Hearing intervention versus health education control to reduce cognitive decline in older adults with hearing loss in the USA (ACHIEVE): a multicentre, randomised controlled trial

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Summary

Background Hearing loss is associated with increased cognitive decline and incident dementia in older adults. We aimed to investigate whether a hearing intervention could reduce cognitive decline in cognitively healthy older adults with hearing loss.

Methods The ACHIEVE study is a multicentre, parallel-group, unmasked, randomised controlled trial of adults aged 70–84 years with untreated hearing loss and without substantial cognitive impairment that took place at four community study sites across the USA. Participants were recruited from two study populations at each site: (1) older adults participating in a long-standing observational study of cardiovascular health (Atherosclerosis Risk in Communities [ARIC] study), and (2) healthy de novo community volunteers. Participants were randomly assigned (1:1) to a hearing intervention (audiological counselling and provision of hearing aids) or a control intervention of health education (individual sessions with a health educator covering topics on chronic disease prevention) and followed up every 6 months. The primary endpoint was 3-year change in a global cognition standardised factor score from a comprehensive neurocognitive battery. Analysis was by intention to treat. This trial was registered at ClinicalTrials.gov, NCT03243422.

Findings From Nov 9, 2017, to Oct 25, 2019, we screened 3004 participants for eligibility and randomly assigned 977 (32·5%; 238 [24%] from ARIC and 739 [76%] de novo). We randomly assigned 490 (50%) to the hearing intervention and 487 (50%) to the health education control. The cohort had a mean age of 76·8 years (SD 4·0), 523 (54%) were female, 454 (46%) were male, and most were White (n=858 [88%]). Participants from ARIC were older, had more risk factors for cognitive decline, and had lower baseline cognitive scores than those in the de novo cohort. In the primary analysis combining the ARIC and de novo cohorts, 3-year cognitive change (in SD units) was not significantly different between the hearing intervention and health education control groups (–0·200 [95% CI –0·256 to –0·144] in the hearing intervention group and –0·202 [–0·258 to –0·145] in the control group; difference 0·002 [–0·077 to 0·081]; p=0·96). However, a prespecified sensitivity analysis showed a significant difference in the effect of the hearing intervention on 3-year cognitive change between the ARIC and de novo cohorts ($p_{interaction}$=0·010). Other prespecified sensitivity analyses that varied analytical parameters used in the total cohort did not change the observed results. No significant adverse events attributed to the study were reported with either the hearing intervention or health education control.

Interpretation The hearing intervention did not reduce 3-year cognitive decline in the primary analysis of the total cohort. However, a prespecified sensitivity analysis showed that the effect differed between the two study populations that comprised the cohort. These findings suggest that a hearing intervention might reduce cognitive change over 3 years in populations of older adults at increased risk for cognitive decline but not in populations at decreased risk for cognitive decline.

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Introduction

The global burden of dementia will increase rapidly over the next 30 years because of the ageing of the world's population. More than 150 million individuals are projected to be living with dementia by 2050, with most living in low-income and middle-income countries.[1] Efforts to address this global health challenge have increasingly focused on identifying potentially modifiable

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See Online for appendix

Research in context

Evidence before this study

We searched PubMed on May 22, 2023, using the search terms "(randomized trial) AND (hearing) AND (cognitive decline)" for studies in English that included a study population of adults without prevalent cognitive impairment or dementia, tested an intervention involving technologies or strategies for hearing loss treatment, had trial follow-up of more than 1 year, and had a primary outcome involving cognition. No published trials were identified that met these criteria. A meta-analysis published in February, 2023, of eight observational studies, including 126 903 participants and a follow-up duration of 2–25 years, concluded that a hearing loss intervention was associated with reduced hazard of long-term cognitive decline and that the "cognitive benefit of hearing restorative devices should be further investigated in randomized trials".

Added value of this study

To our knowledge, the ACHIEVE trial is the first randomised controlled trial to investigate whether a hearing intervention can reduce long-term cognitive change in cognitively healthy older adults (primary prevention trial for cognitive decline and dementia). The primary analysis of the total cohort showed no reduction in 3-year cognitive decline with a hearing intervention, but a prespecified sensitivity analysis revealed a difference in the effect of a hearing intervention between the two distinct study populations that comprised the study cohort. The hearing intervention reduced 3-year cognitive change in the population of older adults at increased risk for cognitive decline but had no effect in those at decreased risk for cognitive decline.

Implications of all the available evidence

Taken together, our findings suggest that hearing loss might be a particularly important global public health target for dementia prevention efforts. Hearing loss is highly prevalent in adults aged 70 years and older and is treatable with an established intervention (ie, hearing aids and related support services) that is underused and confers essentially no medical risk. Results from this randomised trial suggest that a hearing intervention can reduce cognitive change within 3 years when implemented in older age for adults at increased risk for cognitive decline.

risk factors that could be addressed at scale to help reduce the risk of dementia and the cognitive decline that precedes dementia onset.

Over the past 5 years, consensus studies[2–5] investigating these risk factors have consistently identified hearing loss, prevalent in 65% of adults older than 60 years,[6] as being a key risk factor of interest. Reports from the *Lancet* Commission on dementia[2,5] have identified hearing loss as being the single largest potentially modifiable risk factor for dementia in high-income and low-to-middle-income countries. Hypothesised mechanisms through which hearing loss and degraded peripheral sound encoding could affect cognitive decline and dementia risk include effects of hearing loss on cognitive load, brain structure, and reduced engagement in social and cognitively stimulating activities.[7] Importantly, these pathways might be modifiable with existing interventions for hearing loss that remain underused (<10% of individuals in low-income countries and <20–30% in high-income countries with hearing loss use hearing aids[8]).

Previous studies on the role of hearing aids in dementia prevention have principally been based on observational data and have shown encouraging results suggestive of a positive effect of hearing intervention on reducing risk for cognitive decline and dementia.[9,10] However, inferences from these observational studies are limited because measured (eg, education and income) and unmeasured factors (eg, health behaviours) might confound observed associations of hearing aid use with reduced cognitive decline. Therefore, we aimed to investigate the effects of a hearing intervention (*vs* health education control) on cognitive decline among community-dwelling older adults.

Methods

Study design and participants

The Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study is a 3-year, multicentre, parallel-group, unblinded, randomised controlled trial that is based within the scientific and physical infrastructure of the Atherosclerosis Risk in Communities (ARIC) study,[11] an ongoing longitudinal study of adults who were aged 45–64 years when initially recruited in 1987–89 (n=15 792) from a random sample of the surrounding communities at four community-based field sites in the USA (Forsyth County, NC; Jackson, MS; Minneapolis suburbs, MN; and Washington County, MD). The aim of the observational ARIC study is to understand risk factors for heart disease and stroke and the connections between cardiovascular and cognitive health. ARIC participants have been followed up since 1989 at six in-person study visits, during which neurocognitive testing was administered at four of the visits. The ACHIEVE study was done at the same four field sites, and both studies shared study personnel, protocols, and methods. The trial's study design and methods have been previously published.[12]

ACHIEVE participants were recruited from two populations at each site: (1) existing ARIC study participants and (2) de novo from healthy volunteers in the communities of the four field sites. De novo participants were recruited through advertisements in local newspaper, radio, and internet advertisements, and

related means.[12] Participants were pre-screened by telephone and completed additional in-person screening. Main inclusion criteria were being aged 70–84 years, with adult-onset bilateral hearing loss with a better-ear 4-frequency (0·5–4·0 kHz) pure tone average (PTA) of 30 or more dB and less than 70 dB, free of substantial cognitive impairment (mini-mental state examination [MMSE] score ≥23 for participants with a high-school degree or less and ≥25 for those with some college education or more), word-recognition score in quiet at least 60% correct in the better-hearing ear, community-dwelling, and being a fluent English speaker. Main exclusion criteria were self-reported disability in two or more activities of daily living, presenting visual acuity worse than 20/63 on the MNREAD acuity chart (Precision Vision, Woodstock, IL, USA; corresponding to inability to comfortably read 14-point font), self-reported hearing aid use in the past year, permanent conductive hearing loss, medical contraindication to hearing aid use, or unwillingness to wear hearing aids on a regular basis. Audiologically related inclusion and exclusion criteria were specified to identify individuals who would be expected to benefit from amplification with conventional hearing aids and related audiological services.

The ACHIEVE trial was approved by the institutional review boards of all participating study sites and academic centres. Participants provided written informed consent. An independent data and safety monitoring board (DSMB) met every 6 months to review study progress, adverse events, and changes to the study protocol and statistical analysis plan.

Randomisation and masking

We randomly assigned eligible participants (1:1) using permuted block randomisation, stratified by severity of hearing loss (PTA <40 dB or ≥40 dB), recruitment source (ARIC or de novo), and field site, to either hearing intervention or a successful ageing health education control intervention. Eligible participants who were spouses or partners were randomly assigned as a unit, stratified by recruitment source and field site. The randomisation allocation schedule was developed by the coordinating centre at the University of North Carolina (Chapel Hill, NC, USA) and completed within the Carolina Data Acquisition and Reporting Tool web-based data management system. Assignment to the hearing intervention (which involves participants' use of hearing aids) is by nature unmasked to participants and study staff collecting outcome data, who might notice if a participant is wearing a hearing aid. To minimise potential bias, participants were masked to the study hypothesis and each participant was informed before randomisation that they would be offered both study interventions, which could promote healthy ageing during study follow-up. Participants were informed that either the hearing intervention or health education intervention would be assigned randomly at baseline, and all participants would then receive the other intervention after 3-year follow-up. Other procedures to minimise bias included use of standardised protocols for training of data collectors and assessment of study outcomes, no access to cognitive testing results from previous study visits for data collectors and study coordinators to avoid unintentional and possibly unconscious bias by study staff during data collection, and masking of accumulating trial data from ACHIEVE investigators and study staff (except coordinating centre staff and one unmasked statistician).

Procedures

Participants who were randomly assigned to the hearing intervention completed four 1-h sessions with a study audiologist held every 1–3 weeks after randomisation. Participants received bilateral hearing aids fitted to prescriptive targets using real-ear measures and other hearing-assistive technologies to pair with the hearing aids (eg, devices to stream smartphones and television and remote microphones to directly hear other speakers in difficult listening environments). The intervention included systematic orientation and instruction in device use and hearing toolkit materials for self-management and communication strategies. Re-instruction in the use of devices and hearing rehabilitative strategies was provided during booster visits held every 6 months. Complete details of the hearing intervention have been previously published.[13]

Participants assigned to the successful ageing health education control met individually with a certified health educator who administered the 10 Keys to Healthy Aging programme,[14] an evidence-based, interactive, health education programme for adults aged 65 years and older on topics relevant to chronic disease and disability prevention, which has been previously implemented as the control intervention in other trials. The format of the health education control intervention was designed to control for general levels of staff and participant time and attention and to match the intensity of the hearing intervention. Participants met with a health educator every 1–3 weeks for a total of four visits after randomisation. Session content was tailored to each participant and included a standardised didactic education component as well as activities, goal setting, optional extracurricular enrichment activities, and a 5–10-min upper-body extremity stretching programme. Participants returned for booster sessions every 6 months.

After baseline assessment, randomisation, and provision of the assigned study intervention, participants were followed up every 6 months. From March, 2020, to June, 2021, all study sites were closed for in-person study visits because of the COVID-19 pandemic. During this period, visits continued with modified procedures for provision of telephone-based intervention booster sessions and telephone-based assessments of study outcomes.

Outcomes

The primary study endpoint is change (in SD units) from baseline to year 3 in a global cognition standardised factor score derived from a comprehensive neurocognitive battery that was administered at baseline and annually for 3 years by psychometrists trained and supervised by a neuropsychologist. Tests included delayed word recall, digit symbol substitution, incidental learning, trail making parts A and B, logical memory, digit span backwards, Boston naming, word fluency, and animal naming (appendix pp 9–11). Standardised factor scores were developed using a latent variable modelling approach that has been previously used and validated.[15] Compared with other summary measures, such as weighted averages (eg, Z scores), factor scores better account for measurement error of individual tests and their relative difficulty and improve precision.[16] In addition to the neurocognitive battery, the MMSE was administered at baseline and every 6 months. During the period of COVID-19-related study-site closures, a telephone-based adaptation of the neurocognitive battery and MMSE was developed and implemented for the annual neurocognitive assessments. This battery included the Consortium to Establish a Registry for Alzheimer's Disease immediate and delayed word recall, digit span backwards, oral trails A and B, word fluency, and animal naming tests. Final year-3 neurocognitive assessments were done in person from June, 2021, to November, 2022. Procedures implemented to help ensure hearing loss would not affect cognitive testing accuracy have been described previously.[12] Of the ten tests comprising the in-person neurocognitive battery, only two tests had exclusively auditory stimuli (digit span backwards and logical memory). All other tests contained visual stimuli or both auditory and visual stimuli.

Secondary cognitive outcomes were 3-year change in cognitive domain-specific latent factor scores[15] (executive function [trail making A and B and digit symbol substitution], language [Boston naming, word fluency, and animal naming tests], and memory [delayed word recall, logical memory, and incidental learning]) and time until cognitive impairment defined as a composite outcome of (1) adjudicated dementia according to in-person or telephone-based assessments, (2) adjudicated mild cognitive impairment according to in-person assessments, or (3) a 3-point reduction from baseline in a 30-item MMSE administered in person or the equivalent in a factor score derived from the ten-item MMSE orientation subscale and 11-item Blessed scale administered by telephone. Incident events of cognitive impairment defined by adjudicated mild cognitive impairment or a 3-point reduction from baseline in the MMSE score or telephone equivalent required subsequent confirmation at the following assessment to ensure persistence of cognitive impairment. Diagnostic adjudication procedures for mild cognitive impairment and dementia diagnoses are provided in the appendix (pp 16–20).

A measure of self-perceived communicative function (Hearing Handicap Inventory for the Elderly-Screening[17] [HHI]) was also assessed at baseline and annually to assess whether the hearing intervention was improving communication. This interviewer-administered ten-item scale assesses the influence of hearing loss on daily communicative function. An HHI score of 0–8 indicates no communication impairment, 10–24 mild-to-moderate communication impairment, and 26–40 significant communication impairment.

Additional exploratory pre-specified outcomes of social, physical, and mental health were also collected at baseline and annually. Brain MRI scans were gathered at baseline and year 3 in a half-sample of the cohort. These outcomes will be reported in future publications.

Statistical analysis

We calculated sample size and power on the following assumptions, based on previous data from ARIC and other representative studies of older adults: (1) change in global cognition standardised factor score of –0·24 SD units over 3 years, (2) SD of 3-year cognitive change of 0·27, (3) drop-in (individuals in the health education control obtaining hearing aids outside of the study) and drop-out (individuals assigned to hearing intervention who discontinue hearing aid use entirely) net total of 15% over 3 years, and (4) withdrawal or missing data from competing events of 27% over 3 years. Under these assumptions, a sample size of 850 participants provided 90% power with two-tailed α of 0·05 to detect a 35% difference in the rate of 3-year cognitive change between the hearing intervention and the health education control. Before reaching this target sample size and on the basis of the favourable rate of recruitment, the DSMB recommended a modest extension to the recruitment period to obtain a larger sample size to account for potential uncertainty. We extended recruitment for 3 months after the initial target sample size of 850 was reached.

Descriptive characteristics were compared by randomisation and recruitment source (ARIC or de novo). We estimated the effect of randomly assigned treatment on the 3-year change in global cognition by fitting a three-level linear mixed effects model with an unstructured covariance matrix to data from the baseline and the year-3 in-person neurocognitive assessment. The model used restricted maximum likelihood with a Kenward-Roger correction to generate parameter estimates, 95% CIs, and p values. A random intercept and time slope were specified at level two for participants and a random intercept was specified at level three for spouses or partners randomly assigned as a unit. We used neurocognitive data from in-person year-1 and year-2 assessments when a participant died before year 3 but completed an assessment less than a year before death. Telephone-based neurocognitive data were only used in sensitivity analyses. A prespecified imputation model generated values for missing covariates

and global cognition factor scores at year 3. We included time from baseline and an interaction between time and randomisation in the model with prespecified, prognostic covariates of hearing loss severity (PTA <40 dB *vs* ≥40 dB), recruitment source, field site, age, sex, education, and the presence of APOE ε4 alleles at baseline. We specified an interaction with time for each covariate except education. We tested a three-way interaction between randomisation, recruitment source, and time before conducting a sensitivity analysis that stratified by recruitment source. The analysis was repeated for the secondary outcomes of executive function, language, and memory.

We used cumulative incidence curves that accounted for the competing risk of death to assess the secondary outcome of incident cognitive impairment. We used a two-level, discrete-time, cause-specific, proportional hazards model with a complementary log-log link to estimate the effect of treatment assignment on incident cognitive impairment. The model used maximum likelihood with a quadrature approximation and a bias-corrected sandwich estimator to generate hazard ratios (HRs), 95% CIs, and p values. We specified a random intercept at level two for spouses and partners. The same prespecified baseline covariates were included in the model and missing covariates were imputed. A two-way interaction between randomisation and recruitment source was tested before stratification by recruitment source.

Statistical significance for the primary outcome was defined as a two-tailed $\alpha<0{\cdot}05$. We assessed the four secondary outcomes with a Hochberg modification to the Bonferroni adjustment, in which estimates are considered statistically significant if the largest p value is below 0·05. If the largest p value exceeds 0·05, then the second largest p value is assessed at <0·025 (0·05/2). If this p value exceeds 0·025, then the third largest p value is assessed at <0·017 (0·05/3). Finally, if this p value exceeds 0·017, the fourth p value is assessed at <0·0125 (0·05/4). The same approach was applied post hoc to stratified analyses. The three-way interaction in mixed effects models and two-way interaction in proportional hazards models were tested at a prespecified $\alpha<0{\cdot}10$.

We used sensitivity analyses to estimate the per-protocol and complier average causal effect (CACE) for each outcome, tested alternative methods of handling missing data, examined different definitions of the outcomes, and compared continuous and discretised time. All analyses were done in SAS (version 9.4), with the exception of multiple imputation (Stata [version 18.0]) and CACE (Mplus [version 8.8]). The trial and analysis plan were registered at ClinicalTrials.gov, NCT03243422, before the unmasking of trial data.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

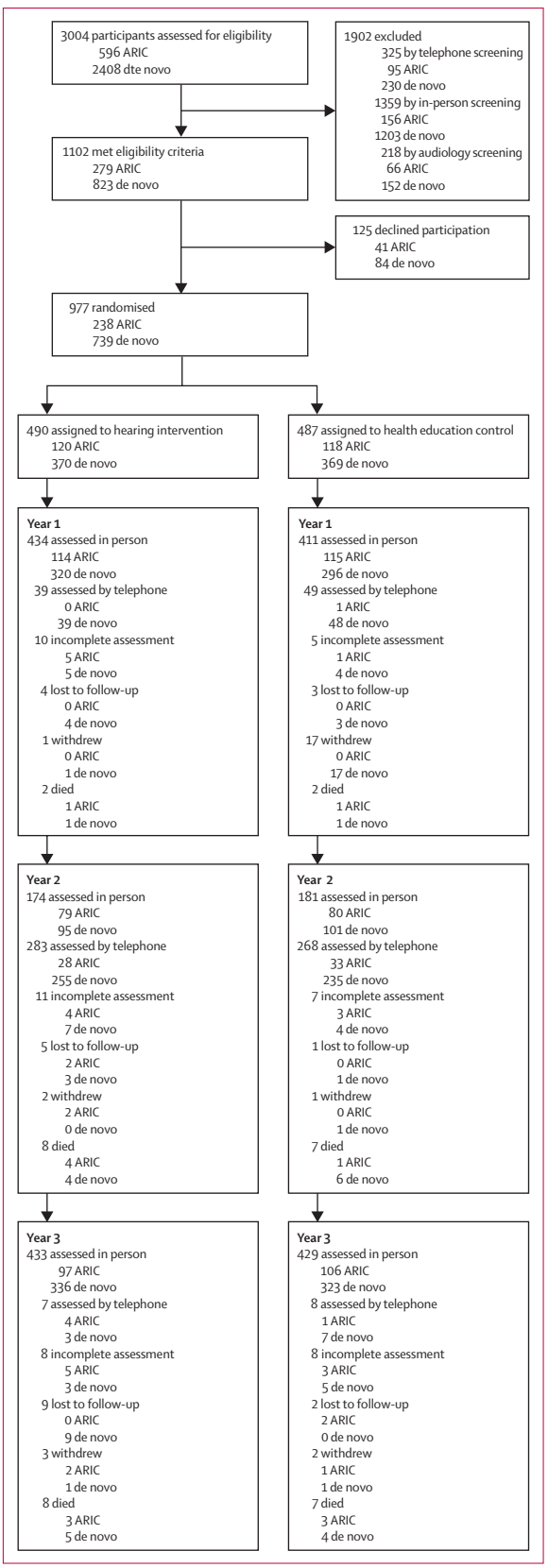

Figure 1: **Trial profile**
ARIC=Atherosclerosis Risk in Communities.

Results

From Nov 9, 2017, to Oct 25, 2019, we screened 3004 participants for eligibility and randomly assigned 977 (32·5%; 238 [24%] participants were from ARIC and 739 [76%] were recruited de novo; figure 1). We randomly assigned 490 (50%) participants to the hearing intervention and 487 (50%) to the health education control (figure 1). All participants were randomly assigned and had received their assigned study intervention before COVID-19 pandemic-related closures of study sites for in-person visits. Sites re-opened for in-person visits in June, 2021, and from June 1, 2021, to Nov 30, 2022, 862 (88%) participants returned for year-3 in-person visits, and 15 (2%) participants had telephone-based year-3 visits. 100 (10%) participants (50 [50%] in each group) did not complete a year-3 visit. Of these 100 participants, 24 (24%) were lost to follow-up by year 3, 26 (26%) had withdrawn from the study by year 3, 34 (34%) had died, and 16 (16%) did not complete neurocognitive assessment at year 3 (incomplete assessment).

Participants assigned to both groups were similar at baseline (table). The cohort had a mean age of 76·8 years (SD 4·0), 523 (54%) were female, 454 (46%) were male, 858 (88%) were White, and participants had a mean 4-frequency PTA of 39·4 dB (SD 6·9), mean MMSE score of 28·2 (1·6), and mean self-perceived communication impairment (HHI) score of 15·3 (9·8) indicative of mild-to-moderate communication impairment. We found substantial differences at baseline between participants from the ARIC versus de novo cohorts (appendix p 2). Participants from ARIC compared with de novo were more likely to be older, female, Black, have lower education and income, have higher rates of diabetes and hypertension, and to live alone (appendix p 2). ARIC participants had slightly lower MMSE scores and significantly lower global cognition and cognitive domain factor scores at baseline compared with those of de novo participants. ARIC and de novo cohort participants had similar audiometric levels of hearing at baseline, but de novo participants had higher HHI scores indicative of greater self-perceived communication impairment.

The hearing intervention showed evidence of target

	All	Total (n=977)		ARIC (n=238)		De novo (n=739)	
		Intervention (n=490)	Control (n=487)	Intervention (n=120)	Control (n=118)	Intervention (n=370)	Control (n=369)
Baseline							
Age, years (n=977)	76·8 (4·0)	76·5 (3·9)	77·0 (4·0)	79·2 (2·9)	78·6 (2·9)	75·7 (3·8)	76·5 (4·2)
Sex (n=977)							
Male	454 (46%)	226 (46%)	228 (47%)	·46 (38%)	45 (68%)	180 (49%)	183 (50%)
Female	523 (54%)	264 (54%)	259 (53%)	74 (62%)	73 (62%)	190 (51%)	186 (50%)
Race (n=977)							
Black	112 (11%)	53 (11%)	59 (12%)	33 (28%)	35 (30%)	20 (5%)	24 (7%)
White	858 (88%)	434 (89%)	424 (87%)	86 (72%)	83 (70%)	348 (94%)	341 (92%)
Other	7 (1%)	3 (1%)	4 (1%)	1 (1%)	0	2 (1%)	4 (1%)
Field site (n=977)							
Forsyth County, NC	236 (24%)	117 (24%)	119 (24%)	31 (26%)	30 (25%)	86 (23%)	89 (24%)
Jackson, MI	243 (25%)	120 (24%)	123 (25%)	30 (25%)	33 (28%)	90 (24%)	90 (24%)
Minneapolis, MN	236 (24%)	120 (24%)	116 (24%)	21 (18%)	22 (19%)	99 (27%)	94 (25%)
Washington County, MD	262 (27%)	133 (27%)	129 (26%)	38 (32%)	33 (28%)	95 (26%)	96 (26%)
Education (n=976)							
Less than high school	37 (4%)	19 (4%)	18 (4%)	12 (10%)	10 (8%)	7 (2%)	8 (2%)
High school, GED, or vocational school	418 (43%)	206 (42%)	212 (44%)	48 (40%)	48 (41%)	158 (43%)	164 (44%)
College, graduate, or professional school	521 (53%)	264 (54%)	257 (53%)	59 (50%)	60 (51%)	205 (55%)	197 (53%)
One or more APOE ε4 alleles (n=908)	224 (25%)	110 (25%)	114 (25%)	26 (23%)	33 (28%)	84 (25%)	81 (24%)
Diabetes (n=977)	195 (20%)	104 (21%)	91 (19%)	36 (30%)	32 (27%)	68 (18%)	59 (16%)
Hypertension (n=974)	651 (67%)	333 (68%)	318 (66%)	87 (73%)	82 (71%)	246 (67%)	236 (64%)
Living alone (n=967)	290 (30%)	153 (32%)	137 (28%)	44 (38%)	39 (34%)	109 (30%)	98 (27%)
Income, US$ (n=950)							
<$25 000	147 (15%)	73 (15%)	74 (16%)	29 (25%)	31 (28%)	44 (12%)	43 (12%)
$25 000–49 999	283 (30%)	156 (33%)	127 (27%)	47 (41%)	30 (27%)	109 (30%)	97 (27%)
$50 000–74 999	210 (22%)	91 (19%)	119 (25%)	22 (19%)	25 (23%)	69 (19%)	94 (26%)
$75 000–100 000	140 (15%)	68 (14%)	72 (15%)	8 (7%)	13 (12%)	60 (17%)	59 (16%)
>$100 000	170 (18%)	90 (19%)	80 (17%)	8 (7%)	12 (11%)	82 (23%)	68 (19%)
Pure tone average, dB (n=977)	39·4 (6·9)	39·5 (7·1)	39·3 (6·7)	39·5 (6·7)	38·7 (6·7)	39·6 (7·2)	39·5 (6·8)

(Table continues on next page)

	All	Total (n=977)		ARIC (n=238)		De novo (n=739)	
		Intervention (n=490)	Control (n=487)	Intervention (n=120)	Control (n=118)	Intervention (n=370)	Control (n=369)
(Continued from previous page)							
Baseline and follow-up							
Hearing handicap inventory score							
Baseline (n=970)	15·3 (9·8)	15·7 (10·2)	14·9 (9·3)	12·7 (10·3)	11·4 (8·6)	16·7 (9·9)	16·0 (9·3)
Year 1 (n=926)	9·8 (9·0)	5·7 (5·9)	14·0 (9·8)	5·1 (5·4)	10·1 (7·3)	5·9 (6·0)	15·3 (10·1)
Year 2 (n=892)	10·3 (9·2)	6·6 (6·6)	14·0 (9·9)	5·1 (6·0)	10·2 (8·3)	7·1 (6·6)	15·3 (10·1)
Year 3 (n=863)	12·0 (9·6)	7·8 (7·3)	16·2 (9·9)	7·6 (8·6)	12·4 (9·2)	7·8 (6·8)	17·4 (9·8)
Mini-mental state examination							
Baseline (n=977)	28·2 (1·6)	28·2 (1·6)	28·2 (1·6)	28·1 (1·7)	27·9 (1·8)	28·3 (1·6)	28·3 (1·5)
Year 3 (n=856)	27·8 (2·3)	27·9 (2·4)	27·7 (2·2)	26·9 (2·8)	26·6 (2·7)	28·2 (2·1)	28·0 (1·8)
Global cognition	0·000 (0·926)	0·012 (0·949)	−0·011 (0·902)	−0·411 (1·024)	−0·346 (1·062)	0·149 (0·883)	0·096 (0·818)
Baseline (n=977)	..	..	..	..	..	..	..
Year 3 (n=859)	−0·161 (1·098)	−0·136 (1·139)	−0·186 (1·057)	−0·604 (1·274)	−0·643 (1·156)	−0·001 (1·060)	−0·037 (0·980)
Executive function							
Baseline (n=977)	−0·001 (0·888)	0·020 (0·897)	−0·021 (0·879)	−0·327 (1·042)	−0·310 (0·958)	0·132 (0·815)	0·072 (0·833)
Year 3 (n=856)	−0·236 (1·060)	−0·224 (1·096)	−0·248 (1·025)	−0·608 (1·228)	−0·652 (1·122)	−0·112 (1·029)	−0·116 (0·956)
Language							
Baseline (n=977)	0·000 (0·837)	−0·011 (0·851)	0·012 (0·823)	−0·436 (0·883)	−0·352 (0·965)	0·126 (0·794)	0·128 (0·737)
Year 3 (n=859)	−0·115 (0·930)	−0·111 (0·949)	−0·119 (0·912)	−0·485 (1·026)	−0·563 (0·969)	−0·002 (0·898)	0·025 (0·845)
Memory							
Baseline (n=977)	0·000 (0·909)	0·016 (0·938)	−0·016 (0·879)	−0·223 (0·918)	−0·159 (0·959)	0·093 (0·933)	0·030 (0·849)
Year 3 (n=859)	0·012 (1·070)	0·067 (1·091)	−0·043 (1·046)	−0·220 (1·128)	−0·254 (1·116)	0·151 (1·068)	0·026 (1·015)
Hours of hearing aid use per day							
Year 1 (n=470)	8·1 (4·6)	8·1 (4·6)	..	7·2 (4·4)	..	8·3 (4·7)	..
Year 2 (n=456)	7·1 (5·0)	7·1 (5·0)	..	6·8 (4·8)	..	7·2 (5·1)	..
Year 3 (n=431)	7·2 (5·2)	7·2 (5·2)	..	5·8 (5·0)	..	7·6 (5·2)	..
Intervention drop-in (n=462)	76 (16·5)	..	76 (16·5)	..	9 (7·8)	..	67 (19·4)
Intervention drop-out (n=488)	10 (2·0)	10 (2·0)	..	5 (4·2)	..	5 (1·4)	..

Data are n (%) or mean (SD). Denominators for percentages are based on the number of participants with complete data, as indicated after each characteristic. Sex (male or female) was based on self-report. Diabetes was defined as present if the participant reported using medication for diabetes or self-reported a medical practitioner diagnosis of diabetes of any type. Sitting blood pressure was measured using a random zero sphygmomanometer. Hypertension was defined as present based on the use of antihypertensive medication, systolic blood pressure greater than or equal to 140 mm Hg, or diastolic blood pressure greater than or equal to 90 mm Hg. Income was based on participant self-report of all family income over the past 12 months. Factor scores of global cognition, executive function, language, and memory were developed using a validated latent variable modelling approach and standardised to the baseline with higher scores indicating better cognitive function. Hearing aid use was based on average self-reported hours of use per day. ARIC=Atherosclerosis Risk in Communities. GED=general educational development credential.

Table: **Demographic and clinical characteristics at baseline, hearing aid use, and cognitive outcomes of ACHIEVE participants stratified by randomly assigned treatment and recruitment source**

engagement according to self-reported hours of hearing aid use and reduction in self-perceived communication impairment after the hearing intervention (table). Participants receiving the hearing intervention reported a mean of 7·2 h (SD 5·2) of hearing aid use per day at year 3 and had HHI scores that declined from a mean of 15·7 (10·2) at baseline to 7·8 (7·3) at year 3, which is indicative of no communication impairment (table). By contrast, the HHI score among health education control participants increased from a mean of 14·9 (9·3) at baseline to 16·2 (9·9) at year 3 (table). We found a similar pattern of hearing intervention target engagement between the ARIC and de novo cohorts but with hearing intervention participants in the de novo cohort reporting more hours of daily hearing aid use (table). During follow-up, ten (2%) of 488 participants in the hearing intervention group dropped out (ie, discontinued hearing aid use; table). 76 (16%) of 462 participants dropped in (ie, were assigned to health education control but chose to obtain hearing aids on their own outside of the study), with a higher rate of drop-in observed among control participants in the de novo than in the ARIC cohort (19·4% *vs* 7·8%; table).

In the primary outcome analysis of 3-year global cognitive change combining both the ARIC and de novo cohorts, global cognitive change (in SD units) was not significantly different between hearing intervention and health education control participants (difference 0·002 [95% CI −0·077 to 0·081]; p=0·96; figure 2, 3). However, prespecified sensitivity analyses stratified by recruitment source showed significant differences in the effect of the hearing intervention on 3-year cognitive change between

the ARIC and de novo cohorts ($p_{interaction}$=0·010; figure 2, 3). In the ARIC cohort, the hearing intervention was associated with a 48% reduction in 3-year cognitive change compared with in the health education control group (difference 0·191 [0·022 to 0·360]; p=0·027). In the de novo cohort, 3-year cognitive change was not significantly different between the hearing intervention and health education control groups (difference –0·061 [–0·151 to 0·028]; p=0·18). Other key differences between the ARIC and de novo cohorts were lower baseline cognitive scores among ARIC participants (figure 3) and a 2·7-times greater rate of 3-year cognitive change among control participants in the ARIC versus de novo cohort (–0·402 [–0·536 to –0·267] *vs* –0·151 [–0·215 to –0·087]). Sensitivity analyses that varied the analytical approach did not substantively change the observed results for the primary outcome (appendix pp 3, 5–6, 8), although the protective effect of the hearing intervention became greater in per-protocol and CACE analyses than with intention-to-treat analyses in the ARIC cohort (appendix p 3).

In the secondary outcome analyses of the of domain-specific cognitive factor scores in executive function, language, and memory domains, we did not find differences between the hearing intervention and health education control groups in analyses of the combined ARIC and de novo cohorts (figure 2, 3). In a stratified analysis of the ARIC cohort, the hearing intervention was significantly associated with a reduced 3-year decline in the language domain (difference 0·229 [95% CI 0·050–0·408]; p=0·012) compared with the health education control. We found no effect of hearing intervention on 3-year change in cognitive domains in the de novo cohort (figure 2, 3). For the secondary outcome of incident cognitive impairment, the cumulative incidence of cognitive impairment was greater in the ARIC versus de novo cohort by year 1 (figure 4). The hearing intervention was not associated with a reduced hazard of cognitive impairment in analyses of the total cohort (HR 0·90 [0·61–1·33]; p=0·59) or in analyses stratified by the ARIC (0·94 [0·54–1·64]; p=0·83) or de novo cohort (0·89 [0·48–1·67]; p=0·72).

Adverse events of otitis externa, cerumen impaction or ear foreign body requiring removal by a physician, and death from any cause were monitored by study investigators and the DSMB throughout the study. We found no adverse events that were unexpected and

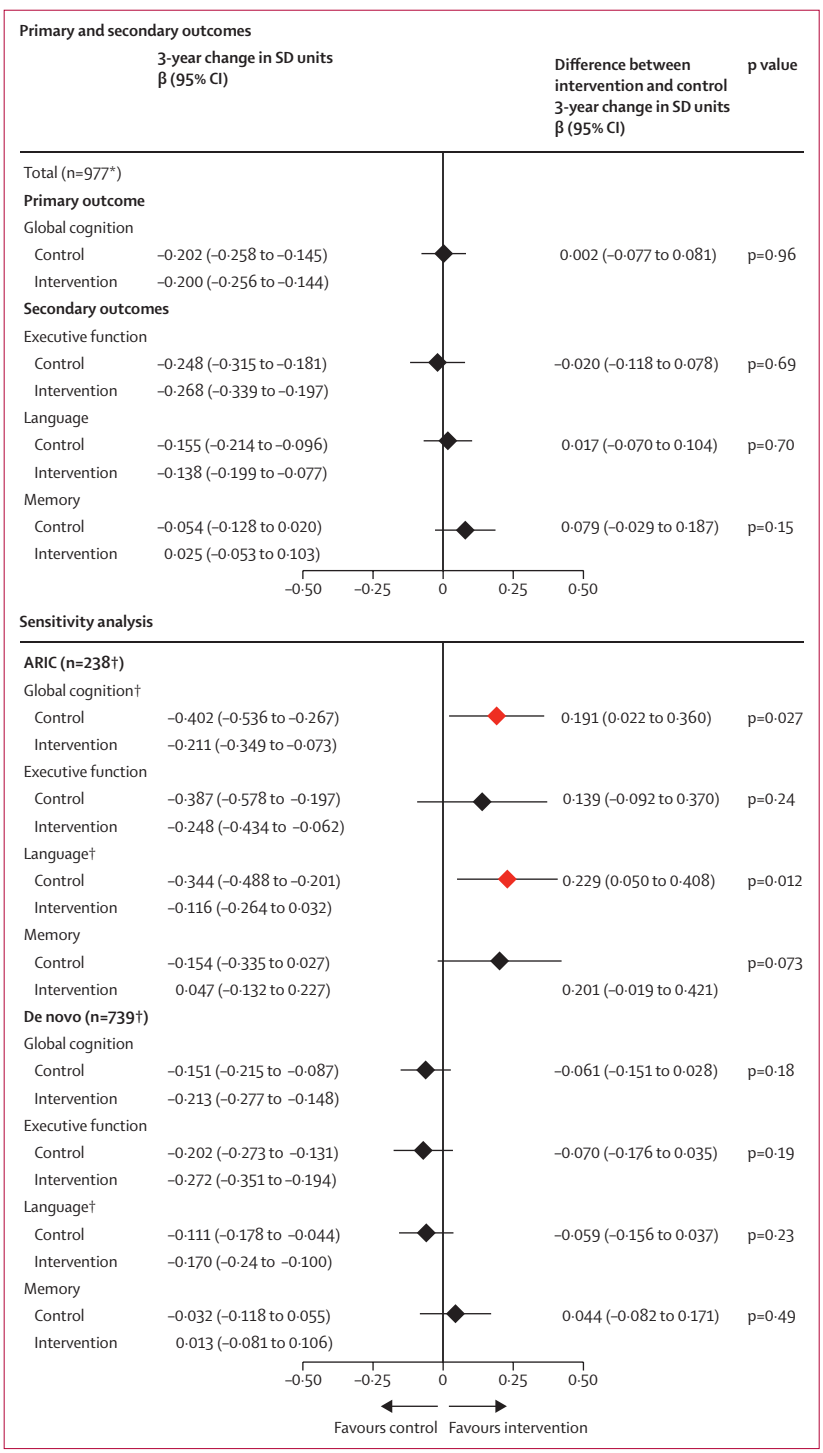

Figure 2: **Covariate-adjusted analysis of 3-year cognitive change by randomly assigned treatment among the total cohort and stratified by recruitment source (n=977)**

Parameter estimates, 95% CIs, and p values were calculated from a linear mixed effects model that adjusted for hearing loss (pure tone average <40 dB *vs* ≥40 dB), recruitment source, field site, age, sex, education, and the presence of APOE ε4 alleles at baseline. An interaction with time was specified for each covariate except education. A three-way interaction between randomisation, recruitment source, and time was tested for each model before stratification. ARIC=Atherosclerosis Risk in Communities. *The analytic sample for the primary analysis comprised 977 in-person assessments from baseline, 862 in-person assessments from year 3 (203 ARIC and 659 de novo), nine in-person assessments (five ARIC and four De Novo) from participants who died before year 3 but completed an assessment less than a year before death, and 106 missing year-3 assessments (30 ARIC and 76 de novo) with values generated from a prespecified multiple imputation model. †Statistically significant (p<0·05) three-way interaction between randomisation, recruitment source, and time.

judged to be related to study participation (data not shown).

Discussion

In this first-in-kind randomised trial investigating the long-term effects of hearing intervention on reducing cognitive decline, our results showed differences in the effect of a hearing intervention between the two study populations that comprised the trial cohort. The primary analysis of the total cohort, which combined both study populations, showed no effect of the hearing intervention on reducing cognitive decline. However, in prespecified stratified analyses, the hearing intervention was associated with a 48% reduction in 3-year global cognitive decline in the ARIC cohort, but we found no effect of the hearing intervention in the de novo cohort. Compared with the de novo cohort of healthy volunteers, the ARIC cohort had more risk factors for cognitive decline and dementia, lower baseline cognitive scores, and faster rates of 3-year cognitive decline. Taken together, our results suggest that hearing intervention might differ in its effect on 3-year cognitive change across different populations. Hearing intervention in adults aged 70 years and older who are at increased risk for cognitive decline and dementia might have an important effect on reducing cognitive change within 3 years. By contrast, the hearing intervention might not have appreciable effects on reducing cognitive change within 3 years in populations at decreased risk for cognitive decline. A follow-up study of the ACHIEVE cohort is underway to study longer-term effects of hearing intervention on cognition and other outcomes (NCT05532657).

Results of the ACHIEVE trial are consistent with the findings of previous observational studies[9,10,18,19] that have suggested that hearing loss treatment might have beneficial effects on reducing cognitive decline and dementia. A pooled meta-analysis[9] of 126 903 participants in eight observational studies with periods of follow-up ranging from 2 to 25 years found a lower hazard of cognitive decline in hearing aid users compared with those with untreated hearing loss. However, inferences from these larger observational studies are often limited by residual confounding and lack of information about the duration and characteristics of the hearing loss treatment. The ACHIEVE study provides randomised trial evidence of the effect of a well defined hearing intervention on cognitive decline. These findings are supportive of previous conclusions from the 2020 *Lancet* Commission on dementia,[2] the 2021 US National Plan to Address Alzheimer's Disease,[20] and other research[10,21] that has called for treating hearing loss in older adults to supplement existing national dementia risk-reduction strategies. Results from the ACHIEVE study show that any benefits of a hearing intervention in reducing cognitive change within 3 years are likely to vary across populations depending on risk for cognitive decline.

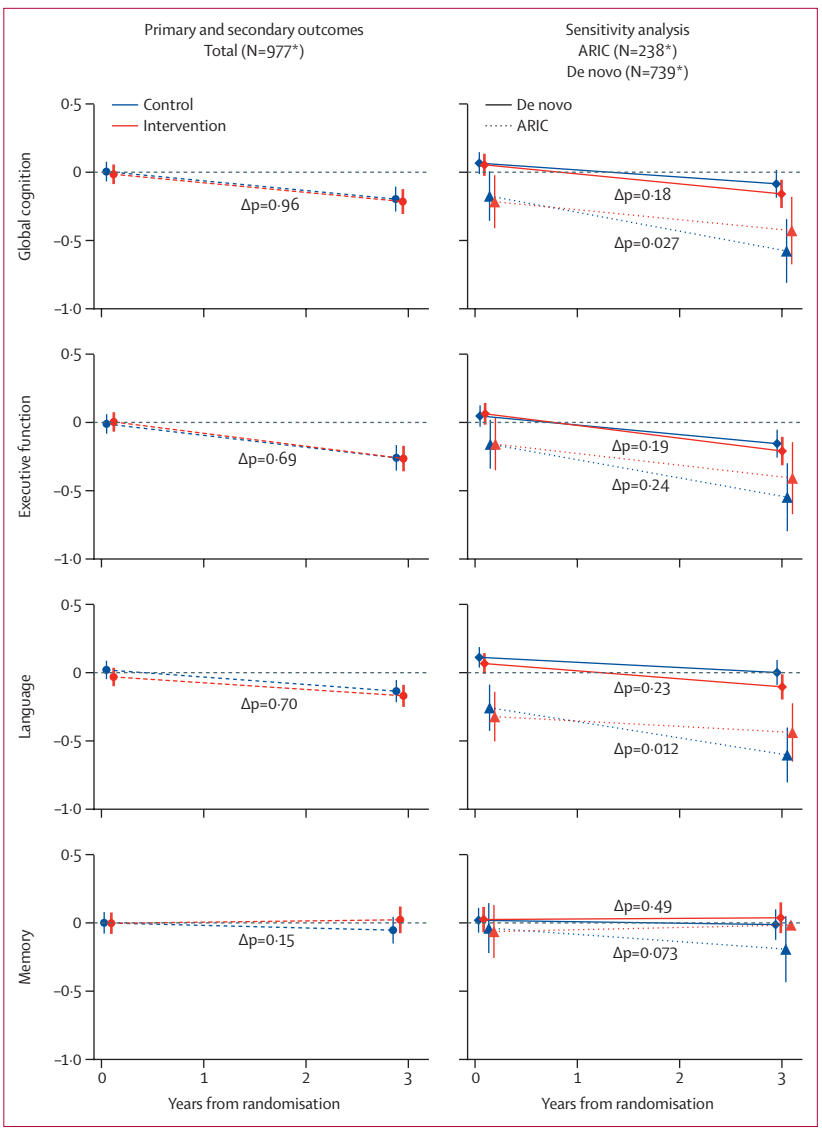

Figure 3: **Trajectories and pointwise estimates of cognitive function by randomly assigned treatment assignment among the total cohort and stratified by recruitment source (n=977)**

Y-axis values are cognitive factor scores that were developed using a validated latent variable modelling approach and standardised to the baseline with higher scores indicating better cognitive function. Parameter estimates, 95% CIs, and p values were calculated from a linear mixed effects model that adjusted for hearing loss (pure tone average <40 dB *vs* ≥40 dB), recruitment source, field site, age, sex, education, and the presence of APOE ε4 alleles at baseline. An interaction with time was specified for each covariate except education. Visualisation was based on a hypothetical participant whose characteristics equalled the sample means. Δp refers to the p value of the interaction between time and randomisation. ARIC=Atherosclerosis Risk in Communities. *The analytic sample for the primary analysis comprised 977 in-person assessments from baseline, 862 in-person assessments from year 3 (203 ARIC and 659 de novo), nine in-person assessments (five ARIC and four de novo) from participants who died before year 3 but completed an assessment less than a year before death, and 106 missing year-3 assessments (30 ARIC and 76 de novo) with values generated from a prespecified multiple imputation model.

Hypothesised mechanisms through which hearing loss could potentially increase risk for cognitive decline and dementia have been previously described[7,22,23] and include cognitive load (information degradation hypothesis), structural effects on brain integrity (sensory deprivation hypothesis), and reduced social engagement and participation in cognitively stimulating activities.

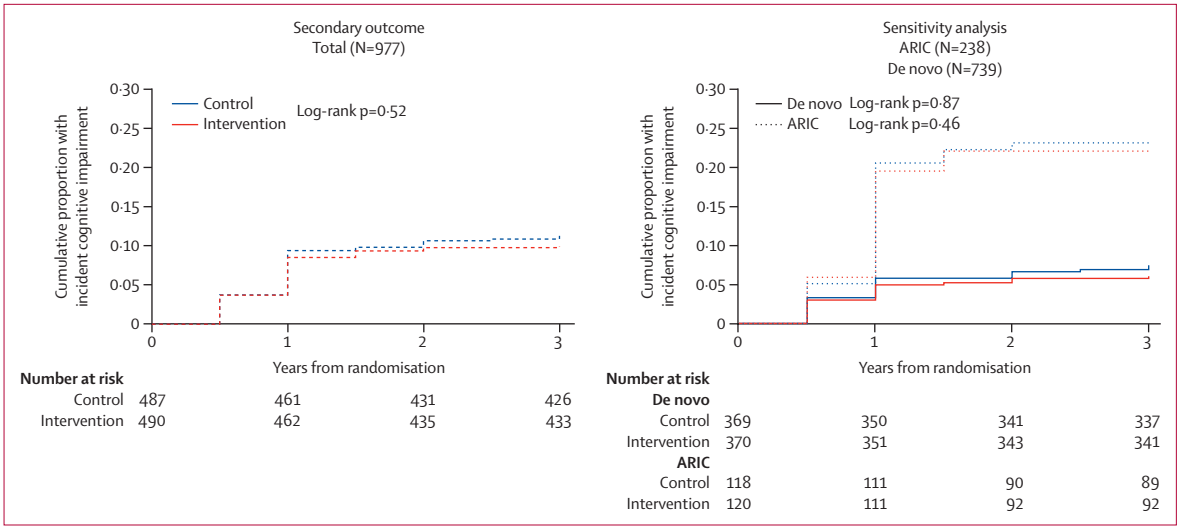

Figure 4: **Cumulative incidence of cognitive impairment by randomly assigned treatment among the total cohort and stratified by recruitment source (n=977)**

Cumulative incidence curves depict the proportion of participants with cognitive impairment after accounting for the competing risk of death. ARIC=Atherosclerosis Risk in Communities.

These mechanisms are not mutually exclusive, and our findings in the ACHIEVE study suggest that a hearing intervention could mitigate the effects of hearing loss on cognitive decline through one or more of these pathways. Future analyses of brain MRI and social engagement data that were collected in the ACHIEVE study will allow for further elucidation of the pathways through which hearing intervention might reduce cognitive decline.

A key finding from the ACHIEVE study is the notable difference between the effect of hearing intervention in the ARIC and de novo cohorts despite similar levels of baseline hearing and more pronounced evidence of target engagement with the hearing intervention in the de novo cohort than in the ARIC cohort (as shown by the larger reduction in HHI scores and greater number of hours of hearing aid use in the de novo cohort). This finding might be attributable to the nearly 3-times difference in rates of cognitive change observed in the control participants between the two cohorts. The annual rate of cognitive change observed in de novo control participants is consistent with a slow rate of cognitive change (estimated at –0·04 SD units per year in a previous study[24]), and the rate in ARIC control participants is more consistent with a moderate rate of cognitive decline (estimated at –0·19 SD units per year[24]). Based on the hypothesis that a hearing intervention could potentially reduce cognitive decline, the slow rate of cognitive change observed in the de novo cohort might limit any effect of a hearing intervention in potentially further reducing this decline within a 3-year period of follow-up.

A possible explanation for the de novo cohort having a slower rate of cognitive change over 3 years compared with that of the ARIC cohort is that the de novo cohort was younger, had fewer risk factors for cognitive decline (eg, higher education, fewer cardiovascular risk factors, and less likely to be living alone), and higher baseline levels of cognition. These characteristics might be related to a healthy volunteer effect of the de novo participants being newly recruited into this trial. A healthy volunteer effect has been described in previous cohort studies,[25,26] whereby participants who newly elect to participate in studies generally represent a healthier subset of the target population. By contrast, participants from ARIC were recruited more than 30 years ago, over which time there would be expected to be declining differences[27] between these participants and the potential target population of community-dwelling older adults who met study inclusion criteria. Another possible explanation for the slower rate of cognitive decline in the de novo cohort relates to practice or learning effects with repeat neurocognitive testing in the de novo participants, who were naive to cognitive testing. Other large trials[28,29] involving repeated assessments of cognition have shown continued improvement in neurocognitive performance over 2 or more years, and the magnitude of these practice effects might vary based on the type of neurocognitive test administered.[30] By contrast, participants in the ARIC cohort had already undergone numerous cognitive assessments before being randomly assigned in ACHIEVE, which would minimise benefits from continued practice effects.

This trial has limitations. Understanding the possible effects of hearing intervention on populations at decreased risk for cognitive decline will require longer-term follow-up of the de novo cohort beyond 3 years. Participants and study technicians also could not be feasibly masked to study intervention assignment, which could possibly bias collected results. Two of the ten tests that comprised the in-person neurocognitive battery also

contained only auditory stimuli, and individuals receiving the health education control with untreated hearing loss could potentially perform more poorly on these measures if the auditory stimuli were not correctly understood by the participant. However, in secondary analyses of the three cognitive domains, the strongest effect of hearing intervention in ARIC participants was observed in the language domain, which did not consist of any tests with exclusively auditory stimuli. Finally, we were not able to observe effects of the hearing intervention on incident cognitive impairment, but these analyses might be underpowered given the somewhat short period of follow-up. Continued follow-up of the ACHIEVE cohort is underway to understand these longer-term effects of hearing intervention on cognitive function.

Results from the ACHIEVE study add to the growing evidence base that suggests addressing modifiable risk factors for cognitive decline and dementia could be effective in reducing the future global burden of dementia. Based on evidence from the ACHIEVE study, hearing loss might be a particularly important global public health target for dementia prevention efforts given that hearing loss is highly prevalent among older adults and is treatable with an established intervention (ie, hearing aids and related support services). Such interventions are underused around the world, confer essentially no medical risk, and have been shown to reduce cognitive decline within 3 years when implemented in later life for at-risk older adults.

Contributors

FRL, JRP, MSA, MA, TC, DC, JAD, NWG, TG, KMH, TM, JSP, NSR, VS, JAS, and JC conceptualised and designed the study. FRL and JC acquired funding. FRL, JRP, MSA, SB, TC, AMG, NWG, TG, LG-M, KMH, DK, TM, JSP, VS, BGW, and JC contributed to the investigation, data collection, and data curation. JRP analysed the data and FRL, JRP, DC, JAD, ARH, TM, NSR, and JC contributed to the methodology. FRL, JRP, SB, AMG, LG-M, KMH, ARH, CMM, TM, JSP, VS, and JC contributed to project administration and supervision. All authors had access to the data, contributed to interpretation of the data, participated in writing and reviewing the manuscript, approved the final version for submission, and agreed to be accountable for the accuracy and integrity of the data.

Declaration of interests

FRL reports research grants from the US National Institutes of Health and Eleanor Schwartz Charitable Foundation; consulting fees from Frequency Therapeutics and Apple; payment for expert testimony and participation on a scientific advisory board for Fondation Pour L'Audition and Sharper Sense; being a volunteer board member for Access HEARS; donation in-kind from Sonova/Phonak to Johns Hopkins University for hearing technologies used in the present study; and being the director of a public health research centre funded in part by a philanthropic donation from Cochlear to the Johns Hopkins Bloomberg School of Public Health. KMH reports consulting fees from Fred Hutchinson Cancer Research Center; support for attending meetings (National Institute for Health Center for Scientific Review and Hebrew Senior Life); participation on the Wake Forest School of Medicine DSMB (unpaid); and leadership roles for peer-reviewed journals (*Alzheimer's & Dementia: Translational Research and Clinical Interventions* and *Alzheimer's & Dementia: Diagnosis, and Assessment & Disease Monitoring* [unpaid]). DK serves on a DSMB for the Dominantly Inherited Alzheimer Network Treatment Unit study. He served on a DSMB for a tau therapeutic for Biogen (until 2021) but received no personal compensation. He is an investigator in clinical trials sponsored by Biogen, Lilly Pharmaceuticals, and the University of Southern California. He has served as a consultant for Roche, Samus Therapeutics, Magellan Health, Biovie, and Alzeca Biosciences but receives no personal compensation. He attended an Eisai advisory board meeting for lecanemab on Dec 2, 2022, but received no compensation. VS reports industry-sponsored clinical research contract (to institution) to support research activity from Otonomy, Frequency Therapeutics, Pipeline Therapeutics, Aerin Medical, Oticon Medical, and Helen of Troy; consulting fees from Autifony Therapeutics and Boehringer Ingelheim; honoraria from Oticon Medical, Sonova Holding, and Phonak USA; and hearing technology devices donated for educational or research proposes from Sonova Holding and Phonak USA. MA reports consulting fees from GN Resound, National Institute on Deafness and Other Communication Disorder (NIDCD), and the National Institute on Aging (NIA); travel support from NIDCD and NIA; and receipt of equipment from Sonova. NSR reports being Editor of the *American Journal of Audiology* (paid) and Scientific Chair of the American Academy of Audiology, Advisory Board Member with stock options for Neosensory, and being a member of the Scientific Advisory Board for Shoebox. All other authors declare no competing interests.

Data sharing

A de-identified dataset and data dictionary will be made available in 2024 on a publicly available US data repository pending approval by the funding sponsor (National Institute on Aging). Additional details on data access policies will be made available at https://www.achievestudy.org at that time. The study protocol and statistical analysis plan are available at https://www.clinicaltrials.gov. Access to ACHIEVE study manuals and forms are available by contacting the corresponding author.

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