**ARIC Manuscript Proposal #H4351**

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| **PC Reviewed: 10/24/23** | **Status: _____** | **Priority: 2** |
| **SC Reviewed: _____** | **Status: _____** | **Priority: ____** |

**1.a. Full Title**:

Effects of Hearing Intervention with Hearing Aids on Self-reported Physical Activity: Findings from the ACHIEVE Study

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

**2. Writing Group**:
Writing group members: Order of coauthors TBD.

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

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## 3. Timeline:

Analyses, preparation, and submission of manuscript to be completed within 6 months.

## 4. Rationale:

A large body of evidence has shown numerous health benefits of regular engagement in leisure-time moderate to vigorous intensity physical activity (MVPA) for older adults, including reduced risk of falls and better physical functioning.[1] Based on the U.S. Department of Health and Human Services' 2018 Physical Activity Guidelines for Americans,[2] sufficient physical activity is defined as "engaging in at least 150 minutes of moderate physical activity (MPA) per week, or 75 minutes of vigorous activities (VPA), or an equivalent combination of MVPA (where 1 minute of VPA=2 minutes of MPA)." Hearing loss is highly prevalent among older adults,[3] and is associated with lower levels of physical activity and poorer physical function.[4–6] However, it is unclear whether treating older adults with hearing loss affects physical activity levels. Previous cross-sectional studies have looked at hearing loss and physical activity, defining the latter as meeting the abovementioned physical activity guidelines. One study by Gispen, et al. found that moderate or greater hearing loss was associated with lower physical activity (higher odds of being in a lower category of activity compared to no hearing loss), but did not find that self-reported hearing aid use modified this association.[7] Another study by Choi, et al. similarly found an association between hearing loss and lower physical activity among older adults,[8] but a study by Loprinzi, et al. only found a significant association among adults with diabetes.[9,10] Evidence of potential effects of hearing aid use on physical activity is thus scarce, and the few studies investigating it are observational and cross-sectional, making them insufficient to conclude whether hearing interventions play a role in improving physical activity.

## 5. Main Hypothesis/Study Questions:

*Study Question:*

To determine the effect of a best-practice hearing rehabilitation intervention, versus a successful aging health education control intervention, on levels of reported leisure-time moderate to vigorous intensity physical activity in 70-84-year-old community-dwelling adults with hearing loss.

*Main Hypotheses:*

Older adults with hearing loss who receive the hearing intervention (versus successful aging health education control) will have a slower decline in levels of leisure-time moderate to vigorous physical activity 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). The study recruited 238 participants 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[11], 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, and 7) plan to remain in the area during the study period
- 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, and 7) self-reported hearing aid use in the past year.

**Outcome Variables**

The primary outcome of interest is leisure-time physical activity (LTPA), defined as engaging in moderate to vigorous physical activity (MVPA) during leisure time. LTPA was measured at enrollment and at follow-up using a standardized interviewer-administered questionnaire (modified Baecke) that utilizes a past-year recall time frame.[12] Participants were asked to report up to 4 leisure-time activities or sports that they engaged in and the frequency and duration (minutes/week) for each activity. Physical activity intensity was estimated by assigning each reported activity type a metabolic equivalent of task (MET) value ranging from 1 to 12 METs based on the 2011 Compendium of Physical Activities.[13]. Activity-specific estimates for MET-min/week and min/week of MVPA were obtained by multiplying the reported intensity, duration, and frequency. Estimates of LTPA (MET-min/week) were obtained by summing activity-specific estimates. For estimates of min/week, minutes spent in vigorous-intensity activities were counted twice (following the physical activity guidelines); additionally, minutes of MVPA were used to categorize participants' activity based on current guidelines as inactive (0 MVPA min/week), insufficiently active (1–149 MVPA min/week), and sufficiently active/meeting guidelines (≥150 MVPA min/week).[2,14]
For analyses, LTPA will be assessed using MET-min/week and min/week of MVPA as continuous outcomes; we will also categorize activity levels based on national guidelines using MVPA min/week as described above.

Additionally, the physical activity questionnaire asks participants about frequency (never, seldom, sometimes, often, very often) of television watching and walking during leisure time. Television watching is the most common sedentary behavior among US adults,[15] and has been used as a proxy for sedentary time in previous ARIC analyses. In a recent study using data from a nationally representative sample of

US adults, hearing loss was associated with self-reported leisure-time walking, and among those with hearing loss, hearing aid users were more likely to report leisure-time walking.[16] In secondary analyses, we will investigate the effect of the hearing intervention on self-reported frequency of TV viewing and leisure-time walking compared to a successful aging education control group.

**Exposure Variables**

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

**Other Variables**

Baseline hearing loss, ARIC vs de novo status, center, age (years), sex (male/female), educational attainment (less than high school/ high school or equivalent/ greater than high school), and short physical performance battery composite scores, body mass index, marital status, IADL/ADL questionnaire, and spousal pair (randomized as a pair).

**Analytic Plan**

We will estimate the change in LTPA from baseline to year three of follow-up using mixed-effects models that account for the correlation of repeated measures within a person. We will include time from baseline as a continuous term in our models and an interaction term between time and intervention group to estimate differences by treatment assignment. The primary analysis may include adjustments for baseline hearing loss. We will also investigate if 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 short physical performance battery composite scores may modify the effect of treatment assignment on LTPA change over three years. The COVID-19 lockdowns in 2020 may have impacted the ability of older adults to be physically active; thus, we will conduct sensitivity analyses including a calendar time spline in our models. The knot(s) of the spline will be placed at different times, corresponding to major changes in lockdowns in the US (and March 31$^{st}$, 2020, when the in-person ACHIEVE operations were suspended, and another one in June 30$^{th}$,2021, when the in-person ACHIEVE operations resumed). We will also explore complier average causal effect (CACE) analyses to aid in comparing the results to those reported in observational studies. Finally, because the successful aging health education control group received a module regarding increasing physical activity, and the module was delivered at different visits, we will conduct a sensitivity analysis including only the control participants who received the physical activity module during their first year in the study (n=483). For the secondary outcomes of this manuscript, we will use mixed-effects multinomial models with interaction terms between treatment assignment and time to estimate the change (baseline to year three) in the odds of being in lower TV-viewing categories (very often as the outcome of reference), or higher leisure-time walking categories (the scale will be reversed for ease of interpretation [never as the outcome of reference]) comparing the hearing intervention to the control group.

**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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