ARIC Manuscript Proposal # 3112

PC Reviewed: 2/13/2018  Status: _____  Priority: 2
SC Reviewed: _________  Status: _____  Priority: ______

1.a. Full Title: Factors Predicting Speech-in-Noise Change: Results from the Aging, Cognition, and Hearing Evaluation in Elders Pilot (ACHIEVE-P) Study

b. Abbreviated Title (Length 26 characters): QuickSIN Change ACHIEVE-P

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I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. _NSR_____ [please confirm with your initials electronically or in writing]

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3. Timeline:
Manuscript will be completed in 2 months.

4. Rationale:
Hearing loss is highly prevalent among older adults, such that nearly two-thirds of adults over the age of 70 have a clinically significant hearing loss\textsuperscript{1,2}. Understanding speech-in-noise is a fundamental aspect of communication in the modern world and a common complaint among persons with hearing loss. However, the ability to understand speech in the presence of background noise deteriorates with age due to both peripheral and central changes in auditory processing\textsuperscript{3-6}. Peripherally, age-related hearing loss degrades the precise encoding of sound in the cochlea while, centrally, cognitive changes may affect the ability to interpret and process precise signals in the presence of auditory distractions\textsuperscript{4}.

Several studies have highlighted the impact of peripheral and central auditory, and cognitive factors on speech-in-noise understanding among those with hearing loss\textsuperscript{4-7}. Of these measures, cognitive factors have received significantly less attention\textsuperscript{4}. A review of the literature reveals that, often, cognitive measures used in speech-in-noise studies are overly simplistic and/or singular in nature (i.e. measure one specific process)\textsuperscript{6,7}. An area that has received even less attention is how amplification affects these relationships. Improving speech-in-noise understanding with hearing aids, assistive devices, and counseling is among the primary goals of audiologic intervention\textsuperscript{8}. However, the impact of hearing aid use on speech-in-noise understanding over time is understudied. Moreover, whether cognitive factors influence this relationship has never been studied.

The Aging, Cognition, and Hearing Evaluation in Elders Pilot (ACHIEVE-P) Study is a randomized pilot study of 40 cognitively intact older adults nested within the Atherosclerosis Risk in Communities (ARIC) Study. ACHIEVE-P was designed to test the feasibility of a best practices hearing intervention (vs. successful aging intervention) trial in older adults with audiometric hearing loss, and secondarily, to explore for an efficacy signal on 6-month proximal and cognitive outcomes. During the hearing intervention arm of the study, participants completed a baseline hearing and cognitive measures. Importantly, participants also completed the QuickSIN test (a measure of speech-in-noise understanding) at baseline as well as follow up tests at 2- and 6-months post hearing aid fitting.

Here we propose to leverage the robust cognitive measures in ACHIEVE-P to assess the association of hearing loss and cognition with baseline performance on the QuickSIN. Moreover, we propose to assess how these variables influence the change from unaided QuickSIN score to aided QuickSIN scores at 4- and 6-months post hearing aid fitting.

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

**Aim 1:** To explore the association of hearing loss and cognition on the baseline performance on QuickSIN measure

**Aim 2:** To quantify the association of hearing loss and cognition with change from unaided QuickSIN score to aided QuickSIN scores at 2- and 6-months post hearing aid fitting

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:** Within-subject analysis a 20-person cohort in the best-practices hearing intervention arm of a 40-person randomized controlled pilot trial of a best practices hearing intervention (vs. successful aging intervention) in older adults with hearing loss. The influence of pure-tone audiometry (hearing
loss) and cognition on the within-subject change in QuickSIN score at baseline and a 6-month follow-up session will be assessed.

**Study population:** ACHIEVE-P participants were recruited from ARIC participants in Washington County, MD, and de novo from surrounding communities. Eligibility criteria included: age 70-84 years, adult onset hearing loss [pure tone average (PTA) across 3 frequencies (0.5, 1, 2 kHz) ≥ 30 and <70 decibels hearing level (dB HL) in the better-hearing ear] without current hearing aid use, community-dwelling, fluent English speaker, plans to remain in the area, and free of cognitive impairment [Mini-Mental State Exam ≥ 23 if ≤ high-school degree and ≥ 25 if some college or more]. Exclusion criteria included: dementia diagnosis, self-reported difficulty in ≥ 2 activities of daily living, medical contraindication to hearing aid use, untreated conductive hearing loss, and unwillingness to regularly wear hearing aids.

**Interventions and randomization**
Participants were randomized 1:1 to the best practices hearing intervention or the successful aging intervention in blocks within strata defined by hearing loss severity, defined as mild (PTA ≥ 30 dB and < 40 dB) or moderate (PTA ≥ 40 dB and < 70 dB); field center staff were masked to block size.

Post-baseline and randomization, during 4 study visits with an audiologist over 10-12 weeks, participants in the best-practices hearing intervention received binaural hearing aids, rehabilitative counselling and were offered assistive listening devices.

**Outcomes** The QuickSIN® is a validated measure of speech-in-noise understanding. Participants repeat a set of 5-sentences in the presence background noise. The background noise increases in intensity with each sentence until it is the same presentation level as the last sentence. A measure of signal-to-noise ratio loss is calculated as the outcome measure based on the level of background noise at which the participant loses the ability to repeat sentences.

**Statistical analysis:** The association of hearing loss and cognition with baseline QuickSIN will be assessed using multivariable linear regression model adjusted for potential covariates including age, sex, and education. Estimates between baseline unaided QuickSIN and 6-month aided and hearing loss will be investigated using multivariable regression (adjusted for potential covariates including age, sex, education, and average daily hours of hearing aid usage). Given small sample size and pilot nature of this study, inferences from this study will be considered exploratory rather than as definite hypothesis-testing; p-values will be reported only as a guide for hypotheses for future studies.

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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  ____ No
8.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.cscce.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 #2880 - A Randomized Pilot Trial of Hearing Treatment for Reducing Cognitive Decline: Results from the Aging, Cognition, and Hearing Evaluation in Elders Pilot (ACHEIVE-P) Study

Proposal 2418: Hearing impairment and physical function in the Atherosclerosis Risk in Communities (ARIC) Hearing Pilot Study

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

Aging, Cognition, and Hearing Evaluation in Elders (ACHEIVE) Randomized Trial (PIs: Lin, Coresh)

11.b. If yes, is the proposal
___X___ A. primarily the result of an ancillary study (list number* __2016.03_______)
____ 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.cscce.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.cscce.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