ARIC Manuscript Proposal #H4106

PC Reviewed: 10/11/22 **Status: _____** **Priority: 2**
SC Reviewed: _____ **Status: _____** **Priority: ____**

1.a. Full Title: Patient-centered selection of the Hearing Intervention for the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) Randomized Controlled Trial

b. Abbreviated Title (Length 26 characters): ACHIEVE RCT: Hearing Intervention

2. Writing Group:
Writing group members: (Alphabetical; *Additional members welcome)

Michelle Arnold
Terry Chisolm
Allison Huang
Sarah Faucette
Nick Reed
Vicky Sanchez
For the ACHIEVE study group*

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

First author: **Victoria Sanchez**
Address: 12901 Bruce B. Downs Blvd., MDC 73; Tampa, FL 33612

Phone: 8134143491 Fax: n/a
E-mail: vasanchez@usf.edu

ARIC author to be contacted if there are questions about the manuscript and the first author does not respond or cannot be located (this must be an ARIC investigator).
Name: Nick S. Reed
Address: Cochlear Center for Hearing and Public Health; Johns Hopkins Bloomberg School of Public Health 2024 East Monument Street, Suite 2-700, Baltimore, MD, 21205
Phone: 410-502-4332 Fax: N/A
E-mail: nreed9@jhmi.edu

3. Timeline: Manuscript submitted within 6 months of approval. Targeting end of 2022.

4. Rationale:

Much attention has been paid to the development of evidence-based practice (EBP) for the management of hearing loss in adults (BSA, 2016; Valente et al., 2006). While such guidelines are useful, they do not provide the kind of structured intervention protocol that is needed in a large-scale multisite randomized controlled trial. Thus, we developed an evidence-based hearing intervention (Sanchez et al., 2020) for use in the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) multi-site clinical trial. ACHIEVE was designed to investigate whether hearing loss intervention vs. a health education control reduces the risk of cognitive decline and dementia in older adults [ClinicalTrials.gov Identifier: NCT03243422; for description of the trial protocol, see Deal et al. 2018]. The evidence-based elements of the ACHIEVE hearing intervention, which were provided in 4 sessions and delivered over an 8- to 10-week period of time following a comprehensive audiometric evaluation included: (a) the identification of individualized listening goals; (b) hearing aid technology selection and fitting to meet auditory needs and listening goals; (c) technological intervention using hearing assistive devices to meet individualized needs and listening goals; and, (d) orientation to hearing aid use, assistive device use, and educational counseling aimed at self-management of communication situations. The overarching goal of protocol was to provide optimal, individualized, evidence-based hearing intervention.

The implementation of the hearing intervention protocol across the four ACHIEVE clinical trial sites required the selection of differing levels of hearing aid technology to optimize the ability to meet participants' individual auditory needs. As occurs in real-world settings, three primary levels of hearing aid technology, which are typically described as *standard, advanced,* and *premium,* were utilized. These technology levels are differentiated based on the number of features that are included for manipulation, with more features allowing for greater device programming flexibility. While the level of hearing aid technology is a critical factor in hearing aid intervention, so too are the multitude of fitting decisions, such as selection of appropriate receiver strengths and dome sizes, to ensure that the individual auditory needs are met. Thus, the overarching auditory goals of any hearing aid fitting are: (a) to make soft sounds, especially those of speech, audible; (b) to ensure acceptable sound quality; (c) to prevent acoustic feedback: and (d) to prevent loud sounds from being uncomfortable. While in the ACHIEVE trial hearing aid fitting adjustments were made to meet the auditory needs of each individual participant, we also utilized hearing assistive devices, designed to improve: (a) hearing in noise, (b) hearing at a distance: and/or (c) hearing the television and/or on the telephone. There were 8 different hearing assistive technologies utilized which varied in terms of their technological sophistication. Assistive devices were selected to optimize technological aspects of the hearing intervention based on individual non-auditory characteristics as well as auditory needs and individualized listening goals.

Prior to examining the outcomes of the ACHIEVE clinical trial it is relevant to examine the technologies selected for the participants and the relation of those technologies to demographic characteristics, audiological profiles, and participants' listening goals. Thus, this manuscript will provide descriptive baseline data about select demographic characteristics, audiological profiles,

and listening goals for the ACHIEVE participants randomized to the hearing intervention. We will additionally describe hearing device data, including hearing aid technology levels, receiver and dome types, and assistive devices provided to hearing intervention arm participants. Specifically, we will examine relationships between select demographic and audiometric variables, speech understanding in noise, self-report of hearing disability/handicap and category of individualized listening goals with the levels of technology and the hearing assistive devices utilized by the participants. The information obtained will help us to determine whether we were successful in the goal of our protocol of providing optimal, evidence-based best practices intervention to the participants in the hearing intervention arm of the ACHIEVE clinical trial.

References

British Society of Audiology. (2016). Common Principles of Rehabilitation for Adults in Audiology Services. British Society of Audiology

Deal, J. A., Goman, A. M., Albert, M. S., et al. (2018). Hearing treatment for reducing cognitive decline: Design and methods of the Aging and Cognitive Health Evaluation in Elders randomized controlled trial. Alzheimers Dement (N Y), 4, 499–507.

Sanchez, V. A., Arnold, M. L., Reed, N. S., Oree, P. H., Matthews, C. R., Clock Eddins, A., Lin, F. R., & Chisolm, T. H. (2020). The Hearing Intervention for the Aging and Cognitive Health Evaluation in Elders Randomized Control Trial: Manualization and Feasibility Study. Ear & Hearing, 41(5),1333–1348.

Valente M, Abrams H, Benson D, Chisolm T, Citron D, Hampton D. 2006; Guidelines for the audiological management of adult hearing impairment. Audiol Today 18: 32-36.

5. Main Hypothesis/Study Questions:

The primary aim of this paper is to describe hearing device (hearing aids; assistive devices) technology selection and provision for participants randomized to a comprehensive hearing intervention in a large, multisite randomized clinical trial.

A secondary analysis will explore how hearing device technology needs vary based on sociodemographic factors (e.g., age, race, sex, study site) and hearing-related factors (e.g., audiometric variables, speech-perception in noise, self-perceived hearing disability/handicap, communication goals) and what interactions between sociodemographic and audiometric factors impact hearing device technology selection.

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).

Design: Cross-Sectional

Participants: All participants who are enrolled and randomized in the ACHIEVE hearing intervention arm

Inclusion/Exclusion: Participants randomized to the hearing intervention arm and completed the first hearing aid fitting session will be included.

Outcome: Provision of hearing device technology as defined as:

1. Hearing aid type and technology level
2. Hearing assistive devices type

Exposure/Covariates: Outcomes will be presented by the following variables:

1. Baseline demographic variables
    a. Gender
    b. Age
    c. Education level
    d. Significant communication partner participant
2. Audiometric Data
    a. Degree of hearing loss defined by pure tone threshold average (Better Ear; Poorer Ear; Right Ear, Left Ear)
    b. Word recognition in quiet
    c. Speech understanding in noise (QuickSIN)
    d. Hearing Handicap Inventory for the Elderly -Screening version baseline scores
    e. Client Oriented Scale of Improvement (COSI) baseline scores and goal category frequencies

Analysis:

1. Descriptive statistics (means, medians, frequencies, measures of variability when applicable) will be used to describe the provision of hearing device technology by the covariates listed above
2. Secondary analysis will explore the intersection of audiometric factors and sociodemographic factors by describing the provision of hearing device technology by audiometric variables stratified by sociodemographic variables.

a. Relationships between audiometric data, speech recognition in quiet and noise data, self-reported hearing disability/handicap data individualized COSI goals baseline scores as a function of categories and technology intervention options of level of hearing aid technology and assistive devices, utilizing appropriate parametric and non-parametric techniques will be presented.

b. Multinominal logit regression analyses will be conducted to determine if predictors of level of technology and hearing assistive technologies selected can be identified.

7.a. Will the data be used for non-ARIC analysis or by a for-profit organization in this manuscript? ____ Yes _X___ No

b. If Yes, is the author aware that the current derived consent file ICTDER05 must be used to exclude persons with a value RES_OTH and/or RES_DNA = "ARIC only" and/or "Not for Profit" ? ____ Yes ____ No
(The file ICTDER has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

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

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the current derived consent file ICTDER05 must be used to exclude those with value RES_DNA = "No use/storage DNA"? ____ Yes ____ No

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/mantrack/maintain/search/dtSearch.html

__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)?

- # H3579 – Arnold et al., Development, assessment, and monitoring of audiologic treatment fidelity in the Aging, Cognition, and Health Evaluation in Elders (ACHIEVE) randomized controlled clinical trial
    - Michelle L. Arnold, William Haley, Frank R. Lin, Sarah Faucette, Laura Sherry, Kaila Higuchi, Kerry Witherell, Elizabeth Anderson, Nicholas S. Reed, Theresa H. Chisolm & Victoria A. Sanchez (2021) Development, assessment, and

monitoring of audiologic treatment fidelity in the aging and cognitive health evaluation in elders (ACHIEVE) randomised controlled trial, International Journal of Audiology, DOI: 10.1080/14992027.2021.1973126

#2880 – Deal et al. A Randomized Pilot Trial of Hearing Treatment for Reducing Cognitive Decline: Results from the Aging, Cognition, and Hearing Evaluation in Elders Pilot (ACHIEVE-P) Study

#H3556 – Reed et al. The Aging and Cognitive Health Evaluation in Elders (ACHIEVE) trial: Recruitment and baseline data of a randomized trial of hearing treatment for reducing cognitive decline

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

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 https://sites.cscc.unc.edu/aric/approved-ancillary-studies

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.