Results from AD-HEARING (ADherence to and adjustment of HEARING aids in clinical routine care as preventive dementia strategy): a prospective 6-month follow-up study on cognition and psychological well-being

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Background: Age-related hearing loss (ARHL) is a modifiable dementia risk factor and often associated with psychological symptoms. Hearing aid use might reduce this risk by preserving cognitive and psychological functions.

Objective: This study aims to investigate the influence of ARHL and hearing aid use on cognition and different aspects of psychological well-being.

Methods: During 05/2021 and 05/2023, 31 subjects with audiometrically confirmed ARHL were included and 28 underwent follow-up 6 months later (final analysis sample). Successful hearing aid adjustment was controlled by fitting protocols, and hearing aid use was self-reported (IOI-SH). The following primary outcomes were analyzed by general linear models (GLM) for repeated measures and compared between hearing aid users (>8 h of daily use) vs. non-users (≤ 8 h of daily use) at baseline and follow-up: (1) cognition: Consortium To Establish a Registry for Alzheimer's Disease (CERAD-plus, Chandler score), (2) depression: Geriatric Depression Scale, 15-item short form (GDS-SF), (3) social isolation: Lubben Social Network Scale-6-item form (LSNS-6), (4) psychological burden: Symptom Checklist-90®-Standard General Symptom Index (SCL-90®-S GSI), and (5) health-related quality of life: visual analogue scale of the EQ-5D.

Results: Mild cognitive impairment was diagnosed in 11 participants with ARHL at baseline (39.3%). Only a minority exhibited psychological symptoms ($n = 1-2$, 3.6%–10.7% with pathological values in psychological outcomes). All primary outcomes failed to differentiate between hearing aid users vs. non-users over time (all interaction effects ns). At follow-up, between-group differences in psychological burden and quality of life were more pronounced in favor of hearing aid users vs. non-users.

Conclusion: ARHL has a considerable impact on cognition. Whether hearing aid use is able to substantially attenuate cognitive impairment in a short term remains unclear. Further large-scale and long-term follow-up studies are needed to

additionally address specific subgroups who might have more benefit from hearing aid use.

Clinical Trial Registration: https://drks.de/search/de/trial/DRKS00025111, identifier DRKS00025111.

Introduction

As a consequence of demographic change, the prevalence of age-related diseases is steadily increasing. Dementia, as a prototype of such diseases, currently accounts for approximately 47 million cases worldwide (1), including 1.9 million cases in Germany. Moreover, dementia prevalence is expected to heavily increase over the next decades with more than 150 million individuals predicted to be living with dementia by 2050 (1). Being not only a life-limiting disease, dementia puts a great burden on affected individuals as well as caregivers during its progression. It results in high socio-economic costs, in total culminating to a significant global burden. Although great hopes are currently placed on upcoming disease-modifying therapies for the treatment of early Alzheimer's disease (AD; inclusive stages of mild cognitive impairment (MCI) due to AD and mild dementia) as the most frequent cause of dementia, complementary preventive approaches also receive increasing attention. In this context, a reduction of 14 modifiable risk factors as proposed by the Lancet Commission in 2024 (2) is estimated to theoretically prevent or delay 45% of worldwide dementia cases. Risk factor management can thus be considered crucial for dementia prevention.

In particular, midlife or age-related hearing loss (ARHL) is recognized as one of the strongest factors contributing around 7% to an all-cause dementia risk (2–4). This conclusion has been drawn from a multitude of datasets—mainly originating from observational studies with reviews and meta-analyses thereof—strongly supporting the association of ARHL and cognitive impairment (5–7), cognitive decline (8–18), and/or dementia (9, 12, 13, 16, 17, 19–23). Similar to dementia, ARHL is also a widely prevalent health condition driven by global demographic trends. For 2019, the GBD Hearing Loss Collaborators reported that 1.57 billion people are affected by hearing loss (24, 25), and the ARHL cases are projected to be doubled by 2050 (24, 25) due to higher life expectancy.

Several mechanisms potentially linking ARHL, subsequent cognitive decline and dementia have been proposed: (1) common cause (both sharing neuropathological/neurodegenerative pathways, probably predominantly (cardio)vascular), (2) cognitive load/depletion (reallocation of cognitive resources toward auditory processing, thereby depleting cognitive reserve), (3) overdiagnosis/ harbinger theory (ARHL biasing cognitive performance and causing the overestimation of cognitive impairment or vice versa), and/or (4) cascade by impoverished sensory input hypothesis (ARHL driving neurodegenerative processes via (4a) sensory deprivation and/or (4b) social deprivation and depression) (26–33). Supporting the cascade hypothesis, ARHL has also repeatedly been reported to be negatively associated with several aspects of psychological well-being, like depression and depressive symptoms (34–40), social isolation (41–44), decreased quality of life (37, 45–47), or several of those mentioned above (14, 48–52). Most likely, at least some of these relationships with ARHL are bi-directional, and the mechanisms described above are not mutually exclusive in the sense of a multifactorial phenomenon (28, 32, 40, 52–54).

In recent years, steadily emerging evidence investigates how these negative effects of ARHL may be attenuated. For ARHL, conventional hearing aids are available, compensating for the increase of hearing thresholds by means of appropriate sound amplification. It seems most logical that hearing rehabilitation by provision and use of hearing aids should preserve cognitive and psychological functions and thus prevent cognitive decline and the psychological symptoms associated with ARHL. However, data from retrospective and prospective observational studies, as well as reviews and meta-analyses thereof, yielded mixed results so far: Some of them present positive effects of hearing aid use on cognition, slowing of cognitive decline, and reduction of dementia risk (6, 11, 15, 27, 33, 55–57). In other studies, these beneficial effects are restricted to specific cognitive tests/functions (58–64) or to particular subgroups at risk (65, 66), while other publications fail to show positive associations of hearing aid use and cognition (5, 7, 8, 19, 67–69). As a great advantage, these observational studies are capable of providing evidence based on large-scale datasets but suffer from extremely varying information on ARHL and/or hearing aid use (ranging from self-reported to audiometric data and hearing aid use classification by self-report (e.g., "have you ever…?") to automated readouts from hearing aid devices). Prospective, quasi-experimental pre-/post-single-arm or non-randomized controlled studies allow better specification and control of ARHL and hearing aid use albeit at the cost of small sample sizes. Yet, from these studies with follow-up periods of 6 weeks up to 18 months, it also remains unclear whether hearing aid use exerts beneficial effects on a subset of cognitive functions (70–

74) or not (75–77). The recent years have brought first small randomized controlled trials (RCTs with N = 13–40) of 3 to 6 months of trial duration with different control groups (placebo/sham hearing aids, no hearing aid, and/or health education). A clear positive effect on cognition could only be gathered from Brewster et al. (78), whereas in other RCTs this was confined to specific memory functions (79–81). The negative results of a French RCT might be due to too far progressed dementia states (82). In 2023, the results of the ACHIEVE study have been published, a 3-year RCT comparing n = 490 subjects receiving hearing aids to n = 487 health education controls. The primary analysis did not achieve statistical significance between both groups, but an older subgroup at a higher risk for cognitive decline receiving hearing aids showed less cognitive change over time (83).

Besides cognition as a primary outcome, most RCTs and other hearing intervention studies assessed different aspects of psychological functioning as secondary endpoints in parallel [mostly depressive symptoms and quality of life (22, 45, 70, 73, 75, 78, 81, 84)], while some observational studies were subject to the potential effects of hearing aid use on depressive symptoms, social isolation, and/or quality of life exclusively (34, 35, 38, 39, 46, 85). The results were again heterogeneous, showing the presence (34, 35, 45, 70, 73, 78, 84, 85) as well as the absence (22, 38, 39, 75, 81, 86) of positive effects of hearing aid use on psychological well-being. The deliverables of the ACHIEVE study on 3-year follow-up data for mental health outcomes other than cognition are forthcoming.

As a summary of available evidence and while further studies are ongoing, it remains inconclusive whether hearing aid use is able to alleviate the negative cognitive and psychological effects of ARHL. With our study, we aimed to extend the existing evidence (1) by quantifying the impact of ARHL, confirmed by audiometry, on cognition and different facets of psychological well-being and (2) by prospectively and longitudinally investigating the influence of hearing aid use on these parameters in a sample of well-characterized hearing aid users vs. non-users upon initiation of hearing aid use and at 6 months later.

Materials and methods

Study design

AD-HEARING (*ADherence to and adjustment of HEARING aids in clinical routine care as preventive dementia strategy: Improvement of cognition and well-being*) is a monocentric, prospective, longitudinal, and quasi-experimental intervention study of hearing aid use under conditions of regular healthcare delivery in Germany. Starting in 2021, participants were recruited consecutively via various sources (active involvement of regional otolaryngologists and hearing care professionals as well as geriatric departments of other hospitals in the vicinity, including provision of flyers and posters for potential participants, intranet and social media announcements on the website of the University Medical Center (UMC) Göttingen, local press releases, and public dementia events). In-house recruitment at the Department of Psychiatry and

Psychotherapy or the Department of Otolaryngology at the UMC Göttingen was also possible.

The potential participants had to meet the following inclusion criteria: (1) ability to give informed consent, (2) age ≥60 years, (3) speaking German fluently and being able to adequately perform the Freiburg Speech Test as a readout for ARHL and adequacy of hearing rehabilitation, (4) no dementia diagnosis of any cause prior to baseline, and (5) bilateral mild to moderate sensorineural hearing loss (HL) as an indication for a provision with hearing aids. HL was defined according to the recommendations of the World Health Organization (87), i.e., mean value of hearing thresholds at 0.5, 1, 2, 4 kHz (pure tone average, PTA-4) between 20 and 60 dB HL of the better ear. The participants with a conductive component of >20 dB HL at 0.5, 1, 2, or 4 kHz as well as the subjects for whom optimal hearing rehabilitation would probably have required ear surgery (e.g., insertion of an implantable hearing system) were excluded. The participants with a diagnosis of purely unilateral HL could also not qualify for this study. Participation was only possible for first-time hearing aid users (i.e., beginning of hearing aid use within the past 6 months prior to study participation).

The eligible subjects with a hearing aid prescription underwent baseline study procedures. Afterwards or in parallel, hearing aid provision as part of the routine healthcare in Germany (compensated by the individuals' health insurance) was initiated by hearing care professionals. Approximately 6 months later, a second study visit (follow-up) was scheduled. For this follow-up visit, hearing aid users had to provide a fitting protocol for their hearing aids by their hearing care professional as an objective outcome for fitting quality. Following the German guidelines, an improvement of ≥20% in the Freiburg Speech Test in quiet was defined as adequate and successful hearing rehabilitation (88).

Participation was voluntary, and withdrawal was possible at any time. No financial incentives were offered for participation. All participants gave written informed consent. The study and all procedures involving human subjects were approved by the ethics committee of UMC Göttingen, Germany (#36/2/21), and pre-registered at the German Clinical Trials Registry (#DRKS00025111). All study procedures have been conducted according to the Helsinki Declaration of 1975, as revised in 2008.

Study outcomes

Baseline and follow-up study parameters were collected in a time-period from May 28, 2021 to November 28, 2023, with an average number of 195 ± 3.7 days between baseline and follow-up assessment (median time-interval of 6.2 months). The predefined primary study outcomes comprised the parameters of (1) cognition [Consortium to Establish a Registry for Alzheimer's Disease-Plus test battery; CERAD-plus (89), Chandler Score (90)] and psychological well-being, in particular (2) depression [Geriatric Depression Scale—15-item short form; GDS-SF (91, 92)], (3) social isolation [six-item short version of the Lubben Social Networking Scale; LSNS-6 (93, 94)], (4) psychological burden [General Symptom Index (GSI) T-values of the Symptom Checklist-90®-Standard; SCL-90®-S (95)], and (5) health-related quality of life [visual analogue scale of the EQ-5D (96)].

All exploratory secondary outcomes were mainly derived from the assessments on cognition and psychological well-being as listed above. For (1) cognition, the Mini Mental Status Test [MMST (97)] as part of the CERAD-plus battery (range: 0–30), the CERAD Memory Index (range: 0–100%) as well as the CERAD Memory Score (range: 0–41 (98), and the sum score of digit spans (forward and backward, range: 0–36) of the Wechsler Adult Intelligence Scale —4th edition [WAIS-IV (99, 100)] have also entered analysis (digit spans were used to additionally assess working memory). Normative values of CERAD-plus single test results and WAIS-IV digit spans were considered to differentiate between normal cognitive performance and MCI [according to the operationalized MCI criteria by Molinuevo et al. (101)]. At baseline only, the participants additionally gave estimations on their subjective cognitive performance level on a numeric rating scale (0 = "very bad" to 10 = "very good"; descriptive variable). As secondary outcomes for (4) psychological burden, the indices Positive Symptom Total (PST, T-values) and the Positive Symptom Distress Index (PSDI, T-values) of SCL-90®-S were included.

Hearing aid-related healthcare outcomes comprised fitting protocols for hearing aids (baseline and follow-up) and the results from the International Outcome Inventory for Hearing Aids (IOI-HA, German version (102, 103); follow-up only). Additionally, the participants rated their subjective hearing ability on a numeric rating scale (0 = "very bad" to 10 = "very good"; descriptive variable). The fittings protocols contained results from audiometric assessments performed by hearing care professionals to detect ARHL and during the process of routine hearing aid provision and adjustment to assure successful hearing rehabilitation. PTA-4 served as a readout of ARHL and was determined as the mean of the hearing thresholds in dB HL for 0.5, 1, 2, and 4kHz frequencies of both ears. In the IOI-HA, the participants gave a self-report on successful hearing aid use. Item 1 denotes daily use of hearing aids during the past 2 weeks (ratings from 1 = "never" to 5 = "more than 8 hours"), and items 2–7 allow ratings for satisfaction with hearing aid use (ratings from 1 to 5 with varying wording anchors). A mean value ≥3 of the items 2–7 is regarded as general satisfaction with hearing aid use.

Procedures of hearing aid-related regular healthcare (audiometric assessments, prescription of hearing aids) were realized by otolaryngologists and hearing care professionals. Study procedures (psychometric assessments) were performed by trained and experienced neuropsychologists. It took approximately 60–90 min to complete all study-related baseline and follow-up procedures for each participant (including informed consent, medical history, and study assessments).

Group design/study sample

A total of 53 individuals were screened, of whom 31 with ARHL met all of the eligibility criteria described above and underwent baseline study procedures (inclusion between 05/2021 and 05/2023). Reasons for screening failure were (1) already being provided with/using hearing aids >6 months, (2) the ARHL was too mild for the patient to receive a hearing aid prescription, (3) subjective ARHL not confirmed by an otolaryngologist, and (4) age <60 years. After baseline assessment, one participant withdrew his consent, and two more were lost to follow-up. The final analysis sample with baseline and follow-up data comprised $N = 28$ participants (dropout rate of 9.7%; see Figure 1).

At follow-up, the final analysis sample was subdivided into two groups differing in successful hearing aid use. *Post hoc* classification was based on the rating of daily hearing aid use for the past 2 weeks [item 1 of the IOI-HA (102, 103)]. Such $n = 17$ were defined as hearing aid non-users (daily use ≤8 h) and $n = 11$ as hearing aid users (daily use >8 h, i.e., most time of the day; see Figure 1).

Statistical analyses

For data analysis, IBM SPSS Statistics 29 was used. Means with standard deviations (M ± SD), frequencies, Pearson correlations (r), and mean differences (M_{Diff}) were calculated for descriptive representation, respectively. Multiple t-tests for independent samples and chi-square tests were used to test for significant differences between both subsamples (users vs. non-users) at baseline.

To analyze the predefined five primary outcomes (cognition, depression, social isolation, psychological burden, and quality of life), five general linear models (GLM) for repeated measures were created. Baseline and follow-up data were integrated as two-staged within-subjects factor, with both subgroups (users vs. non-users) as two-staged between-subjects factor. Besides both main effects, we tested for interaction effects to analyze possible different trajectories between both subgroups over time and conducted uncorrected pairwise comparisons between both groups for baseline and follow-up (alpha set at 0.05, two-sided).

Additionally, exploratory analyses on our secondary outcomes were conducted (please see Supplementary Material S1 and the results for further information).

Results

Baseline characteristics of the final analysis sample (before provision with hearing aids)

Please see Table 1 for an overview of the baseline characteristics. Of $N = 28$ participants, 60.7% ($n = 17$) were female with a mean age of 72.21 ± 6.94 years, ranging from 60 to 86 years. The majority of subjects were married ($n = 18$, 64.3%). Mean education amounted to 15.88 ± 2.32 years. All participants were German native speakers. Medical history (past and current) mainly revealed cardiovascular diseases ($n = 18$, 64.3%; i.e., hypertension in most cases), followed by endocrinological diseases (i.e., thyroid dysfunction/hypothyroidism; $n = 9$, 32.1%), psychiatric disorders (i.e., depression, bipolar disorder, past post-operational delirium; $n = 9$, 32.1%), metabolic conditions (i.e., diabetes and hypercholesterolemia; $n = 8$, 28.6%), and neurological disorders (i.e., past traumatic brain injury, childhood epilepsy, seizure-free for years; $n = 2$, 7.1%). In single cases, the
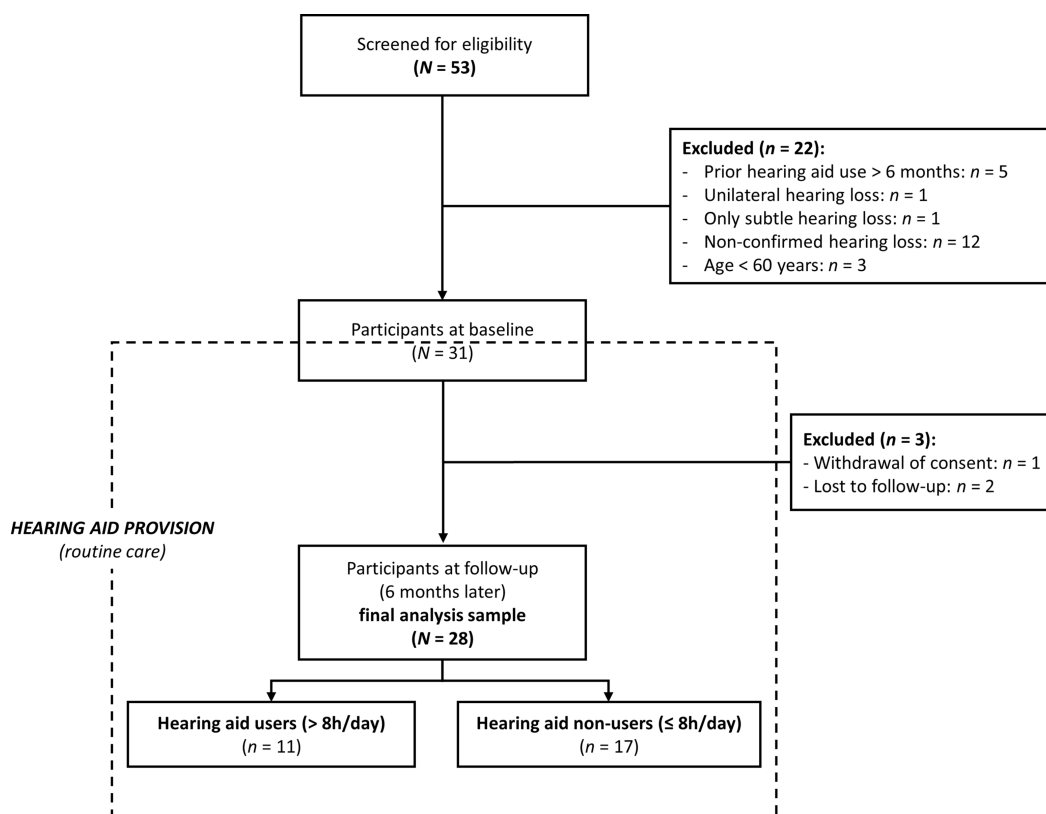
FIGURE 1
Flow of the subjects.

participants suffered from chronic obstructive pulmonary disease and polyneuropathy, rheumatism, and juvenile meningitis (summarized as "others"; n = 3, 10.7%). In three cases, malignancies were reported, all of them backdated for several years. According to their self-reported medical history, antihypertensives were mentioned as the most frequently prescribed concurrent medication (n = 18, 66.7%). Other regular drug use comprised l-thyroxine (n = 8, 29.6%), statins (n = 6, 22.2%), and antidepressants (n = 3, 11.1%).

With a mean of 33.34 ± 7.25 dB, pure tone average (PTA-4) was indicative of mild hearing impairment (i.e., 20–40 dB HL). While all participants had been diagnosed with at least mild ARHL, they rated their hearing ability in the middle range at baseline (11-point numeric rating scale: 0 = "very bad" to 10 = "very good"; 6.66 ± 1.69, ranging from 3 to 10).

Impact of ARHL on cognition and psychological well-being (baseline; without hearing aid use)

The participants rated their subjective cognitive performance as 7.10 ± 1.96, i.e., in the upper range of the numeric rating scale ranging from 0 to 10. The MMST sum scores (28.96 ± 1.20) revealed mild cognitive deficits in n = 2 (7.1%, i.e., MMST ≤26), while n = 26 (92.9%, MMST >26) showed normal cognitive performance. Applying the normative cutoff >69 for cognitive performance of cognitively healthy

older controls presented by Paajanen et al. ([98]), CERAD compound scores (CERAD Chandler Score: 82.34 ± 6.99; CERAD Memory Index ([98]): 92.10 ± 12.45) were mildly impaired in n = 2 (7.1%). According to the operationalized MCI criteria by Molinuevo et al. ([101]), cognitive performance in CERAD-plus and WAIS-IV digit spans at baseline had to be classified as MCI in n = 11 (39.3%) and as normal in n = 17 (60.7%). Patients with MCI differed significantly from those without MCI in the following cognitive parameters: CERAD Memory Score (18.93 ± 4.23 vs. 22.36 ± 1.77; p = .025); z-values of CERAD Figure Recall (-0.41 ± 1.20 vs. 0.96 ± 0.72; p = .004) and CERAD Figure Savings (-0.50 ± 0.93 vs. 0.49 ± 0.50; p = .006). In none of the cases an incident diagnosis of dementia had to be made.

Interpreting the GDS-SF sum scores (2.07 ± 2.73, range 0–11), n = 25 (89.3%) had no or not more than subsyndromal depression, n = 2 (7.1%) mild to moderate depression, and n = 1 (3.6%) severe depression. In n = 3 (10.7%) LSNS-6 sum scores (18.39 ± 4.95, range 5–24), the ratings characterized the subjects as socially isolated (cutoff for social isolation at 12 points). For the SCL-90®-S GSI (48.54 ± 9.65, range 31–75), n = 2 (7.2%) showed T-values >60, i.e., above-average psychological burden. An EQ-5D rating on a visual analogue scale (0–100) reached 74.36 ± 18.69 (range 11–98), with n = 2 (7.1%) rating their health-related quality of life <50.

As to be expected, most primary outcomes for psychological well-being showed a strong covariation (please see Table 2 for correlations between primary outcomes at baseline). This mainly comprised positive correlations between symptom-oriented scales

TABLE 1 Baseline characteristics of the final analysis sample (N = 28).

Variable	Total sample (N = 28)	Hearing aid users (>8 h/day) (n = 11)	Hearing aid non-users (≤8 h/day) (n = 17)	p
Gender (% female)	17 (60.7%)	06 (54.5%)	11 (64.7%)	.591
Age (years)	72.21 ± 6.94	71.18 ± 6.85	72.88 ± 7.11	.536
Marital status (% married)	18 (64.3%)	07 (63.6%)	11 (64.7%)	.954
Education (in years)	15.88 ± 2.32	15.73 ± 2.11	15.97 ± 2.50	.792
Medical history				
Cardiovascular	18 (64.3%)	06 (54.5%)	12 (66.7%)	.387
Metabolic	08 (28.6%)	03 (27.3%)	05 (29.4%)	.903
Endocrinological	09 (32.1%)	04 (36.4%)	05 (29.4%)	.700
Neurological	02 (07.1%)	01 (09.1%)	01 (05.9%)	.747
Psychiatric	09 (32.1%)	03 (27.3%)	06 (35.3%)	.657
Others	03 (10.7%)	01 (09.1%)	02 (11.8%)	.823
Current medication[a]				
Antihypertensives	18 (66.7%)	05 (45.5%)	13 (81.3%)	.053
L-Thyroxine	08 (29.6%)	03 (27.3%)	05 (31.3%)	.824
Statins	06 (22.2%)	02 (18.2%)	04 (25.0%)	.675
Antidepressants	03 (11.1%)	01 (09.1%)	02 (12.5%)	.782
Hearing ability (subjective rating)	6.66 ± 1.69	7.00 ± 1.90	6.44 ± 1.56	.403
Pure tone average (PTA-4) in dB[b]	35.93 ± 5.45	37.78 ± 4.23	34.47 ± 5.99	.135

Means ± standard deviations or frequencies (%) presented. The comparisons are based on two-tailed independent t-tests or chi-square tests. For subjective hearing ability, the participants were asked to rate their hearing ability on an 11-point numeric scale (ranging from 0 = complete hearing loss to 10 = perfect hearing ability).
[a]N = 27 due to missing data for n = 1 with hearing aid use ≤8 h.
[b]N = 25 due to missing data for n = 3 with hearing aid use ≤8 h.

(e.g., GDS-SF and SCL-90®-S GSI; r = .688, p <.001) and negative correlations between symptom-oriented vs. resource-based scales (e.g., SCL-90®-S GSI and EQ-5D; r = -.573, p = .001).

Influence of hearing aid use on cognition and psychological well-being

Hearing aid users did not differ significantly from non-users in any of the sociodemographic and clinical baseline characteristics (please see Table 1, all comparisons ns). Five participants stated at

follow-up to have never used hearing aids (17.9%). Of those using hearing aids (n = 23), satisfaction with hearing aid use (quantified as mean of items 2–7 of the IOI-HA) was high in general (3.99 ± 0.56 for the final analysis sample) with significantly higher ratings of users (4.30 ± 0.36) compared to non-users (3.68 ± 0.55; p = .006). At follow-up, all participants who had provided a fitting protocol showed successful hearing aid provision, resulting in at least 20% improvement of the Freiburg Speech Test.

For primary outcome analysis, please see Figure 2 for the trajectories from baseline to follow-up for hearing aid users vs. non-users and Table 3 for all GLM with tests for (main) effects and

TABLE 2 Primary outcomes at baseline: Correlations and descriptive results for the final analysis sample (N = 28).

Variable	1	2	3	4	M ± SD
1. CERAD Chandler Score	–				82.34 ± 6.99
2. GDS-SF	.340	–			2.07 ± 2.73
3. LSNS-6	-.380*	-.550**	–		18.39 ± 4.95
4. SCL-90-S GSI (T-values)	.234	.688**	-.437*	–	48.54 ± 9.65
5. EQ-5D	-.173	-.428*	.119	-.573**	74.36 ± 18.69

Pearson correlations (*p <.05, **p <.01), means ± standard deviations presented. CERAD Chandler Score (Consortium to Establish a Registry for Alzheimer's Disease; 0–100); GDS-SF (Geriatric Depression Scale—short form; 0–15); LSNS-6 (Lubben Social Network Scale—six-item short form; 0–30); SCL-90®-S GSI T-values (Symptom Checklist-90®-Standard General Symptom Index; l 20-80); EQ-5D (0–100).

pairwise comparisons. For (1) cognition (CERAD Chandler Score, Figure 2A) and (3) social isolation (LSNS-6, Figure 2C), we did not find any significant (main or interaction) effect or pairwise comparison between both groups at baseline or follow-up. For (2) depression (GDS-SF, Figure 2B), a significant between-subjects effect was found ($F(1, 26) = 4.94$, partial $\eta^2 = 0.16$, $p = .035$). Both at baseline ($M_{Diff} = 1.91$, $p = .033$) and follow-up ($M_{Diff} = 1.83$, $p = .031$), hearing aid users showed significantly fewer depressive symptoms. For both assessment time-points, this significant between-group differences remained at a stable level, resulting in a non-significant interaction effect ($F(1, 26) = 0.01$, ns). Although for (4) psychological burden (SCL-90(R)-S GSI, Figure 2D), the

interaction effect failed to reach significance ($F(1, 26) = 1.30$, ns), the descriptive analysis suggested that hearing aid users had a decrease of psychological burden from baseline (42.45 ± 7.70) to follow-up (39.09 ± 6.66). Furthermore, a significant between-subjects effect was found ($F(1, 26) = 13.00$, partial $\eta^2 = 0.33$, $p = .001$), which was more pronounced in pairwise comparisons at follow-up ($M_{Diff} = 12.56$, $p < .001$) than at baseline ($M_{Diff} = 10.02$, $p = .005$) with less psychological burden for hearing aid users than in non-users. A similar pattern was found for (5) health-related quality of life (EQ-5D, Figure 2E). The interaction effect failed to reach significance ($F(1, 26) = 2.44$, ns) as did the within-subjects effect ($F(1, 26) = 0.36$, ns), and the EQ-5D ratings varied between both subgroups between
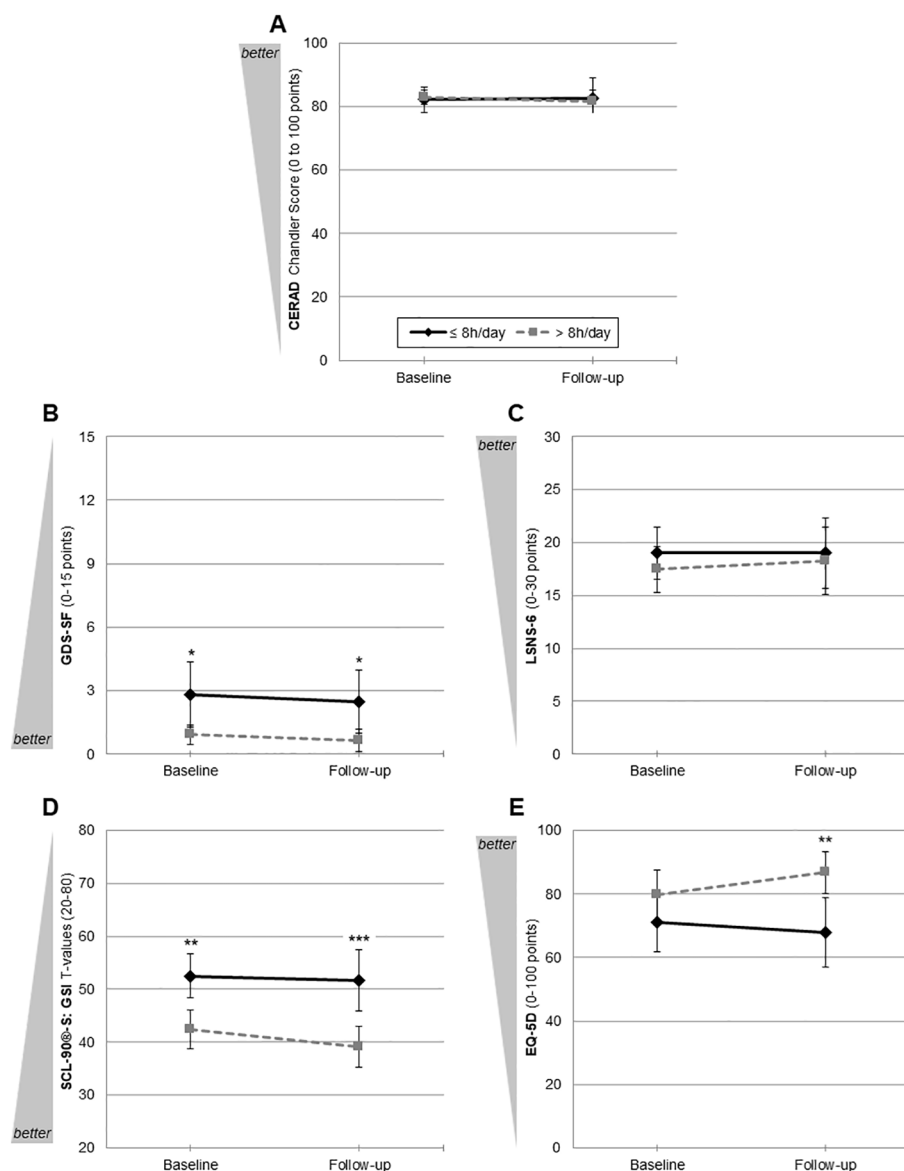

FIGURE 2
Trajectories from baseline to follow-up of primary outcomes for hearing aid users ($n = 11$) and non-users ($n = 17$). **(A)** Cognition: CERAD Chandler Score (Consortium to Establish a Registry for Alzheimer's Disease; 0−100); **(B)** depression: GDS-SF (Geriatric Depression Scale—15-item short form; 0−15); **(C)** social isolation LSNS-6 (Lubben Social Network Scale—six-item short form; 0−30); **(D)** psychological burden: SCL-90®-S GSI T-values (Symptom Checklist-90®-Standard General Symptom Index; 20−80); **(E)** quality of life: EQ-5D (visual analogue scale; 0−100). *$p < .05$, **$p < .01$, ***$p < .001$. Mean values with 95% CIs uncorrected pairwise comparisons for each outcome parameter.

TABLE 3 GLM results and pairwise comparisons for primary outcomes between hearing aid users and non-users ($N = 28$).

Variable	Within-subjects	GLM ($F_{(1, 26)}$, η^2, p) Between-subjects	Interaction	Pairwise comparisons (M_{Diff}, p) Baseline	Follow-up
CERAD Chandler Score	$F = 0.12$, $\eta^2 = 0.01$, $p = .734$	$F = 0.01$, $\eta^2 < 0.01$, $p = .945$	$F = 0.75$, $\eta^2 = 0.03$, $p = .393$	$M_{Diff} = -0.70$, $p = .779$	$M_{Diff} = 1.11$, $p = .758$
GDS-SF	$F = 0.79$, $\eta^2 = 0.03$, $p = .382$	$F = 4.94$, $\eta^2 = 0.16$, **$p = .035*$**	$F = 0.01$, $\eta^2 < 0.01$, $p = .910$	$M_{Diff} = 1.91$, **$p = .033*$**	$M_{Diff} = 1.83$, **$p = .031*$**
LSNS-6	$F = 0.71$, $\eta^2 = 0.03$, $p = .407$	$F = 0.33$, $\eta^2 = 0.01$, $p = .569$	$F = 0.71$, $\eta^2 = 0.03$, $p = .407$	$M_{Diff} = 1.55$, $p = .430$	$M_{Diff} = 0.73$, $p = .736$
SCL-90®-S GSI	$F = 3.54$, $\eta^2 = 0.12$, $p = .071$	$F = 13.00$, $\eta^2 = 0.33$, **$p = .001**$**	$F = 1.30$, $\eta^2 = 0.05$, $p = .264$	$M_{Diff} = 10.02$, **$p = .005**$**	$M_{Diff} = 12.56$, **$p <.001***$**
EQ-5D	$F = 0.36$, $\eta^2 = 0.01$, $p = .551$	$F = 5.50$, $\eta^2 = 0.18$, **$p = .027*$**	$F = 2.44$, $\eta^2 = 0.09$, $p = .130$	$M_{Diff} = -8.70$, $p = .236$	$M_{Diff} = -18.86$, **$p = .005**$**

F-/p-/η^2 values for within-subject effects (change from baseline to follow-up), between-subject effects (hearing aid use: non-users: ≤8 h/day; users: > 8 h/day) and interaction effects for each GLM. Mean differences (M_{Diff}) and uncorrected pairwise comparisons between non-users and users for baseline and follow-up. *$p < 0.05$, **$p < 0.01$, 05, ***$p < 0.001$ (significant differences bolded). CERAD Chandler Score (Consortium to Establish a Registry for Alzheimer's Disease; 0–100); GDS-SF (Geriatric Depression Scale—short form; 0-15); LSNS-6 (Lubben Social Network Scale—six-item short form; 0–30); SCL-90®-S GSI T-values (Symptom Checklist-90®-Standard General Symptom Index; 20–80); EQ-5D (visual analogue scale; 0–100). Please see also Figure 2 for all trajectories.

baseline and follow-up, with numerically higher quality-of-life estimations for users at both time-points. While at baseline the between-group difference did not reach significance ($M_{Diff} = -8.70$, $p = .236$), it did so at follow-up ($M_{Diff} = -18.86$, $p = .005$). Within the GLM, this was mainly expressed by a significant between-subjects effect ($F(1, 26) = 5.50$, partial $\eta^2 = 0.18$, $p = .027$).

Data on exploratory secondary outcomes can be found in Supplementary Material S1. The trajectories from baseline to follow-up for hearing aid users vs. non-users are visualized in Supplementary Figure S1. Please see also Supplementary Table S1 for all GLMs with tests for main and interaction effects and pairwise comparisons. For (1) cognition parameters, MMST, CERAD Memory Index, CERAD Memory Score, and WAIS-IV digit spans neither significant (main or interaction) effects nor significant pairwise comparisons between the subgroups at baseline or follow-up were found (see Supplementary Figures S1A–F). As an additional readout for (1) cognition, the chi-square tests did not reveal a significant deviation of frequencies of syndromal MCI diagnoses between hearing aid users vs. non-users, both at baseline (users: $n = 3$ (27.3%); non-users: $n = 8$ (47.1%); ns) and follow-up (users: $n = 3$ (27.3%); non-users: $n = 7$ (41.2%); ns). For (4) psychological burden, the additional outcomes PST and PSDI did not reach significance for interaction effects ($F(1, 26) = 2.25$ and 0.01, both ns, Supplementary Figures S1E,F) as well. However, for PST, a significant between-subjects effect was found ($F(1, 26) = 15.79$, partial $\eta^2 = 0.38$, $p <.001$), with hearing aid users experiencing significantly less psychological burden at baseline ($M_{Diff} = 9.41$, $p = .033$). This difference increased at follow-up ($M_{Diff} = 12.87$, $p <.001$; Supplementary Figure S1E). A significant between-subjects effect was also detected for PSDI ($F(1, 26) = 5.26$, partial $\eta^2 = 0.17$, $p = .030$). The hearing aid users showed less psychological burden in general, barely missing significance at baseline ($M_{Diff} = 6.52$, $p = .057$) but reaching significance at follow-up ($M_{Diff} = 9.41$, $p = .033$) due to a lowered standard deviation (see also Supplementary Figure S1F for 95% CIs).

Discussion

The results of the present AD-HEARING study add another important piece of evidence on the effects of both ARHL per se and hearing aid use on cognition and different aspects of psychological well-being. We were able to show that ARHL is potentially associated with a considerable impact on cognition as indicated by a high rate of MCI diagnoses at baseline. At the same time, we only found mild negative effects of ARHL on psychological well-being in our sample. In this quasi-experimental approach, all ARHL participants who qualified for a hearing aid provision had the possibility to benefit from hearing aids. Although after 6 months of hearing aid use all primary outcomes failed to improve exclusively for hearing aid users in comparison to non-users over time, it could be shown that hearing aid use for most time of the day is associated with an attenuation of psychological burden and an improved quality of life compared to non-use or infrequent/irregular/occasional use.

With respect to the cognitive effects of ARHL, we found syndromal MCI in 39.3% of included ARHL subjects. MCI is common among older adults of the general population with prevalence estimates for individuals aged ≥65 between 16% and 23% worldwide (104) and 20.3% for individuals 60–75 years old in Germany (105). This indirectly supports the associations of ARHL and impaired cognition, cognitive decline, and dementia replicated many times [for a summary, see (2, 4)]. As pre-existing dementia was an exclusion criterion, the probability to detect new dementia diagnoses was low, and no dementia diagnoses had to be made in this study. Another important research topic in this field would be to further identify cognitive profiles and/or potential cognitive resources in ARHL, e.g., for non-auditory-based cognitive tests [visuospatial ability, i.e., visuoconstruction and visual memory (106)]. Such findings could not only lead to more specific treatment targets in hearing rehabilitation but may also contribute to gain deeper insights into mechanisms linking ARHL

to cognition. For the AD-HEARING study, we chose not to analyze single test results due to a limited sample size (risk of over-interpretation of single test results). More specifically, in a high-functioning sample as in our study, it would have been unlikely for potential differences to survive Bonferroni correction.

The minor negative effects of ARHL with respect to depression, social isolation, psychological burden, and quality of life of the present study stand in contrast to other findings (14, 34–52). For example, Mulrow et al. (45) reported that 24% of their participants with ARHL were depressed and 82% had adverse effects on their quality of life—compared to 10.7% with relevant depressive symptoms and 7.1% with low quality-of-life ratings in our study, indicative of a high-functioning ARHL sample. Yet, psychological outcomes revealed high interdependencies. Reviews also suggest an interplay of these variables in ARHL, especially for social isolation and depression (49, 51). This would also be supported from our correlational findings relating depressive symptoms, social isolation, psychological burden, and quality of life. Associations might be bi-directional (40, 52) and—at least in parts—independent associations (27, 38). Furthermore, no or no plausible correlations emerged between cognition and different aspects of psychological well-being, which might indicate cognition playing an at least partially independent role with respect to psychological outcomes in ARHL. In this line of thought, Brewster et al. (22) claimed that ARHL and depression may be independent risk factors for cognitive decline. From another perspective, it might also be argued whether decreased levels of psychological well-being, such as higher levels of depressive symptomatology or higher psychological burden before the initiation of hearing aid use as found here, might prevent ARHL individuals from using hearing aids. As a practically relevant conclusion, depressive symptomatology and perceived psychological burden should be taken into consideration when counseling for hearing aids to achieve higher compliance and adherence rates in hearing aid use.

Although for hearing aid users vs. non-users predefined primary outcomes in this study yielded no significantly different trajectories over time, the question on the effects of hearing aid use on cognition and psychological well-being has to be left unanswered as yet. While others also failed to prove the beneficial effects of hearing aid use (22, 38, 39, 75, 81, 86) or had positive proof for specific subgroups with a specific risk profile only (66, 83), reasons for the absence of positive effects of hearing aid use may be manifold, namely:

1. Sample size: As in our study, the study samples are small in most of the cases, preventing from reaching statistical significance.
2. Follow-up duration: A follow-up of 6 months is most likely too short to allow detection of significant cognitive decline and subsequent conversion to dementia, underlining the need for long-term trials of more than one or even several years. Although the first evidence is available showing signs of cortical reorganization (107) and restoration of neural function (80) already after 6 months of hearing aid use, these timeframes are probably too short to exert overall and

clear dementia-preventive effects of hearing aids surpassing clinical thresholds.

3. Selection of study populations: A considerable proportion of subjects voluntarily participating in studies may be high-functioning and not severely affected enough by negative consequences of ARHL to show considerable changes within 6 months or 1 year (inclusion/selection bias). This additionally calls for studies with longer follow-ups. It is a tough challenge to meet a critical time-point for prevention trials: For more advanced cognitive deficits (i.e., dementia), studies on hearing aid use are most likely to fail, e.g., as shown by several studies (61, 76, 82, 108). On the other hand, trials including cognitively healthy subjects at baseline would have to be designed at the cost of longer follow-ups challenging adherence to study interventions and assessments. Positively, better cognitive functioning may predispose toward a more frequent or persistent hearing aid use (33). Furthermore, on the basis of two recent studies, it becomes likely that hearing aid use exerts positive effects only on subgroups with specific risk profiles (66, 83).

4. Outcome parameters and study design: The mixed results on hearing aid use may be caused by different choices of outcome parameters. For cognition and different psychological functions expected to be affected by ARHL, a multitude of assessment methods are available. Irrespective of the specific parameters selected, assessments should be comprehensive and sensitive enough to allow valid classifications and detection of changes and should not rely on cognitive screening instruments (e.g., like the MMST) or single questions on psychological states only. The MMST is still a well-established international instrument but has limitations in terms of diagnostic accuracy. Especially in the detection of first cognitive changes (as in MCI), its sensitivity is considerably lower compared to the Montreal Cognitive Assessment [MoCA, e.g., (109–111)]. Accordingly, for the present study, the MMST entered analyses as exploratory secondary outcome. Beyond cognitive screening tests, the CERAD plus test battery as gold standard in German-speaking countries/memory clinics is a comprehensive and valid tool to detect more subtle changes, and its composite Chandler score has been chosen as primary outcome for cognition in this study. A quantitative meta-analysis (112) reported a sensitivity level of 82.4% and a specificity level of 76% with an area under the SROC of 0.856 for the CERAD plus test battery in MCI. The CERAD compound scores showed 87%–89% sensitivity and 84%–86% specificity in screening for prodromal AD (98). For neuropsychological assessments in ARHL, it has to be additionally considered that audiological status may interfere with the results of traditionally performed cognitive tests (113). Given that all cognitive tests make demands on auditory processing to varying degrees, ranging from low (comprehension of test

instructions) to high (purely relying on auditory processing like in the WAIS-IV digit spans or WMS-IV logical memory), an ARHL-related effect on cognitive test performance may be expected to occur more likely in tests with high auditory demands [e.g., (114)]. Despite this, other recent studies [e.g., the ACHIEVE RCT, see (83)] also used those high-demanding tests as cognitive outcomes. For the CERAD plus test battery, there is more recent data (115) showing that none of its subtests is correlated to visual and hearing dysfunction or—vice versa–acuity (except for a correlation between worse visual acuity and Trail Making Test). Although not excluding ARHL-related decline from a high level in our high-functioning ARHL sample, WAIS-IV digits spans were within in the normal range for the vast majority of participants at baseline (data not shown). Solutions to overcome a potential bias when assessing the cognitive functions of interest might be to modify traditional assessments in order to reduce auditory demands (at the cost of additional validation studies for modified versions) or to replace single tests by those with low auditory demands (e.g., for working memory assessment: replacing WAIS-IV digit spans by Corsi block tapping test).

By not exclusively focusing on cognition, our psychological outcome parameters acknowledge their independent contribution or mediating role to cognitive decline in ARHL. Studies assessing additional parameters besides cognition were mainly restricted to depression and/ or health-related quality of life, and only a few studies have integrated more than these aspects. Very similar to our study design, a non-randomized controlled trial (75) and a single-arm pre-/post-comparison study (74) measured comparable outcomes (cognition, depression/mood, social isolation, and quality of life/well-being). However, the non-randomized controlled trial in mild to moderate ARHL with a follow-up of 6 months also missed an effect of hearing aid use in all domains (75), while the single-arm study reported relative stability and clinically and statistically significant improvement in cognition (executive functions) and quality of life after 18 months of hearing aid use (74). At least for quality of life and very consistently for psychological burden, we found a tending greater increase in quality of life and less pronounced psychological burden in hearing aid users vs. non-users after 6 months.

5. Heterogenous definitions of ARHL and hearing aid use: Mixed findings may be additionally facilitated by different methods in defining ARHL (e.g., self-report vs. audiometry), assuring adequacy of hearing rehabilitation via fitting protocols and quantifying hearing aid use (single-question approaches: "do you use hearing aids?" vs. self-report vs. self-report based psychometric assessment vs. hearing aid use vs. automated log-in readouts of hearing devices). In contrast to epidemiological or other observational data, prospective, quasi-experimental pre-/

post-single- or multiple-arm as well as non-randomized controlled studies and RCTs bear the potential for a better characterization of ARHL and hearing aid use. Audiometric data to substantiate ARHL and its degree as well as valid information whether hearing aid provision was successful (via fitting protocols) and quantitative information about hearing aid use should deliver more profound evidence when investigating the effects of ARHL and hearing aid use on cognition and psychological parameters rather than self-report alone (38). In some cases, self-reported or informant-based vs. objective data even showed divergent results for the associations of ARHL and dementia (18) or depression (38). Audiometric assessments and objective reassurance of successful hearing aid provision should therefore be mandatory elements of such studies. Accordingly, more and more studies provide data on the adequacy/success of hearing rehabilitation, e.g., via fitting protocols (34, 71, 73–77, 79–83). For hearing aid use, it is unclear as yet how long hearing aids should be worn per day to be probably of use or greater use in preventing from adverse effects on cognition and psychological well-being. We have categorized the ARHL participants into users based on daily hearing aid use for more than 8 h per day (derived from IOI-HA item 1) interpretable as regular, habitual, or frequent users. This criterion for hearing aid use may be considered strict. However, similar negative findings for primary outcomes resulted when using a 4-h criterion or when analyzing pre–post comparisons for the complete analysis sample (data not shown). Furthermore, comparable studies applied definitions to distinguish between users and non-users or provided data on hearing aid use within the range of our distinction [ranging from ≥5 to 12 h a day (27, 71, 72, 74, 75, 78–80, 82–84, 107)]. Nevertheless, it is an unmet need to identify boundaries for frequent, habitual, or regular use vs. infrequent, occasional, or irregular use. Finally, it has to be restated that ARHL is yet underdiagnosed or underrecognized and undertreated (25) with less than 15% in the US (116) and 9% in the UK (117) of subjects with ARHL using hearing aids. This underlines the efforts that still have to be made for a higher awareness of ARHL and the associated effects.

Strengths and limitations

Our study was deliberately designed to combine cognitive outcomes with different aspects of psychological well-being like depression, social isolation, psychological burden, and quality of life. For this purpose of a multifaceted approach, we have chosen established cognitive tests and psychometric instruments. It is also a clear strength of our study design to present a well-characterized sample of subjects with ARHL and to rely on audiometric data for the measurement of ARHL, fitting protocols to assure adequate and

successful hearing aid rehabilitation and on psychometric data for hearing aid use (IOI-SH). With these procedures, it was able to limit self-report bias and ARHL severity bias. For hearing aid use, automated readouts of hearing aid logs could additionally improve the quality of our study design.

Most obviously, our sample size was too small to make definitive claims on the prospects of hearing aid use for cognition and psychological well-being. However, comparable prospective studies (70–72, 74–77) and even RCTs (78–82) share similar or even smaller sample sizes. Although this issue might have prevented the present study from achieving significant results, we found some mild positive effects on psychological burden and quality of life in hearing aid users. Furthermore, a follow-up period of 6 months of hearing aid use may be too short to obtain noticeable preventive effects on cognitive decline and dementia and is at best suitable to detect rather short-term changes in cognitive performance and psychological well-being. Importantly, follow-up in study designs like the present can easily be prolonged without ethical considerations because of not preventing participants eligible for hearing aids from their use. Although our study cannot compete with the standards of large-scale RCTs like the ACHIEVE study (83), the ethical concern has to be raised whether subjects of the control conditions may be prevented from using hearing aids for such a long time (i.e., 3 years in the ACHIEVE RCT). Even if it is unclear if hearing aid use is helpful in preventing cognitive impairment, decline, and dementia, it is a treatment which is definitely helpful in treating ARHL, combining cost-effectiveness in dementia prevention with quality-of-life gains (118)—and is yet undertreated. We therefore put up for discussion if non-randomized controlled trials or quasi-experimental studies like ours may be ethically more appropriate and comparably suitable to ultimately draw definite conclusions on the effects of hearing aid use for dementia prevention. For this purpose, (multiple) future long-term studies are needed—at best overcoming interfering factors as described above. Large samples in those trials will also enable to identify subgroups with more clear and substantial benefits for dementia prevention through the use of hearing aids.

Conclusions

Despite the negative primary outcomes of the present AD-HEARING study and with mild effects on psychological burden and quality of life in hearing aid users, preventive efforts should be strongly pursued in terms of increasing awareness for underrecognized ARHL and the underuse of hearing aids. Whether effective in preventing dementia or adverse psychological effects or not, hearing aids bear no medical risk and might be cost-effective in reducing the risk of developing dementia. Underdiagnosis might be reduced by implementing hearing tests in the evaluation of geriatric populations and in those suspected of having cognitive dysfunction (119) or by referring to audiometric testing. Subsequently, adherence to hearing aid use should be

supported by repeated follow-up visits, and psychological states probably restricting its regular use should be considered during counseling. To receive convincing proof on hearing aid use for dementia prevention, future studies are needed to hopefully resolve methodological and ethical issues and as add-on integrating fluid/blood biomarker analyses. Those studies may identify subgroups within this highly prevalent health condition who might benefit most from hearing aid use. For this purpose, the AD-HEARING study shows feasibility and provides a valuable approach to be further pursued and performed on larger samples and longer follow-ups.

Data availability statement

The datasets presented in this article are not readily available due to privacy or ethical restrictions. Requests to access the datasets should be directed to claudia.bartels@med.uni-goettingen.de.

Ethics statement

The studies involving humans were approved by the ethics committee of the UMC Göttingen, Germany. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

Funding

Conflict of interest

RK was supported in part by the medical hearing implant company MED-EL for collaboration on a purely technical study in 2023. CB received honoraria as a commercial advisory board member for Lilly and honoraria for lectures from Roche, Lilly, Esai and Boehringer Ingelheim.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2025.1494197/full#supplementary-material

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