1.a. Full Title: Determinants of Hours of Hearing Aid Usage

b. Abbreviated Title (Length 26 characters): Hours Hearing Aids

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3. Timeline:
Analysis and Manuscript will be completed in 8 months.

4. Rationale:
Hearing loss impacts two-thirds of adults over the age of 70 in the United States\textsuperscript{1,2}. Moreover, the prevalence of hearing impairment is projected to rise given the United States’ aging society\textsuperscript{1}. Recent studies have found associations with hearing impairment and negative health outcomes in older adults, including cognitive decline and dementia\textsuperscript{3-5}.

Hearing aids represent the gold standard and only treatment path for age-related, permanent hearing loss\textsuperscript{6}. Despite the high prevalence of hearing loss and associated negative health outcomes, hearing aid uptake is low (<20\%)\textsuperscript{7,8}. Previous studies have indicated that sociodemographic variables such as race and income are significant predictors of hearing aid ownership and self-reported use\textsuperscript{9}. Research also suggests that up to 40\% of older adults who possess hearing aids report that they do not use them citing poor benefit, negative side effects and cost of upkeep as primary reasons for non-adherence\textsuperscript{10,11}.

Investigations into predictors of hearing aid use have largely reported the outcome as binary, comparing users to non-users. There is a paucity of research that examines the degree of daily hearing aid use (hours/day) as an outcome. The limited research to date that has examined this outcome has primarily focused on aspects of hearing intervention rehabilitative counseling, hearing aid technology, and pre-fitting attitudes as predictors of usage\textsuperscript{12-14}. To our knowledge, there are no studies in the literature that present descriptive statistics of hours of hearing aid use in a population-based study and none that investigate individual determinants of hearing aid users that contribute to hours of use.

Healthcare utilization models such as the Andersen-Aday behavior model\textsuperscript{15}, categorize factors that predict the utilization of various care services into: 1) predisposing (e.g. age, sex, race, etc), 2) enabling (e.g. finances, education, employment, etc.), and 3) need (e.g. health status, degree of hearing loss, etc.) factors. The conceptual framework provided by this model can be used to guide our assessment of individual characteristics that may contribute to hours of daily hearing aid use.

Exploring characteristics associated with a more granular measure of hearing aid usage (i.e., hours) is crucial in the pursuit of improving the precision of hearing care. Clinical decision-making could take into account these factors to maximize cost-benefit of hearing care. A better understanding of these characteristics will assist public health efforts aiming to improve usage and benefit of rehabilitative hearing interventions.

This analysis will inform future analyses and studies from ARIC and ACHIEVE data.

5. **Main Hypothesis/Study Questions:**

We hypothesize that predisposing, enabling, and need characteristics will be associated with hours of hearing aid use. Our aims are:

**Aim 1:** To describe the descriptive hours of hearing aid use among ARIC participants

**Aim 2:** to describe the association of predisposing, enabling, and need characteristics with hours of hearing aid use

6. **Design and analysis (study design, inclusion/exclusion, outcome and other variables of interest with specific reference to the time of their collection, summary of data analysis, and any anticipated methodologic limitations or challenges if present).**

**Study Design:** Cross-sectional study of ARIC visit 6 participants who report hearing aid ownership
Outcomes:
Primary:
Self-reported hours of daily hearing aid use among ARIC participants who own hearing aids (HNE form), reported as average hours of daily use over the past 12-months. The HNE form was offered to all ARIC participants presenting at their clinic visit. Hours of hearing aid use will be analyzed as a dichotomous outcome with with 8 hours of daily use as a cut-off. Variable will be treated as a continuous variable and categorically based on clinically recommend daily hours of hearing aid use.

Exposure:
Exposure: In our analysis, Exposures will be categorized in to predisposing, enabling and need factors in accordance with the Anderson-Aday model of healthcare utilization.

Need Factors:
-Objective hearing ability: All ARIC Visit 6 Participants were offered hearing measures as part of their regular ARIC clinic visit. Pure tone air-conduction audiometry and speech perception testing were conducted in a sound-treated booth within a quiet room meeting ANSI standards. Pure tone audiometry is the gold-standard test to determine the faintest tones that a person can detect for a range of pitches. We will calculate a frequency pure tone average (PTA) across sound intensity thresholds of perception at 0.5, 1, 2, and 4 kHz in the better-hearing ear in accordance with the World Health Organization definition of hearing impairment. Hearing ability will be categorized in to three categories based on PTA in the better hearing ear (normal: <25 dB HL, mild: 26-40 dB HL, moderate or greater >40db HL) in line with clinical standards. We will also model PTA as a continuous variable.

-Signal to noise ratio (SNR) loss: All ARIC participants received a speech in noise perception test (QuickSIN). This test involves playing tracks of six sentences with five key words in each at varying SNR ratios to determine SNR loss.

-Subjective tinnitus assessment: As part of the HNE form, participants are asked the following question:
  • In the past 12 months, have you been bothered by ringing, roaring, or buzzing in your ears or head that lasts for 5 minutes or more?
    o Yes
    o No

-Hearing Handicap Inventory for the elderly (HHIE): 10-item questionnaire that seeks to roughly evaluate the impact of hearing impairment on an individual. Each item receives a score of 0,1 or 2 based on responses of no, sometimes or yes respectively.

Predisposing Factors:

-Age measured as a continuous variable
-Sex as a binary variable
-Race as a categorical variable

Enabling
Education level: Categorical variable with the following categories
- Less than high school
- High school
- More than high school

Marital Status modeled as a binary variable.

Marital Status modeled as a binary variable.

Combine family income: continuous outcome

Cognitive Status: Visit 6 global cognition score

Depressive symptoms: Visit 6 CES depression scale score. 20-item questionnaire that evaluates burden of depressive symptoms in individuals.

**Statistical analysis:** Descriptive statistics will be used to examine average hours of daily use among participants with hearing aids. Plots will be used to explore data distribution of the data. Multivariable linear and logistic regression will be used to estimate the association of daily hours of hearing aid use and various determinants (need, predisposing, enabling factors). Models will include all pre-determined determinants above (based on a framework of potential contributing factors). Depending on distributions, stratification may be used to explore outcomes (note: it is likely we will further stratify analyses by race [white and black] as we hypothesize based on previous experience that these groups are different in their distribution of outcome and exposure status). We will explore for possible statistical interactions by stratification and inclusion of interaction terms in the models. We acknowledge a priori that limited sample size (i.e., only those who own and use hearing aids) will limit statistical power to assess interactions and this analysis is exploratory in nature. Further, inference will have limited generalizability and relatively small sample size, but will add to the literature given the lack of studies quantifying determinants of hours of hearing aid use.

7.a. Will the data be used for non-CVD analysis in this manuscript? ____ Yes    _X___ No

b. If Yes, is the author aware that the file ICTDER03 must be used to exclude persons with a value RES_OTH = “CVD Research” for non-DNA analysis, and for DNA analysis RES_DNA = “CVD Research” would be used? _____ Yes   ____ No
   (This file ICTDER has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

N/A

8.a. Will the DNA data be used in this manuscript? ____ Yes    _X___ No

b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER03 must be used to exclude those with value RES_DNA = “No use/storage DNA”? _____ Yes   ____ No

N/A

9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to
the publications lists under the Study Members Area of the web site at: 
http://www.cscc.unc.edu/ARIC/search.php

_X____ Yes _______ No

10. What are the most related manuscript proposals in ARIC (authors are encouraged to contact lead authors of these proposals for comments on the new proposal or collaboration)?

Proposal 2327: Hearing impairment and cognitive performance in the Atherosclerosis Risk in Communities Neurocognitive Study (ARIC NCS): cross-sectional and longitudinal results

Proposal #2880 - A Randomized Pilot Trial of Hearing Treatment for Reducing Cognitive Decline: Results from the Aging, Cognition, and Hearing Evaluation in Elders Pilot (ACHEVE-P) Study

11.a. Is this manuscript proposal associated with any ARIC ancillary studies or use any ancillary study data? _____ Yes _X___ No

11.b. If yes, is the proposal

__ _ A. primarily the result of an ancillary study (list number* _________)
___ B. primarily based on ARIC data with ancillary data playing a minor role (usually control variables; list number(s)* _________ _________ _________)

*ancillary studies are listed by number at http://www.cscc.unc.edu/aric/forms/

12a. Manuscript preparation is expected to be completed in one to three years. If a manuscript is not submitted for ARIC review at the end of the 3-years from the date of the approval, the manuscript proposal will expire.

12b. The NIH instituted a Public Access Policy in April, 2008 which ensures that the public has access to the published results of NIH funded research. It is your responsibility to upload manuscripts to PubMed Central whenever the journal does not and be in compliance with this policy. Four files about the public access policy from http://publicaccess.nih.gov/ are posted in http://www.cscc.unc.edu/aric/index.php, under Publications, Policies & Forms. http://publicaccess.nih.gov/submit_process_journals.htm shows you which journals automatically upload articles to PubMed central.

13. Per Data Use Agreement Addendum, approved manuscripts using CMS data shall be submitted by the Coordinating Center to CMS for informational purposes prior to publication. Approved manuscripts should be sent to Pingping Wu at CC, at pingping_wu@unc.edu. I will be using CMS data in my manuscript _____ Yes _X___ No.
References


