



## Short Report

# A randomized feasibility pilot trial of hearing treatment for reducing cognitive decline: Results from the Aging and Cognitive Health Evaluation in Elders Pilot Study

Jennifer A. Deal<sup>a,b,\*</sup>, Marilyn S. Albert<sup>c</sup>, Michelle Arnold<sup>d</sup>, Shrikant I. Bangdiwala<sup>e</sup>, Theresa Chisolm<sup>d</sup>, Sonia Davis<sup>e</sup>, Ann Eddins<sup>d</sup>, Nancy W. Glynn<sup>f</sup>, Adele M. Goman<sup>b</sup>, Melissa Minotti<sup>g</sup>, Thomas Mosley<sup>h</sup>, George W. Rebok<sup>i,j</sup>, Nicholas Reed<sup>b</sup>, Elizabeth Rodgers<sup>f</sup>, Victoria Sanchez<sup>d</sup>, A. Richey Sharrett<sup>a</sup>, Josef Coresh<sup>a,g,k</sup>, Frank R. Lin<sup>a,b,j</sup>

<sup>a</sup>Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

<sup>b</sup>Department of Otolaryngology-Head and Neck Surgery, Johns Hopkins School of Medicine, Baltimore, MD, USA

<sup>c</sup>Department of Neurology, Johns Hopkins School of Medicine, Baltimore, MD, USA

<sup>d</sup>Department of Communication Sciences and Disorders, University of South Florida, Tampa, FL, USA

<sup>e</sup>Department of Biostatistics, Gillings School of Global Public Health, University of North Carolina, Chapel Hill, NC, USA

<sup>f</sup>Department of Epidemiology, University of Pittsburgh School of Public Health, Pittsburgh, PA, USA

<sup>g</sup>George W. Comstock Center for Public Health Research and Prevention, Johns Hopkins Bloomberg School of Public Health, Hagerstown, MD, USA

<sup>h</sup>Department of Medicine, University of Mississippi Medical Center, Jackson, MS, USA

<sup>i</sup>Department of Mental Health, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

<sup>j</sup>Center on Aging and Health, Johns Hopkins Medical Institutions, Baltimore, MD, USA

<sup>k</sup>Department of General Internal Medicine, Johns Hopkins School of Medicine, Baltimore, MD, USA

**Abstract**

**Introduction:** Hearing loss (HL) is prevalent and independently related to cognitive decline and dementia. There has never been a randomized trial to test if HL treatment could reduce cognitive decline in older adults.

**Methods:** A 40-person (aged 70–84 years) pilot study in Washington County, MD, was conducted. Participants were randomized 1:1 to a best practices hearing or successful aging intervention and followed for 6 months. [clinicaltrials.gov](http://clinicaltrials.gov) Identifier: NCT02412254.

**Results:** The Aging and Cognitive Health Evaluation in Elders Pilot (ACHIEVE-P) Study demonstrated feasibility in recruitment, retention, and implementation of interventions with no treatment-related adverse events. A clear efficacy signal of the hearing intervention was observed in perceived hearing handicap (mean of 0.11 to –1.29 standard deviation [SD] units; lower scores better) and memory (mean of –0.10 SD to 0.38 SD).

**Discussion:** ACHIEVE-P sets the stage for the full-scale ACHIEVE trial (N = 850, recruitment beginning November 2017), the first randomized trial to determine efficacy of a best practices hearing (vs. successful aging) intervention on reducing cognitive decline in older adults with HL.

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**Keywords:**

Clinical trials; Cognition; Dementia; Epidemiology; Hearing; Longitudinal study; Memory; Presbycusis

**1. Introduction**

Novel approaches are urgently needed to reduce risk of age-related cognitive decline, Alzheimer's disease (AD), and other dementias in older adults. In observational studies,

\*Corresponding author. Tel.: +1-410-502-3115; Fax: +1-410-614-9625.

E-mail address: [jdeal1@jhu.edu](mailto:jdeal1@jhu.edu)

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hearing loss (HL) is independently associated with accelerated cognitive decline [1,2] and incident dementia [3,4]. Hypothesized mechanistic pathways underlying this association include effects of distorted peripheral encoding of sound on cognitive load, brain structure/function, and/or reduced social engagement [5]. Importantly, these pathways may be modifiable with comprehensive HL treatment. HL in older adults is prevalent, affecting nearly two of three adults aged more than 70 years [6], yet hearing aids remain grossly underutilized (<20% of adults with HL [7]). To date, there has never been a randomized trial to determine whether HL treatment could reduce cognitive decline and dementia in older adults. Here, we present the results of the Aging and Cognitive Health Evaluation in Elders Pilot (ACHIEVE-P) Study, a randomized pilot study of 40 cognitively intact older adults nested within the Atherosclerosis Risk in Communities (ARIC) Study, primarily designed to test feasibility of a best practices hearing (vs. successful aging) intervention trial in older adults with audiometric HL, and secondarily, to explore an efficacy signal on 6-month proximal and cognitive outcomes. The 2013 Standard Protocol Items: Recommendations for Interventional trials checklist [8] is included as Appendix 1.

## 2. Methods

### 2.1. Study objectives

The primary objective of this 40-person pilot study was to determine feasibility of recruitment, randomization procedures, retention, and the implementation of study interventions. Although the goal of the pilot study was not to formally test intervention efficacy, secondarily, we assessed for an early efficacy signal on proximal outcomes that may mediate downstream effects of hearing treatment on cognitive functioning and cognitive outcomes gathered 6 months after intervention.

### 2.2. Participants

ARIC is a prospective study of 15,792 men and women aged 45 to 64 years in 1987 to 1989 from four US communities. ACHIEVE-P participants were recruited from ARIC participants in Washington County, MD, and *de novo* from surrounding communities. Consistent with the parent study, transportation costs were covered for all participants.

*Eligibility* criteria included age 70 to 84 years, untreated adult onset bilateral HL (better-hearing ear three-frequency (0.5, 1, and 2 kHz) pure tone average [PTA]  $\geq 30$  and <70 decibels hearing level [dBHL]), community-dwelling, fluent English speaker, plans to remain in the area, and cognitively intact (Mini-Mental State Examination score  $\geq 23$  if high-school degree or less and  $\geq 25$  if some college degree or higher).

*Exclusion* criteria included dementia diagnosis, self-reported difficulty in two or more activities of daily living [9], medical contraindication to HL treatment, untreatable conductive HL, and unwillingness to regularly wear hearing aids.

Informed consent was obtained from all participants, and study procedures were approved by the Johns Hopkins University Institutional Review Board.

### 2.3. Best practices hearing intervention

Developed and manualized at the University of South Florida, the hearing intervention consists of evidence-based best practices to address participant's audiological and lifestyle needs. Training for the study audiologist consisted of 2-day onsite training before study start, as well as data monitoring and a site visit for quality assurance.

After baseline and randomization, participants met with the study audiologist for four 1-hour sessions over a period of 10 to 12 weeks. At the first visit, participants' hearing needs were assessed using the Client Oriented Scale of Improvement [10]. Participants received bilateral receiver-in-the-canal hearing aids fit to prescriptive targets using real-ear measures. At each subsequent visit, hearing aids were adjusted to targets and/or needs. Participants were offered assistive listening devices that were paired with their hearing aids (e.g., devices to stream cell phones and television, remote microphones to directly access other speakers in difficult listening environments). Rehabilitative counseling was provided to manage expectations and optimize technology use in real-world settings.

### 2.4. Successful aging intervention

The successful aging control intervention followed the protocol and materials developed for the 10 Keys to Healthy Aging [11], an evidence-based, interactive health education program for older adults on topics relevant to chronic disease and disability prevention, that was previously implemented in the Aging Successfully with Pain randomized study [12]. Training for the research nurse consisted of online certification and half-day onsite training before study start.

After baseline and randomization, participants met individually with a research nurse certified to administer the program for four 1-hour visits over a period of 10 to 12 weeks; each session focused on a "Key" chosen by the participant.

### 2.5. Randomization

Randomization procedures were designed and implemented by the study's Data Coordinating Center at the University of North Carolina. Participants were randomized 1:1 to the best practices hearing or successful aging intervention in blocks within strata defined by HL severity in the better-hearing ear, mild (PTA  $\geq 30$  and <40 dB), or moderate (PTA  $\geq 40$  and <70 dB); field center staff were masked to block size.

### 2.6. Study outcomes

The Hearing Handicap Inventory for the Elderly (screening version) [13] measures perceived hearing handicap. The 12-item Cohen Social Network Index [14] assesses participation in different types of social

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