE study, to fully understand these relationships. A more recent systematic review by Yeo et al (2022) reported meta-analytic results from 31 observational studies indicating a decreased risk of cognitive decline from the use of hearing aids and cochlear implants. However, the detailed objective and subjective audiological data were not included in all reviewed studies.

The work presented here provides comprehensive information about the baseline hearing characteristics of the ACHIEVE study participants and the rigorous methods used to collect these data. Our findings were consistent with what is known clinically and in the literature. The ACHIEVE participants had mild to moderate hearing loss, aligning with the WHO estimation of debilitating hearing loss among older adults (World Health Organization, 2021). The audiological profiles of the ACHIEVE participants are similar to large population-based reports (Humes, 2023; Reed et al., 2023). The degree

of trouble listening in background noise, measured with the QuickSIN test, was consistent with similar patient populations, including community-dwelling adults and Veterans (McArdle & Wilson, 2006; Ou & Wetmore, 2020; Ross et al., 2021; Wilson et al., 2007). It was interesting to see statistically significant difference in speech-noise performance across sites, which may be clinically meaningful and warrant future analyses including multivariable modeling to determine the influence of non-auditory variables (e.g., social determinants of health). Most participants had "A Little" to "Moderate" trouble hearing and had HHIE-S scores indicating more than a mild-moderate handicap.

Associations between audiologic characteristics and self-reported hearing were consistent in direction and magnitude with expectations and with other reports including participants with similar degrees of hearing loss evaluated with similar measures (Cassarly et al., 2019; Humes, 2023). In future analyses, we plan to evaluate if there are any site and recruitment route differences in the correlations between objective measures and self-reported measures. This may be informative and help disentangle the potential site and recruitment differences and inform future study outcome analyses. As of now, our results highlight the benefit of including both measured hearing performance (i.e., pure-tone and speech audiometry) and self-report assessments for the characterization of hearing loss in older adults, which is also consistent with other reports (Humes, 2019), as both objective and subjective measurements are needed to fully understand the influence of hearing loss (Humes, 2023). In sum, objective and subjective baseline audiological characteristics of ACHIEVE study participants align clinically with what would be expected in older adults meeting study inclusion criteria and with the literature.

Our study had limitations in that subjective hearing results from the ARIC participant group may not generalize to all adults seeking hearing health care. ARIC participants have a long history of volunteering for research and may have agreed to participate even though they did not perceive a hearing loss, while it is possible that *de novo* participants volunteered for a study with a hearing

intervention arm because of self-perceived hearing problems. In addition, because of our long-standing history with ARIC participants, objective hearing loss status was known, so we specifically sought them out to participate in this study. This is unlike the *de novo* participants that presented to the study only after seeing recruitment advertisements. The observation of differences in self-report measures of hearing difficulty and hearing handicap based on recruitment route were not anticipated beforehand; but, also not surprising and similar to other reports that evaluated self-reported hearing ability between those seeking or not seeking hearing heathcare (Humes & Dubno, 2021). Future studies may benefit from inclusion of qualitative data to elucidate motivations for participating in studies such as the ACHIEVE Study. Within the ACHIEVE dataset it will be of interest to determine if there are other non-audiological variables that may influence analyses and interpretations.

We consider that the most likely reason there are site differences observed in our analysis is due to having large sample sizes, as the effect sizes were small and most of the post hoc analyses did not reveal any clinically meaningful differences, at least for the objective data. It is well known that large sample sizes can influence statistical findings (Khalilzadeh & Tasci, 2017), and it is important to note that a p-value does not provide any information on the magnitude of the effect and the clinical meaningfulness. Thus, while we reviewed the statistical analyses, we commented on the effect sizes and clinically meaningful differences. Although we suggest that most differences are likely explained by larger sample sizes, we also acknowledge differences could have been due to procedures being conducted differently across sites, as ensuring precision in methods across many sites is very challenging. We consider this highly unlikely considering the extensive quality assurance and quality control protocol designed for the ACHIEVE Study. As described in detail elsewhere (Arnold et al., 2021), the comprehensive audiological evaluation was completed by licensed, nationally certified audiologists who completed training in ACHIEVE hearing related protocol administration and

audiological procedures were monitored through direct observation and validating data entry. Alternatively, it is also possible that the differences observed are true differences and may be related to variables not considered in the current analyses. We acknowledge that are known geographic, socio-economic, sex-related differences, and many other social determinants of health that can influence audiometric profiles. It will be important to consider these variables in subsequent analyses.

Even with potential limitations in mind, knowing the baseline characteristics of the ACHIEVE Study participants, the results reported here allows clinicians to assess how closely the participants match to the patients seen in their own practice, and therefore, they will be important for generalizability or external validity of the trial. The audiologic characteristics of the ACHIEVE Study participants are appropriate for the hearing intervention designed for the trial (Sanchez et al., 2020). With the majority of the participants presenting with moderate hearing loss, word recognition in quiet performance greater than 60% in at least one ear, mild/moderate difficulty hearing speech in the presence of background noise, and moderate self-reported hearing handicap, the technical aspects of the treatment such as ear-level worn hearing aids with connective applications to additional hearing assistive devices are known to sufficiently meet the needs of these audiometric characteristics. While it is not within the scope of this manuscript to directly evaluate the appropriateness of the hearing intervention for a population with these hearing characteristics, future analyses will address these questions once the outcomes data are unblinded and available. Primary outcome results were recently released (Lin et al., 2023), with several additional outcomes and analyses expected to follow. It is noteworthy to share we've extended the original study to conduct long-term follow-up. The ACHIEVE Brain Health Follow-Up Study (Clinicaltrials.gov Identifier: NCT05532657) will continue following the ACHIEVE cohort for an additional 3 years (i.e., 6 years total) after randomization to determine the long-term effects of hearing intervention on brain health.

The National Institutes of Health requires sharing of scientific data to accelerate biomedical research discovery, enhance research rigor and reproducibility, and promote data reuse for future research studies. Our dataset will be publicly available for the scientific community and the details we provide here may be useful as a template for the level of detail that should be reported in future studies evaluating the effect of hearing intervention on cognition. These data will also be important for reference when the ACHIEVE main trial results are reported to contextualize the trial's major findings.

Conclusion

We present a thorough overview of the baseline audiological characteristics from enrolled ACHIEVE Study participants. These participants were followed for three years with final study visits occurring in late 2022. The baseline audiometric and hearing-related self-report characteristics of the ACHIEVE participants will help to inform the planned analyses and serves as one of several descriptive, genre-specific baseline papers, intended to offer deep complementary information for interpreting the outcome results. We provide a thorough review of the audiologic results from a novel randomized trial that will be used to inform the findings on the association between hearing loss and cognitive decline.

Figure Legends

Figure 1. Air-conduction pure-tone threshold violin plot for the better and poorer ear. The violin plot depicts the distributions of data using density curves with the width of the curve corresponding with the approximate frequency of data points in each region. Our density curves are overlaid on box plots that depict numerical summaries of the data, with a central line marking the median value, the box denoting the 75^{th} and 25^{th} percentiles, lines extending showing the upper and lower fences of the data, and all observations outside the upper and lower fences are plotted individually.

Figure 2 a,b. Speech-in-Noise Psychometric function performance. Left panel shows all participants, while the right panel show functions per study site.

Figure 3. Correlation Matrix showing relationship among the audiologic variables. The correlations are Spearman's Rho, a rank-based correlation, with statistical significance indicated with asterisks (*) and 95% confidence intervals shown in brackets. Also shown are the scatter plots comparing audiologic data. NOTE: PTA: B = PTA of the Better Ear; QS: SNR L = Quick SIN SNR Loss; WR:P = Word Recognition of the Poorer Ear; WR:B = Word Recognition of the Better Ear; and, PTA: P is the PTA of the Poorer Ear.

687 **Author Contributions:**

Contributor Role	Role Definition	Authors
Conceptualization	Ideas; formulation or evolution of overarching research goals and aims.	VAS, MLA, THC, ACE, FRL, NSR
Data curation	Management activities to annotate (produce metadata), scrub data and maintain research data (including software code, where it is necessary for interpreting the data itself) for initial use and later re-use.	VAS, MLA, HNN, JFB, SF, AMG, CMM, ARH,
Formal analysis	Application of statistical, mathematical, computational, or other formal techniques to analyze or synthesize study data.	MLA, VAS, JFB, THC, JRP
Funding acquisition	Acquisition of the financial support for the project leading to this publication.	FRL, THC, VAS, KMH, JC, JP, TM
Investigation	Conducting a research and investigation process, specifically performing the experiments, or data/evidence collection.	SF, EA, JH, KH, LS, KT, KW, KMH, JC, JP, TM, JAS, JAD, NWG,
Methodology	Development or design of methodology; creation of models.	VAS, MLA, THC, FRL, NSR, SF, JFB, HNN
Project administration	Management and coordination responsibility for the research activity planning and execution.	HNN, CMM, AMG, ARH, SF, VAS, MLA, THC, LS
Resources	Provision of study materials, reagents, materials, patients, laboratory samples, animals, instrumentation, computing resources, or other analysis tools.	MLA, HNN, CMM, AMG, VAS, JFB, THC, NSR, FRL, KMH, JC, JP, TM, JAS, JAD, NWG,
Software	Programming, software development; designing computer programs; implementation of the computer code and supporting algorithms; testing of existing code components.	JFB, ARH

Supervision	Oversight and leadership responsibility for the research activity planning and execution, including mentorship external to the core team.	VAS, MLA, NSR, AMG, THC, FRL, KMH, JC, JP, TM, JAS, JAD,
Validation	Verification, whether as a part of the activity or separate, of the overall replication/reproducibility of results/experiments and other research outputs.	JFB, ARH, VAS, MLA, SF, HNN, THC
Visualization	Preparation, creation and/or presentation of the published work, specifically visualization/data presentation.	JFB, VAS, HNN, THC
Writing – original draft	Preparation, creation and/or presentation of the published work, specifically writing the initial draft (including substantive translation).	VAS, MLA, THC
Writing – review & editing	Preparation, creation and/or presentation of the published work by those from the original research group, specifically critical review, commentary or revision – including pre- or post-publication stages.	All Authors

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