ARIC Manuscript Proposal #4280

PC Reviewed: 6/13/23	**Status: _____**	**Priority: 2**
SC Reviewed: _____	**Status: _____**	**Priority: ____**

1.a. Full Title:
Association of a hearing intervention with objectively measured physical activity in older adults: results from the ACHIEVE trial**.**

b. Abbreviated Title (Length 26 characters): Hearing intervention and physical activity

2. Writing Group:
Writing group members:

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

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3. Timeline:

Proposal timeline	June 2023	July-August	September-October
Proposal approval	X		
Data Analysis		X	
Manuscript preparation and submission			X

4. Rationale:

It is estimated that older adults experience a 1-3% decline in physical activity per year (Wanigatunga 2022), which may hasten declines in physical and cognitive functioning with age. Hearing impairment is widespread in older adults, and is associated with lower levels of physical activity, physical functioning, and mobility limitations (Lin 2011; Gispen 2014; Martinez Amezcua 2021), but whether hearing loss treatment can reduce declines in physical activity is unknown. To date, much of the research on hearing loss and physical activity has relied mainly on measures of self-report, which may not adequately capture subtle but important changes in daily activity engagement and may be biased by problems with recall, particularly in older adults (Martinez-Amezcua 2022; Schrack 2016). Objectively measured physical activity using accelerometers provides the opportunity to capture physical activity quantities and patterns in greater detail than questionnaires, but their use in older adults with hearing impairment has been limited. Gipsen and colleagues (2014) examined the relationship between hearing impairment and accelerometer-derived physical activity in adults aged 70 and older participating in the National Health and Nutrition Examination Survey, but focused solely on time spent in moderate and vigorous activities per week, which is not scaled to relative capacity and excludes time spent in lighter intensity activities related to daily living (Schrack, 2014; Schrack 2019). Novel metrics of physical activity patterns and intensity, such as activity fragmentation, activity variability, and diurnal patterns of physical activity, have been linked with measures of physical function and mortality in older adults, over and above traditional measures of total volume and intensity of daily physical activity (Schrack 2014; Schrack 2019; Wanigatunga 2019). In addition, information on timing and variability of daily activities, such as activity peak and nadir (Schrack 2014; Wanigatunga 2019), may provide novel insights into the relationship between hearing impairment and physical activity in older adults.

5. Main Hypothesis/Study Questions:

Study Question:

To determine the association between a hearing intervention, versus a successful aging health education control intervention, and objectively measured physical activity in 70-84 year-old well-functioning adults with hearing loss.

Main Hypotheses:

Hearing intervention (versus successful aging health education control) reduces physical activity decline among older adults with hearing loss over three years of follow-up.

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: Randomized trial of 977 participants enrolled in the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) trial from 2018-2019 and followed for 3 years. Participants were from four U.S. sites (Forsyth County, NC; Jackson, MS; Minneapolis, MN; Washington County, MD). There were 238 participants recruited from the ongoing Atherosclerosis Risk in Communities Neurocognitive (ARIC-NCS) Study, and the remaining 739 participants were recruited de novo from the community.

Inclusion/exclusion criteria: All eligible participants enrolled at baseline in the ACHIEVE study.

- Inclusion criteria: 1) age 70-84 years, 2) community-dwelling adults, 3) mild-to-moderate audiometric hearing impairment, defined as a better-hearing ear pure tone average (PTA) ≥30 and <70 dB hearing level (Deal et al., 2018), 4) MMSE ≥23 for those with high school degree or less, and ≥25 for those with some college education or more, 5) Word Recognition in Quiet score ≥60% correct in the better-hearing ear, 6) fluent English-speaker, 7) plan to remain in the area during the study period, 8) agree to wear the Actigraph accelerometer for 24 hours/day for 7 days after their baseline and 3-year study visits.

- Exclusion criteria: 1) self-reported difficulty in ≥2 activities of daily living, 2) prior dementia diagnosis, 3) vision impairment, 4) medical contraindication to hearing treatment, 5) untreatable conductive hearing impairment, 6) unwillingness to regularly wear hearing aids, 7) self-reported hearing aid use in the past year, 8) refusal to wear the accelerometer after the baseline or 3-year study visit.

Outcome Variables

The primary outcome is objectively measured physical activity. Physical activity will be examined across measures of volume (total activity counts, active minutes per day, number of active bouts per day), intensity (max activity in 10 consecutive minutes, max activity in 30 consecutive minutes), and activity patterns (average bout length, active-to-sedentary transition probability, sedentary-to-active transition probability, diurnal patterns of daily activity) and variability (between- and within-day activity variability).

Exposure Variables

Intervention group (hearing intervention vs. successful aging education) assigned at baseline randomization

Other Variables

The primary analysis may include adjustments for the baseline hearing loss, ARIC vs de novo status, center, age (years), sex (male/female), education (less than high school/ high school or equivalent/ greater than high school), and gait speed.

Analytic Plan

We will examine trends in physical activity from baseline to three years within each activity variable using mixed effects models that account for the correlation among repeated measures as well as the correlation between spouses or cohabitating partners. If a linear trend appears reasonable, we will fit a model with a linear slope. If a nonlinear trend is observed, the model will be adapted to include time splines. Continuous time in years from baseline will be the time scale. An interaction term between treatment assignment and time will be used to test if trends in physical activity differ by treatment assignment. We will also explore stratification by baseline physical activity level (high, medium, and low) to gauge whether the hearing intervention was differential across habitual activity levels. Model fit will be assessed with residual plots and other statistics (Akaike Information Criterion, Bayesian Information Criterion, etc.). The primary analysis may include adjustments for the baseline hearing loss, ARIC vs de novo status, center, age, sex, education, and gait speed. Diurnal patterns of activity will be examined using 4-6 hour time bins and as a continuous curve using function-on-scalar regression. We will also explore complier average causal effect (CACE) analyses to aid in comparing the results to those reported in observational studies.

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)?

The main results of the ACHIEVE trial

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.

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