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RESEARCH ARTICLE

Recruitment and baseline data of the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study: A randomized trial of a hearing loss intervention for reducing cognitive decline

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Abstract

INTRODUCTION: Hearing loss is highly prevalent among older adults and independently associated with cognitive decline. The Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study is a multicenter randomized control trial (partially nested within the infrastructure of an observational cohort study, the Atherosclerosis Risk in Communities [ARIC] study) to determine the efficacy of best-practice hearing

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treatment to reduce cognitive decline over 3 years. The goal of this paper is to describe the recruitment process and baseline results.

METHODS: Multiple strategies were used to recruit community-dwelling 70–84-year-old participants with adult-onset hearing loss who were free of substantial cognitive impairment from the parent ARIC study and de novo from the surrounding communities into the trial. Participants completed telephone screening, an in-person hearing, vision, and cognitive screening, and a comprehensive hearing assessment to determine eligibility.

RESULTS: Over a 24-month period, 3004 telephone screenings resulted in 2344 in-person hearing, vision, and cognition screenings and 1294 comprehensive hearing screenings. Among 1102 eligible, 977 were randomized into the trial (median age = 76.4 years; 53.5% female; 87.8% White; 53.3% held a Bachelor's degree or higher). Participants recruited through the ARIC study were recruited much earlier and were less likely to report hearing loss interfered with their quality of life relative to participants recruited de novo from the community. Minor differences in baseline hearing or health characteristics were found by recruitment route (i.e., ARIC study or de novo) and by study site.

DISCUSSION: The ACHIEVE study successfully completed enrollment over 2 years that met originally projected rates of recruitment. Substantial operational and scientific efficiencies during study startup were achieved through embedding this trial within the infrastructure of a longstanding and well-established observational study.

KEYWORDS
cognitive decline, dementia, hearing aids, hearing, randomized control trial

Highlights

- The ACHIEVE study tests the effect of hearing intervention on cognitive decline.
- The study is partially nested within an existing cohort study.
- Over 2 years, 977 participants recruited and enrolled.
- Eligibility assessed by telephone and in-person for hearing, vision, and cognitive screening.
- The ACHIEVE study findings will have significant public health implications.

1 | INTRODUCTION

Hearing loss is prevalent in nearly two-thirds of adults over the age of 70 years.[1,2] Observational studies have consistently demonstrated independent associations between peripheral hearing loss and accelerated cognitive decline and risk of dementia.[3–5] A recent Lancet Commission report[6] suggests that 8% of global dementia cases are attributable to hearing loss, making hearing loss the largest potentially modifiable risk factor for dementia. However, hearing aids remain underutilized as less than 20% of Americans who could potentially benefit from hearing treatment own and use hearing aids,[7,8] and there is a paucity of evidence for whether treating hearing loss could in fact reduce cognitive decline.

The proposed mechanistic pathways through which hearing loss may contribute to accelerated cognitive decline include increased cognitive load due to degraded auditory signal processing in the cochlea,[9] effects of hearing loss on brain structure and function,[10,11] and social isolation and loneliness[12] due to communication difficulties. These pathways may be amenable to hearing loss treatment with hearing aids and rehabilitative auditory counseling. Importantly, while some mechanistic pathways may be amenable to treatment, observational research has not ruled out a common cause mechanism[11] affecting

both hearing and cognitive decline or dementia that would not be affected by treatment. Moreover, models have proposed interactions between dementia pathologies and demand on cognitive resources from hearing loss (e.g., cognitive load) could create irreversible synaptic changes which highlight the need for early intervention in the context of prevention.[11]

While observational data suggest self-reported hearing aid use among adults with hearing loss is associated with better cognitive function,[3] the implications of these findings are unclear. Detailed data on patterns and duration of hearing aid use (e.g., daily hours and years of use) that could offer insight into the strength of the association are not routinely gathered in observational studies. Moreover, hearing aid use is significantly linked to factors such as higher socioeconomic status and health-seeking behaviors that may be associated with better cognitive function.[13]

Randomized clinical trials are necessary to determine whether interventions for hearing loss could reduce cognitive decline and risk of dementia. A pilot study conducted in 2016 ($n = 40$, Aging and Cognitive Health Evaluation in Elders [ACHIEVE] Pilot Study)[14] demonstrated feasibility of methods for recruitment, retention, and randomization to a hearing intervention versus an aging education control intervention, and a clear efficacy signal of the hearing intervention on hearing-related quality of life at 6 months post-randomization. These results provided the foundation for the ongoing full-scale ACHIEVE study to determine the efficacy of a best practice hearing intervention versus aging education control intervention on reducing cognitive decline among older adults with hearing loss. Here, we present the recruitment results and baseline demographic and health characteristics of the final ACHIEVE study cohort.

RESEARCH IN CONTEXT

1. **Systematic review**: Literature review included traditional sources. Associations between hearing loss and accelerated cognitive decline have been demonstrated. Randomized controlled trials are needed to test whether treating hearing loss is an effective intervention.
2. **Interpretation**: The Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study recruited and enrolled 977 older adults with untreated hearing loss for a multicenter clinical trial testing the effect of a best practices hearing intervention versus a successful aging health education intervention on 3-year cognitive change. Partially nesting this trial within the infrastructure of a well-established observational study provided operational and scientific efficiencies.
3. **Future directions**: Findings from the ACHIEVE study will provide definitive evidence of the effect of hearing treatment on cognitive decline in community-dwelling older adults with hearing loss. Findings will have substantial clinical and public health implications for older adults.

2 | METHODS

2.1 | Study design, setting, and target population

The full design and methods of the ACHIEVE study (Clinicaltrials.gov Identifier: NCT03243422), including comprehensive and detailed eligibility criteria, were previously published.[15] Herein, eligibility criteria are described in the context of the screening evaluations. In brief, the ACHIEVE study is a large multicenter randomized trial designed to determine efficacy of hearing treatment in reducing cognitive decline in older adults. Community-dwelling participants aged 70–84 years with adult-onset hearing loss who were free of substantial cognitive impairment were randomized 1:1 to a best practice hearing intervention[16] or a previously studied successful aging health education control intervention that focuses on empowering older adults with knowledge on key aspects of aging (e.g., physical activity, lowering blood pressure, etc) to make lifestyle changes to optimize aging.[17] The primary outcome is change from baseline to the 3-year follow-up assessment in a global cognitive function factor score that is derived from a comprehensive cognitive test battery. Other prespecified outcomes include loneliness, social network size, depressive symptomatology, health-related quality of life, hospitalization, falls, physical function, and accelerometry-measured physical activity.

The ACHIEVE study is partially embedded within the scientific and physical infrastructure of the ongoing Atherosclerosis Risk in Communities (ARIC) study,[18] a prospective longitudinal study of men and women aged 45–64 years when initially recruited in 1987–1989 ($N = 15{,}792$) from four US communities (Forsyth County, North Carolina; Jackson, Mississippi; Minneapolis, Minnesota; Washington County, Maryland) and who have been followed to the present day. The ACHIEVE study recruited from the well-characterized ARIC participant population as well as de novo from the surrounding communities to reach the required sample size based on sample size calculations. All recruitment and study procedures were approved by each site's Institutional Review Board.

2.2 | Recruitment methods

A central recruitment subcommittee was formed with representatives from each site to develop recruitment strategies and share ideas for local implementation. The committee met weekly during the recruitment period to review detailed recruitment reports produced by the study's data coordinating center (Collaborative Studies Coordinating Center at the University of North Carolina at Chapel Hill) and monitor progress. Multiple site-specific recruitment strategies were implemented including: (1) mailings and phone calls to ARIC participants who were candidates based on data collected during the sixth visit of the ARIC study (2016–2017); (2) word of mouth, particularly among

ARIC participants given their history of research participation, previous introduction and support of ancillary studies, and general support and engagement with the study through ARIC participant events and gatherings over a three-decade period; (3) mass mailing of brochures targeting the age-eligible population in the surrounding communities; (4) local radio and print newspaper interviews, stories, and advertisements; (5) informational events at local community centers and libraries; (6) distribution and placement of brochures and flyers in public locations and healthcare facilities; (7) invitation letters sent to potentially eligible participants based on electronic health record search of linked academic medical institutions; and (8) Web-based advertisements targeting demographics, locations, and user interest (e.g., banner ads on Facebook) directing participants to the study website that contained information on the study and contact request forms. Recruitment materials specified that the outcome of the study was cognition, and the population of interest was older adults (70–84 years) with hearing loss.

2.3 | Telephone screening interview

Participants completed an initial telephone screening interview to assess eligibility for the study based on age (70–84 years), living situation (community-dwelling; not planning to move from the area), English fluency, willingness to be randomized and participate in study interventions, no history of congenital or childhood hearing loss, no hearing aid use within the prior year, no difficulty with ≥2 activities of daily living (i.e., getting in/out of bed or chairs, bathing, dressing, eating, toileting), and no concurrent enrollment in studies focused on auditory or cognitive exposures or outcomes. Specific questions on hearing loss were omitted given inclusion in recruitment materials and concerns over participant ability to accurately self-report specific degree of hearing loss for study inclusion. Immediately following the screening, participants were informed of eligibility. Eligible participants were invited to an in-person screening visit.

2.4 | In-person screening visit

At the in-person screening visit, participants provided written informed consent for the screening procedures. Participants completed brief measures of hearing, vision, and cognition to screen for eligibility. Eligible participants were then invited to complete a comprehensive hearing evaluation to determine eligibility for the hearing intervention arm of the study.

2.5 | Hearing, vision, and cognitive screening

Initial hearing screening was performed by a trained study technician or audiologist in a quiet room using an iPad-based portable audiometer (SHOEBOX Ltd, Ontario, Canada).[19] A pure-tone average (PTA) of the assessed frequencies (0.5, 1, 2, and 4 kHz) was derived for each ear. Participants were eligible if their better ear PTA was ≥30 and <70 dB HL, the level of hearing at which amplification with conventional hearing aids is most likely to be beneficial to hearing and communication.

Vision screening for near visual acuity (reading) was performed with the MNREAD acuity chart[20] with any regularly worn corrective devices (e.g., glasses, contacts) if applicable. The MNREAD acuity chart displays sentences and phrases in increasingly smaller font sizes. Participants were seated 16 inches from the chart in a well-lit room and instructed to read aloud the smallest text they could read. Participants with worse than 20/63 (corresponding to ~14-point font) corrected vision were excluded due to an inability to see well enough to complete the neurocognitive assessment battery.

Cognitive screening using the Mini-Mental State Examination (MMSE) was administered by a trained psychometrist in a quiet room.[21] The MMSE is a brief (30-question), standardized instrument for screening a limited number of cognitive functions, including orientation, registration and recall, attention and calculation, language, and visual construction, and is commonly used for cognitive screening in clinical and research settings. Participants were eligible with an MMSE score ≥23 for individuals with a high-school degree or less and ≥25 for individuals with some college or more.

2.6 | Comprehensive hearing evaluation

Participants who passed the initial hearing, vision, and cognitive screenings were invited to undergo the study's comprehensive hearing evaluation administered by the study audiologist.[16] Audiometric testing (air- and bone-conduction) was conducted in a sound attenuating booth (WhisperRoom) using a calibrated audiometer (Interacoustics Equinox 2.0 AC440). Speech recognition assessments included a word recognition test (scored as percent correct; 0%–100%) assessing the participant's ability to repeat back monosyllabic words presented at a comfortable listening level for the participant and a speech-in-noise assessment (Quick Speech-in-Noise Test [QuickSIN][22]) that determined a participant's ability to recognize and repeat sentences in the presence of competing background noise. Self-report of difficulty hearing was assessed with a single item ("Which statement best describes your hearing? Would you say your hearing is:" ["Excellent; Good; A Little Trouble; Moderate Trouble; A Lot of Trouble, and Deaf"]) and via the Hearing Handicap Inventory for the Elderly – Screening Version (HHIE-S),[23] a validated questionnaire determining self-perceived impact of hearing on one's quality of life (scores range from 0 to 40; categorized into No Handicap [0–8], Mild-Moderate Handicap [10–24], Severe Handicap [26–40]).

Participants were ineligible for the trial if PTA in their better ear was <30 or ≥70 dB HL or word recognition score was <60% (i.e., parameters indicative that a participant may not benefit from conventional hearing aid amplification). Participants with permanent conductive hearing loss (determined by air-bone gap [difference in air audiometry and bone audiometry] >15 dB in two or more contiguous frequencies in both ears that could not be medically resolved) were also ineligible.

Participants with an air-bone gap >15 dB due to a resolvable medical issue (e.g., fluid in the ears) were eligible given medical clearance from a physician to ensure there were no medical contraindications to wearing hearing aids before being enrolled in the study. Participants with medical contraindication to use of hearing aids (e.g., draining ear) were also ineligible.

2.7 | Informed consent, participant expectations, and randomization

Participants who were eligible for the study based on the telephone and in-person screenings were invited to join the study. Participants who chose to enroll provided written informed consent for participation in the trial. The written informed consent for the trial covered the schedule of visits, randomization, interventions, follow-up, use and protection of participant data, and the rights of the participants, prior to data collection at the baseline visit.

Unique features of the ACHIEVE trial include the relatively long duration of the follow-up period (3 years) and the free provision of an available, yet costly, intervention that is often an out-of-pocket expense not covered by insurance (i.e., hearing aids, related assistive technologies, and audiological services). To ensure active participation in the study, enhance retention, and prevent drop-out (of the study) or unplanned drop-in to the intervention arm (i.e., participants in the control arm pursuing hearing care outside the study), the consent process included a participant expectation form that was reviewed with and signed by participants in order to verify that participants fully understood the randomization process and arms of the study. All participants were instructed that they would also receive the other study intervention at the end of the 3-year follow-up period (i.e., participants initially randomized to the successful aging health education intervention would later receive the hearing intervention and vice versa). The participant expectations form outlined that the participant would have an equal chance of being randomly assigned by computer software to either the hearing intervention or successful aging health education intervention and that staff had no control or ability to override the randomization process.

2.8 | Baseline demographic and health covariates

Participants completed interviewer-administered demographic and health history forms and baseline assessments of the primary, secondary, and other outcomes described elsewhere.[14] For the purposes of this baseline description of the cohort, only demographic and health history information are presented. Each form was interviewer-administered in a quiet room. Demographic data gathered includes age, sex, employment status, race, education, and marital status. The health history form documented chronic conditions (e.g., hypertension, diabetes, etc.) and health behaviors (Table S1).

2.9 | Sample size and recruitment progress

An initial target sample size of 850 participants was estimated to have 90% power to detect a standardized effect size of 0.26 for the difference between the intervention and control groups in mean change from baseline to Year 3 in the global cognitive function factor score. An initial soft-launch of recruitment efforts for the trial began at a limited number of sites in November 2017 with full-scale efforts beginning in January 2018 (with one site not beginning recruitment until February 2018 because of delayed IRB approval at the site). The target sample size of 850 participants was achieved in July 2019. Prior to closure of recruitment, a planned interim analysis of two of the parameters used to estimate the initial sample size (expected rates of hearing intervention drop-out and drop-in, and rates of missing data or participant withdrawal due to competing events) were re-estimated with the follow-up data collected through June 2019. Based on this report, the ACHIEVE Data and Safety Monitoring Board (DSMB) concluded that "*the current rates of drop-out, drop-in, and missing data are consistent with the rates that were assumed in the original power calculations, and provide no new reasons to be concerned that statistical power is lower than projected based on the assumptions used in the design [of] the study. However, as in many studies, the trial's power calculations contain substantial uncertainty. Because enrollment into the trial is proceeding at a favorable rate, the infrastructure for enrollment is fully in place, and uncertainty about changes in availability of hearing aids in the later years of the trial that may increase the drop-in rate, the DSMB supports consideration of a modest extension of the planned enrollment period to provide additional robustness of the study design to possible violations in the assumptions used in the power calculations. As this unique trial is likely to provide the only opportunity to determine if a hearing aid intervention slows decline in cognitive function, such an extension can be one cost-effective strategy to increase the chances of obtaining a definitive answer to this important question.*" Subsequently, with support from the National Institute on Aging, the study investigators were authorized to extend the recruitment window through October 2019 to achieve an expanded sample size of up to $n = 1000$. Closure of recruitment occurred on October 27, 2019 with a final sample size of $N = 977$.

2.10 | Data management and statistical analysis

The ACHIEVE trial data coordination and management was performed by the Collaborative Studies Coordinating Center at the University of North Carolina at Chapel Hill which also serves as the coordinating center for the ARIC study. Data was entered by study staff into a custom designed web-based data management tool (Carolina Data Acquisition and Reporting Tool [CDART]). Data reports were reviewed periodically by the study quality assurance/control subcommittee (blinded to randomization) to ensure completeness and compliance with data collection procedures and by the study DSMB for participant safety and integrity of the trial.

Descriptive statistics by study site and recruitment route (ARIC vs. de novo) for the recruitment and screening process were completed by the coordinating center, including participation and eligibility at the telephone screening, in-person screening, and comprehensive hearing evaluation. The numbers of participants eligible but who declined to continue screening or to enroll, as well as any documented reasons for discontinuation of enrollment, were summarized. Descriptive statistics of overall basic demographic, hearing, and health profiles of the final enrolled combined cohort are presented.

3 | RESULTS

3.1 | Recruitment results

ACHIEVE recruitment and randomization occurred from November 2017 to October 2019 with 3004 participants completing initial telephone screening, 2344 completing in-person screening, 1294 completing comprehensive hearing evaluation, 1102 found to be study eligible, and 977 participants ultimately randomized (Figure 1). Screening and enrollment of ARIC participants occurred early during the recruitment period but essentially plateaued by Fall 2018, while the recruitment of de novo participants was initially delayed but accelerated around Summer 2018 and continued throughout the duration of the recruitment period (Figure 2).

Reasons for study ineligibility at the telephone and in-person screening visits are summarized in Table 1. For telephone screening, having worn hearing aids in the past year was the most common reason for ineligibility (n = 145, 4.8%), followed by unwillingness to wear hearing aids (n = 82, 2.7%). Relative to the participants recruited de novo, a higher proportion of participants recruited through the ARIC study were unwilling to wear hearing aids when asked (5.2% vs. 2.1%). Of those eligible (n = 2679) based on the telephone screening, 2344 (87.5%) completed an in-person screening visit. Of the 335 participants who did not complete an in-person screening visit, study team members documented reasons for not continuing with the study for 240 participants (Table S2). The majority (31.4%) reported general disinterest in the study and declined to schedule a visit. Concerns due to time (13.4%) and health (9.0%) preventing participation were also relatively common reasons for not enrolling. A small percent (3.0%) declined to schedule an in-person screening due to a desire to immediately obtain hearing aids and an unwillingness to participate in the successful aging health education control.

For in-person screening, the most common reason for study ineligibility was because of the hearing screening results (41.9%) in contrast to vision (0.8%) and cognitive (2.2%) screening results (Table 1). Ineligibility due to hearing screening was lower among participants recruited through the ARIC study versus recruited de novo (16.6% vs. 46.5%, respectively). Of those who completed the in-person screening, 1320 (56.3%) were eligible to proceed to the comprehensive hearing evaluation. However, 26 participants declined to continue to the comprehensive hearing evaluation. Of those who did complete the hearing evaluation (n = 1294), 147 (11.3%) were ineligible due to audiometric hearing loss (PTA <30 or ≥70 dB HL), 80 (6.2%) for permanent conductive hearing loss or medical contraindications to hearing aid use, and 15 (1.2%) for having a word recognition score <60%.

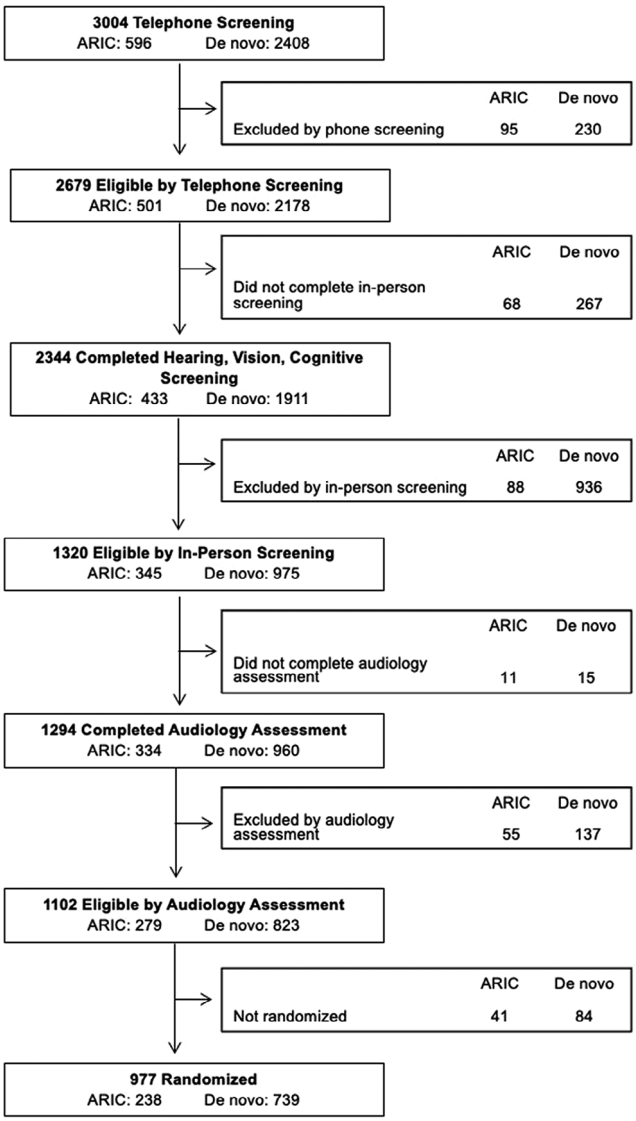

FIGURE 1 Recruitment and screening flow diagram, Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study, recruitment period from November 2017 to October 2019.

Of the 1102 participants eligible for the study following the comprehensive hearing evaluation, 977 (88.7% of eligible) enrolled and were randomized to either the hearing intervention or successful aging health education intervention arms of the study. This represents 32.5% of the total screened (n = 3004) for the study. Of those eligible who did not continue to randomization (n = 125), study team members were able to document a reason for discontinuation in 72 participants (Table S2). General disinterest (23.2%) was the most common reason. Another 7.2% expressed time concerns. Last, 4.8% were unwilling to be randomized at all, 6.4% were unwilling to be randomized to the successful aging health education intervention (e.g., expressed wanting hearing aids right away), and 5.6% were unwilling to be randomized to

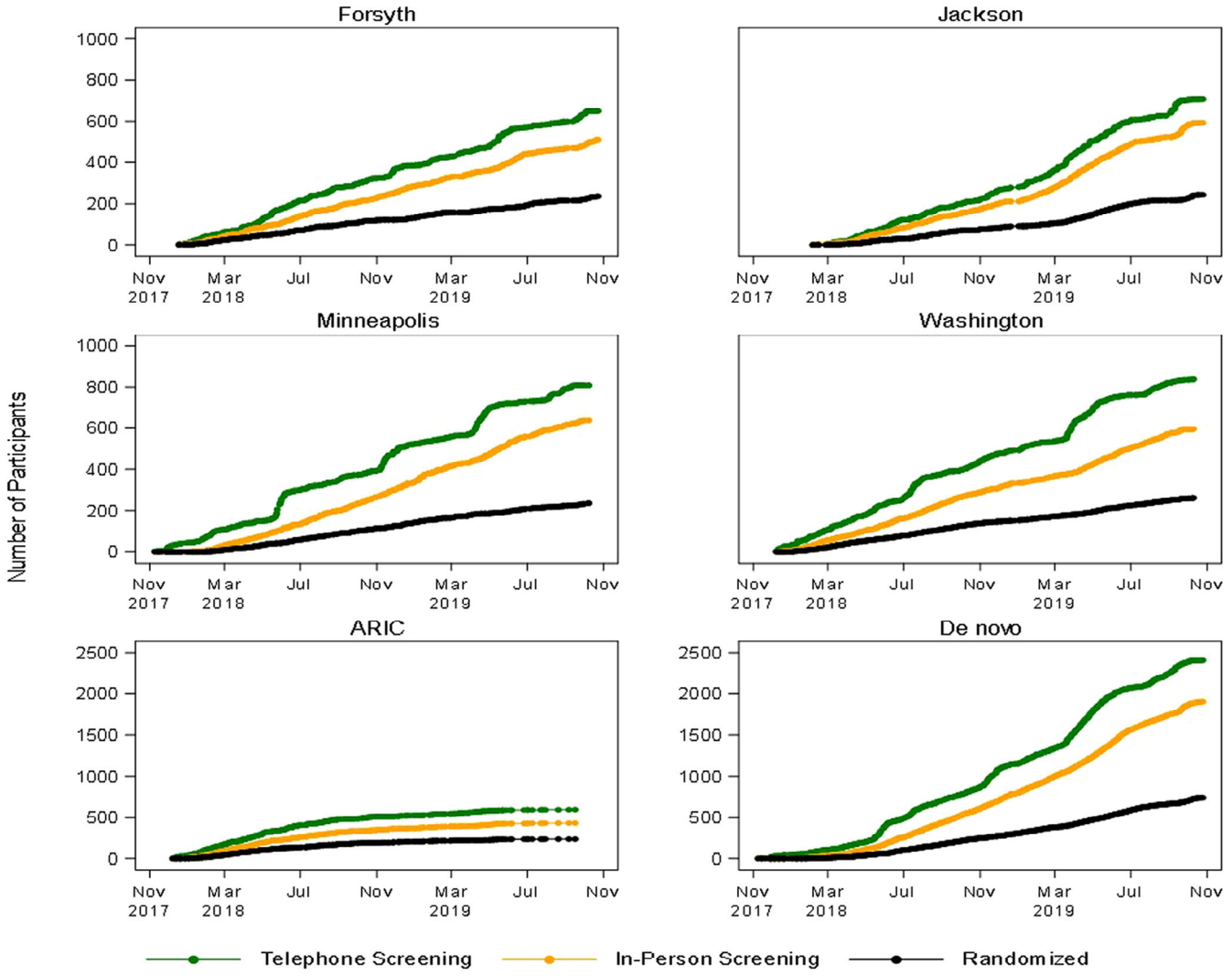

FIGURE 2 Participant cumulative enrollment status by recruitment route and study site, Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study, recruitment period from November 2017 to October 2019.

the hearing intervention (e.g., expressed unwillingness to wear hearing aids).

3.2 | Baseline hearing characteristics by study site and recruitment route

While audiometric values were similar by recruitment route, a higher proportion of participants who were recruited de novo self-reported their difficulty hearing as "moderate trouble" or worse relative to participants recruited through the ARIC study (48.4% vs. 37.4%) (Table 2). Similarly, a higher proportion of participants recruited de novo reported mild-moderate or severe perceived impact of hearing loss on quality of life on the HHIE-S questionnaire relative to participants recruited through the ARIC study (72.5% vs. 54.6%).

3.3 | Baseline demographic and health characteristics by study site and recruitment route

Among the sites, Jackson, MS, had a larger proportion of Black participants (39.1%) relative to other sites (Forsyth, NC: 4.2%; Minneapolis, MN: 2.1%; Washington County, MD: 0.8%), which was expected given the ARIC study limited recruitment in Jackson, MS, to only Black participants (Table 3). Participants from the Minneapolis, MN, site tended to report higher income (> $100,000: 22.9%) and education levels (Bachelor's degree or higher: 65.3%), while participants from Washington County, MD, reported the lowest proportion of participants with a Bachelor's degree or higher education levels (37.4%). Comparing participants recruited through the ARIC study versus de novo, participants recruited trough the ARIC study reported proportionally lower levels of income (> $100,000: 8.4% vs. 20.3%) and educational attainment (Bachelor's degree or higher: 50.0% vs. 54.4%).

TABLE 1 Telephone and in-person screening eligibility by recruitment route and study site, Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study, recruitment period from November 2017 to October 2019.

		Recruitment route		Study site			
Parameter	**Overall**	**ARIC**	**De novo**	**Forsyth**	**Jackson**	**Minneapolis**	**Washington**
Telephone screening	*n* = 3004	*n* = 596	*n* = 2408	*n* = 650	*n* = 708	*n* = 808	*n* = 838
Reasons for ineligibility[a]	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**
Age not between 70 and 84 years	9 (0.30)	1 (0.17)	8 (0.33)	1 (0.15)	5 (0.71)	0 (0.00)	3 (0.36)
Not community-dwelling	4 (0.13)	2 (0.34)	2 (0.08)	3 (0.46)	0 (0.00)	0 (0.00)	1 (0.12)
Not fluent in English	2 (0.07)	1 (0.17)	1 (0.04)	2 (0.31)	0 (0.00)	0 (0.00)	0 (0.00)
Planning to move or health issues	16 (0.53)	5 (0.84)	11 (0.46)	2 (0.31)	3 (0.42)	3 (0.37)	8 (0.95)
Unwilling to be assigned randomly	28 (0.93)	10 (1.68)	18 (0.75)	4 (0.62)	6 (0.85)	1 (0.12)	17 (2.03)
Unwilling to wear hearing aids	82 (2.73)	31 (5.20)	51 (2.12)	11 (1.69)	17 (2.40)	7 (0.87)	47 (5.61)
Wore hearing aids within the past year	145 (4.83)	47 (7.89)	98 (4.07)	26 (4.00)	21 (2.97)	14 (1.73)	84 (10.02)
Congenital or childhood hearing loss	48 (1.60)	11 (1.85)	37 (1.54)	9 (1.38)	8 (1.13)	9 (1.11)	22 (2.63)
Currently enrolled in another cognition/thinking/memory/hearing study	23 (0.77)	4 (0.67)	19 (0.79)	10 (1.54)	2 (0.28)	8 (0.99)	3 (0.36)
Difficulty with the following without help							
Getting in and out of bed	62 (2.06)	12 (2.01)	50 (2.08)	12 (1.85)	23 (3.25)	10 (1.24)	17 (2.03)
Bathing or showering	47 (1.56)	9 (1.51)	38 (1.58)	7 (1.08)	16 (2.26)	14 (1.73)	10 (1.19)
Dressing	33 (1.10)	10 (1.68)	23 (0.96)	3 (0.46)	9 (1.27)	7 (0.87)	14 (1.67)
Eating	18 (0.60)	3 (0.50)	15 (0.62)	2 (0.31)	5 (0.71)	2 (0.25)	9 (1.07)
Toileting	33 (1.10)	3 (0.50)	30 (1.25)	8 (1.23)	6 (0.85)	6 (0.74)	13 (1.55)
Eligibility based on telephone screening	2679 (89.18)	501 (84.06)	2178 (90.45)	591 (90.92)	651 (91.95)	759 (93.94)	678 (80.91)
Hearing, vision, and cognitive screening	*n* = 2344	*n* = 433	*n* = 1911	*n* = 511	*n* = 593	*n* = 638	*n* = 602
Reasons for ineligibility[a]	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**
Hearing screening	960 (40.96)	72 (16.63)	888 (46.47)	183 (35.81)	251 (42.33)	289 (45.30)	237 (39.37)
Vision screening	18 (0.77)	3 (0.69)	15 (0.78)	7 (1.37)	1 (0.17)	7 (1.10)	3 (0.50)
MMSE screening	52 (2.22)	13 (3.00)	39 (2.04)	13 (2.54)	23 (3.88)	4 (0.63)	12 (1.99)
Eligibility based on in-person screening	1320 (56.31)	345 (79.68)	975 (51.02)	309 (60.47)	319 (53.79)	341 (53.45)	351 (58.31)

Note: Description of measures is included in Table S1.

[a]Participants may fulfill more than one criterion for ineligibility; columns do not sum to total.

Abbreviation: ARIC, Atherosclerosis Risk in Communities study; MMSE, Mini-Mental State Examination.

A lower proportion of participants from Minneapolis, MN, self-reported high cholesterol (50.9%), diabetes (12.7%), and arthritis (47.0%) relative to other sites (diabetes: Forsyth, NC: 18.6%, Jackson, MS: 22.2%, Washington County, MD: 25.6%; arthritis: Forsyth, NC: 56.4%, Jackson, MS: 58.4%, Washington County, MD: 60.7%). A higher proportion of participants from Jackson, MS, self-reported hypertension (77.8%) relative to other sites (Forsyth, NC: 62.7%, Minneapolis, MN: 57.2%, Washington County, MD: 68.3%). A larger proportion of participants recruited through the ARIC study versus recruited de novo self-reported hypertension (71.0% vs. 65.2%) and diabetes (28.6% vs. 17.2%). However, a larger proportion of participants recruited through the ARIC study reported clinically significant depressive symptoms (score ≥ 9 on the 11-item Center for Epidemiologic Studies Depression Scale; 5.9% vs. 3.0%) while a smaller proportion self-reported asthma (6.7% vs. 13.0%).

TABLE 2 Baseline audiometric descriptive statistics of randomized participants ($n = 977$), Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study, 2018/2019.

		Recruitment route		Study site			
	Overall	ARIC	De novo	Forsyth	Jackson	Minneapolis	Washington
Parameter	$n = 977$	$n = 238$	$n = 739$	$n = 236$	$n = 243$	$n = 236$	$n = 262$
Pure-tone audiometry (PTA)[a]	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)
30 ≤ PTA < 40,	552 (56.50)	139 (58.40)	413 (55.89)	143 (60.59)	120 (49.38)	144 (61.02)	145 (55.34)
40 ≤ PTA < 70,	425 (43.50)	99 (41.60)	326 (44.11)	93 (39.41)	123 (50.62)	92 (38.98)	117 (44.66)
Hearing-related quality of life[b]	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)
Hearing Handicap Inventory Score, Median (IQR)	14 (14)	10 (14)	16 (16)	16 (12)	18 (18)	12 (10)	12 (16)
No handicap,	304 (31.12)	107 (44.96)	197 (26.66)	53 (22.46)	76 (31.28)	74 (31.36)	101 (38.55)
Mild-moderate handicap	487 (49.85)	103 (43.28)	384 (51.96)	149 (63.14)	103 (42.39)	126 (53.39)	109 (41.60)
Severe handicap	179 (18.32)	27 (11.34)	152 (20.57)	33 (13.98)	61 (25.10)	34 (14.41)	51 (19.47)
Self-report trouble hearing	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)	N(%)
Excellent	12 (1.23)	9 (3.78)	3 (0.41)	1 (0.42)	3 (1.23)	3 (1.27)	5 (1.91)
Good	104 (10.64)	39 (16.39)	65 (8.80)	12 (5.08)	30 (12.35)	25 (10.59)	37 (14.12)
A little trouble	412 (42.17)	99 (41.60)	313 (42.35)	86 (36.44)	80 (32.92)	128 (54.24)	118 (45.04)
Moderate trouble	347 (35.52)	74 (31.09)	273 (36.94)	109 (46.19)	92 (37.86)	70 (29.66)	76 (29.01)
A lot of trouble	99 (10.13)	14 (5.88)	85 (11.50)	27 (11.44)	38 (15.64)	10 (4.24)	24 (9.16)
Deaf	1 (0.10)	1 (0.42)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (0.38)

Notes: For certain measures, categories do not sum to total due to small amounts of missing data. Description of measures is included in Table S1.
[a]A four-frequency (500, 1000, 2000, and 4000 Hz) pure-tone average (PTA) in better hearing ear.
[b]Hearing Handicap Intervention Score: range: 0—40; no handicap: 0–8, mild–moderate handicap: 10–24, severe handicap: 26–40.

4 | DISCUSSION

Over a 24-month period, research staff for the ACHIEVE study completed 3004 telephone screenings, 2344 in-person screenings, and 1294 comprehensive hearing evaluations to ultimately enroll 977 adults between 70 and 84 years of age with hearing loss and without significant cognitive impairment.

Selection bias resulting in differences between participants recruited de novo versus recruited through the ARIC study were evident during the recruitment process. Logistically, recruitment from the well-characterized ARIC cohort provided a pool of essentially pre-screened potential participants to streamline and boost early recruitment while various strategies for de novo recruitment took time to implement (Figure 2). While motivation for study participation was unmeasured, differences may exist between participants recruited de novo and those recruited through the ARIC study. It is plausible that participants recruited de novo were more motivated by concerns about hearing and a strong interest in receiving hearing care relative to the participants recruited through the ARIC study who may have been more motivated by their established rapport with the study staff and history of research participation. This explanation is consistent with the finding that participants recruited through the ARIC study rated their hearing better and were less likely to report that hearing interfered with quality of life relative to participants recruited de novo, despite similar clinical measures of hearing. Further, more participants recruited through the ARIC study were more likely to be ineligible due to unwillingness to wear hearing aids.

Similarly, differences emerged in the baseline characteristics of the participants recruited de novo versus recruited through the ARIC study. Specifically, participants recruited de novo were slightly younger, wealthier, more highly educated, and had lower levels of chronic conditions relative to participants recruited through the ARIC study. This may hint at evidence of a healthy volunteer effect[24] in the participants recruited de novo whereby those who volunteer for research studies, especially observational, prevention, and screening trials, tend to be healthier than the overall population. While the participants from the ARIC study may have also expressed the healthy volunteer effect when initially recruited in 1987, their longstanding participation within an observational cohort may have reduced the effect overtime and possibly served as a form of retention to produce a population of relatively less healthy individuals.

A unique aspect of the ACHIEVE study is the partially nested design within the ARIC study. From a recruitment standpoint, the nested design permitted efficiencies in operational and scientific execution (e.g., shared study staff, data collection manuals, scientific protocols, and clinic infrastructure between ARIC and ACHIEVE). However, nested trials are not without potential drawbacks. Researchers have raised previous concerns regarding nested trials recruiting from a single-source population.[24] The ACHIEVE trial addressed this by including a de novo recruitment pathway. However, despite careful

TABLE 3 Baseline participant characteristics of randomized participants by recruitment route and study site ($n = 977$), Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study, 2018/2019

		Recruitment route		Study site			
Parameter	**Overall**	**ARIC**	**De novo**	**Forsyth**	**Jackson**	**Minneapolis**	**Washington**
	***n* = 977**	***n* = 238**	***n* = 739**	***n* = 236**	***n* = 243**	***n* = 236**	***n* = 262**
Age, median (IQR) (years)	76.42 (6.34)	78.67 (4.66)	75.33 (6.75)	76.58 (5.58)	75.92 (6.92)	76.34 (6.835)	76.92 (6.75)
Female, N(%)	523 (53.53)	147 (61.76)	376 (50.88)	120 (50.85)	139 (57.20)	136 (57.63)	128 (48.85)
Race	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**
Black	112 (11.46)	68 (28.57)	44 (5.95)	10 (4.24)	95 (39.09)	5 (2.12)	2 (0.76)
White	858 (87.82)	169 (71.01)	689 (93.23)	225 (95.34)	148 (60.91)	227 (96.19)	258 (98.47)
Other[a]	7 (0.72)	1 (0.42)	6 (0.81)	1 (0.42)	0 (0.00)	4 (1.69)	2 (0.76)
Income	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**
<$25,000	147 (15.05)	60 (25.21)	87 (11.77)	35 (14.83)	45 (18.52)	19 (8.05)	48 (18.32)
$25,000–$50,000	283 (28.97)	77 (32.35)	206 (27.88)	57 (24.15)	69 (28.40)	68 (28.81)	89 (33.97)
$50,000–$75,000	210 (21.49)	47 (19.75)	163 (22.06)	58 (24.58)	45 (18.52)	54 (22.88)	53 (20.23)
$75,000–$100,000	140 (14.33)	21 (8.82)	119 (16.10)	39 (16.53)	35 (14.40)	37 (15.68)	29 (11.07)
>$100,000	170 (17.40)	20 (8.40)	150 (20.30)	35 (14.83)	45 (18.52)	54 (22.88)	36 (13.74)
Education	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**
Some high school	37 (3.79)	22 (9.24)	15 (2.03)	3 (1.27)	14 (5.76)	2 (0.85)	18 (6.87)
High school diploma or some college	418 (42.78)	96 (40.34)	322 (43.57)	99 (41.95)	93 (38.27)	80 (33.90)	146 (55.73)
Bachelor degree or higher	521 (53.33)	119 (50.00)	402 (54.40)	133 (56.36)	136 (55.97)	154 (65.25)	98 (37.40)
Marital status	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**
Currently married	603 (61.72)	137 (57.56)	466 (63.06)	154 (65.25)	148 (60.91)	141 (59.75)	160 (61.07)
Not currently married	371 (37.97)	101 (42.44)	270 (36.54)	82 (34.75)	95 (39.09)	95 (40.25)	99 (37.79)
Living alone	290 (29.68)	83 (34.87)	207 (28.01)	68 (28.81)	78 (32.10)	71 (30.08)	73 (27.86)
Smoking	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**
Current smoker	25 (2.56)	10 (4.20)	15 (2.03)	3 (1.27)	5 (2.06)	7 (2.97)	10 (3.82)
Former smoker	443 (45.34)	97 (40.76)	346 (46.82)	117 (49.58)	100 (41.15)	118 (50.00)	108 (41.22)
Never smoker	509 (52.10)	131 (55.04)	378 (51.15)	116 (49.15)	138 (56.79)	111 (47.03)	144 (54.96)
Chronic conditions	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**	**N(%)**
Hypertension	651 (66.63)	169 (71.01)	482 (65.22)	148 (62.71)	189 (77.78)	135 (57.20)	179 (68.32)
High cholesterol	584 (59.77)	148 (62.18)	436 (59.00)	143 (60.59)	147 (60.49)	120 (50.85)	174 (66.41)
Diabetes	195 (19.96)	68 (28.57)	127 (17.19)	44 (18.64)	54 (22.22)	30 (12.71)	67 (25.57)
Stroke or TIA	79 (8.09)	23 (9.66)	56 (7.58)	23 (9.75)	19 (7.82)	16 (6.78)	21 (8.02)
Depression	36 (3.68)	14 (5.88)	22 (2.98)	7 (2.97)	14 (5.76)	8 (3.39)	7 (2.67)
Osteoporosis	153 (15.66)	40 (16.81)	113 (15.29)	45 (19.07)	36 (14.81)	33 (13.98)	39 (14.89)
Arthritis	545 (55.78)	137 (57.56)	408 (55.21)	133 (56.36)	142 (58.44)	111 (47.03)	159 (60.69)
Asthma	112 (11.46)	16 (6.72)	96 (12.99)	31 (13.14)	29 (11.93)	22 (9.32)	30 (11.45)
COPD	81 (8.29)	19 (7.98)	62 (8.39)	17 (7.20)	17 (7.00)	13 (5.51)	34 (12.98)
Renal	57 (5.83)	18 (7.56)	39 (5.28)	18 (7.63)	12 (4.94)	7 (2.97)	20 (7.63)

Notes: For certain measures, categories do not sum to total due to small amounts of missing data. Description of measures is included in Table S1.
[a]Other includes Asian, American Indian, Alaskan Native, Native Hawaiian, and Pacific Islands individuals.

consideration to balance the information provided in recruitment messaging between groups, the baseline data suggest slight differences in motivation to join the trial and health and sociodemographic characteristics. Potential differences reinforce the need for pre-specified future analyses stratified by recruitment route.

The perception of hearing loss interfering with quality of life and a desire for hearing aids may have been a strong motivator for some participants to enter the study, regardless of recruitment route (de novo vs. ARIC) and posed a potential challenge to study recruitment, retention, and adherence as some randomized to the successful aging health education control arm may have been unwilling to wait 3 years for hearing aids. Despite this challenge, the overall proportion of screened participants unwilling to accept randomization was low. Efforts at every stage of the recruitment and consent process were made to ensure participants understood the process of randomization, expectations of the trial, and equipoise of the interventions, and to emphasize the study's focus was on cognition rather than hearing loss.

Final study data collection from the 3-year follow-up visit for all participants in the ACHIEVE study concluded in 2022 and findings are expected by late 2023. In addition, an ongoing long-term follow-up study to the ACHIEVE study is in progress now. The ACHIEVE Brain Health Follow-Up study (Clinicaltrials.gov Identifier: NCT05532657) will continue following the ACHIEVE cohort for an additional 3 years (i.e., 6 years total) to determine the long-term effects of hearing intervention on brain health.

An important consideration for interpreting the initial trial and continued observational results is that recruitment of participants was not prospectively designed to be representative of community populations or the demographic make-up of the United States as data collection was limited to four sites. Moreover, the inclusion criteria were limited to older adults in a specific age and degree of hearing loss range among other areas. Generalizability may be limited in applying the main trial findings to other sociodemographic populations and across types and degrees of hearing loss. Notably, given the differences in baseline sociodemographic differences, representativeness of surrounding populations may differ by recruitment route (de novo vs. ARIC), which may warrant consideration for generalizability of secondary analyses by recruitment route. Last, there is potential for the cognitive screening tool used during study recruitment, the MMSE, to fail to detect mild cognitive decline resulting in some individuals with undetected levels of cognitive impairment at baseline; however, the screening cut points were different dependent upon education level to attempt to minimize undetected mild cognitive impairment among adults with higher education levels. Future work should consider representative recruitment efforts to focus on replication of findings in broader populations and improve generalizability. In addition, pragmatic research designs could be used to assess effectiveness as opposed to efficacy in the current randomized control design.

Findings from the ACHIEVE study will provide evidence of the effect of hearing treatment on cognitive decline in community-dwelling older adults with hearing loss. These results have substantial clinical and public health implications for aging. Hearing loss has the unique potential to be a modifiable, mid- to late-life onset risk factor for cognitive decline with a relatively low-risk intervention. Moreover, high-level policy impact from the trial results could include a push for Medicare (US-based state health insurance for adults over 65 years of age) coverage of hearing care given the potential cost-effectiveness of ameliorating other aging outcomes (e.g., cognitive, social, and physical decline).

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CONFLICT OF INTEREST STATEMENT

Dr. Reed reported serving on the scientific advisory boards of Neosensory. Dr. Lin reported being a consultant to Frequency Therapeutics and Apple and being the director of a research center funded in part by a philanthropic gift from Cochlear Ltd to the Johns Hopkins Bloomberg School of Public Health. Dr. Lin is also a board member of the nonprofit Access HEARS. Dr. Sanchez reported industry funding related to consulting or research support from Otonomy Inc., Autifony Therapeutics Ltd., Boehringer Ingelheim, Frequency Therapeutics Ltd., Pipeline Therapeutics, Aerin Medical, Oticon Medical, Helen of Troy Ltd., Sonova Holding AG, and Phonak USA. Theresa Gmelin reports funding by The National Institute on Aging, Epidemiology of Aging training grant at the University of Pittsburgh T32 AG000181. All other authors report no relevant disclosures. Author disclosures are available in the Supporting information

CONSENT STATEMENT

All recruitment and study procedures were approved by each site's Institutional Review Board. All participants provided informed consent during screening and prior to randomization.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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