ARIC Manuscript Proposal #3025

1.a. Full Title: Association of hearing loss and physical, social, and mental activities: Results from the Aging, Cognition, and Hearing Evaluation in Elders Pilot (ACHIEVE-P) Study

b. Abbreviated Title (Length 26 characters): Hearing loss and CHAMPS

2.   Writing Group (alphabetical):
Josh Betz
Jennifer Deal (second senior author)
Tess Gao (joint first author)
Adele Goman (joint first author)
Nicholas Reed
Frank Lin (senior author)

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

First author: **Adele Goman**
        Address:
                2024 East Monument Street, Suite 2-700, Baltimore, MD, 21205

                Phone: 410-287-7195   Fax: N/A
                E-mail: agoman1@jhmi.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: **Frank R. Lin**
        Address:
                2024 East Monument Street, Suite 2-700, Baltimore, MD, 21205

                Phone: 410-502-0150   Fax: N/A
                E-mail: flin1@jhmi.edu

3.   Timeline:
Manuscript will be completed in 1 month.

4.   Rationale:
Hearing loss is highly prevalent among older adults, affecting nearly two-thirds of adults over the age of 70[1,2]. A growing body of evidence has found independent associations between hearing loss and accelerated cognitive decline[3,4], increased risk of falls[5,6], greater hospitalizations[7], and poorer physical

functioning[8–10]. Hypothesized mechanistic pathways underlying the association between hearing loss and physical functioning include the effects of distorted peripheral encoding of sound on cognitive load, social isolation, and/or reduced awareness of the auditory environment[8]. Importantly, these pathways may be modifiable with hearing loss treatment. However, hearing loss treatment remains vastly underutilized with less than 20% of adults with a hearing loss using a hearing aid[11].

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. As part of the present proposal, we will present the results of self-reported activities of older adults who participated in the ACHIEVE-P Study. Self-reported activity was measured with the Community Healthy Activities Model Program for Seniors (CHAMPS)[12], which is a self-reported 41-item questionnaire that assesses levels of physical, social, and mental activities in older adults.

Here we propose to assess firstly, a cross-sectional relationship between hearing loss and physical, mental, and social activity and; secondly asses for an early efficacy signal of the best-practices hearing intervention on physical, mental, and social activity levels gathered 6 months post-intervention.

5.   **Main Hypothesis/Study Questions**:
Aim 1: To quantify the cross-sectional association between hearing and self-reported physical, mental, and social activity.

Aim 2: To quantify the difference in 6-month change in self-reported physical, mental, and social activities in the best practice hearing intervention group and the successful aging intervention group.

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 analysis within a feasibility study of a 40-person randomized controlled pilot trial of a best practices hearing intervention (vs. successful aging intervention) in older adults with hearing loss. Additionally, within-subject changes in self-reported activity levels between baseline and a 6-month follow-up session will be assessed. Between-subject differences in mean change between baseline and 6-month follow up 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[13], medical contraindication to hearing aid use, untreatable 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 ≥ 30dB and < 40dB) or moderate (PTA ≥40 dB and < 70db); 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.

Post-baseline and randomization, participants in the successful aging intervention met with a research nurse for 4 study visits over 10-12 weeks. The intervention followed the protocol and materials developed for the 10 Keys™ to Healthy Aging[15], an evidence-based, interactive health education program for older adults. Each session focused on a "Key" chosen by the participant.

Outcomes The Community Healthy Activities Model Program for Seniors (CHAMPS)[12] is a self-reported 41-item questionnaire that assesses levels of physical, social, and mental activities in older adults. CHAMPS assesses the frequency and duration of various activities over a 4 week time span. Physical activities include, among others, dancing, tennis, walking, and swimming. Social activities include, among others, visiting with family/friends, attending club/group meetings, and going to a senior center. Mental activities include, among others, using a computer, playing a musical instrument, and reading.

Statistical analysis: Associations between baseline activity and hearing loss will be investigated using linear regression (both unadjusted and adjusted for potential covariates including age, sex, and education). Independent t-tests will examine the difference in activity levels between the two intervention groups. Paired-samples t-tests will assess within-subject change from baseline to 6-months.

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

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.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 #2880 - 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

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 (ACHIEVE) 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.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.

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