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A Pilot Randomized Controlled Trial of Hearing Aids to Improve Mood and Cognition in Older Adults

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Abstract

Objectives: Age-related hearing loss (ARHL) is a prevalent condition associated with increased risk for depression and cognitive decline. This 12-week prospective, double-blind pilot randomized controlled trial (RCT) of hearing aids (HAs) for depressed older adults with ARHL evaluated the feasibility of a novel research design.

Methods/Design: N=13 individuals aged ≥60 years with Major Depressive Disorder or Persistent Depressive Disorder and at least mild hearing loss (pure tone average ≥30dB) were randomized to receive full- (active) vs. low-amplification (sham) HAs added to psychiatric treatment as usual. Duration of HA use in hours/day, adverse events frequency, attrition rate, and maintenance of the study blinding were the primary outcome measures.

Results: Compliance with HAs was excellent (>9 hours/day for both groups) and rates of adverse events and drop-outs did not differ between groups. Preliminary data demonstrated differential improvement for active vs. sham HAs on hearing functioning (Hearing Handicap Inventory for the Elderly [nonparametric effect size (np-ES) =.62]), depressive symptoms (Inventory for Depressive Symptomatology [np-ES=.31]), cognition (Repeatable Battery for the Assessment of Neuropsychological Status Immediate Memory [np-ES=.25]), and general functioning (World Health Organization Disability Assessment Schedule [np-ES=.53]). Significantly greater than 50% of both groups correctly guessed their treatment assignment, indicating incomplete concealment of treatment allocation.

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Data Availability Statement: The data that support the findings of this study are available on request from the corresponding author, [KKB]. The data are not publicly available due to their containing information that could compromise the privacy of research participants.

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Conclusions: This pilot RCT for ARHL and late-life depression was feasible to execute and showed clinical promise, but improved methods of blinding the experimental treatments are needed. Larger studies should investigate whether hearing remediation may be an effective preventative and/or therapeutic strategy for late-life depression and cognitive decline.

Keywords

hearing loss; hearing aids; depression; cognitive impairment

INTRODUCTION

Age-related hearing loss (ARHL) is the third most common health condition affecting older adults after heart disease and arthritis.[1] The prevalence of ARHL rises steeply with age, from 3% among adults 20-29, to 45% of adults 60-69, to above 80% in individuals over 80 years.[2,3] Untreated hearing loss affects more than 38 million Americans[2] and has been estimated, by using two different datasets, to result in $852 billion in increased medical costs over 10 years.[4] While historically considered a benign effect of aging or exclusively a quality of life issue, ARHL is in fact associated with psychological and medical morbidity, including social isolation, frailty, and falls.[5,6]

Recently, ARHL has been associated with the development of neuropsychiatric dysfunction, including impaired cognitive performance, increased risk for dementia diagnosis, and late-life depression.[7,8] For example, recent reviews[9,] and meta-analyses[10], and a National Institute on Aging workshop on the topic[11], linked ARHL to cognitive decline and dementia in older adults. Similarly, our group showed in multiple data sets that ARHL is associated with increased depressive symptoms as well as syndromal depression in older adults, in both cross-sectional and longitudinal analyses.[12,13] ARHL may increase risk for depression and cognitive decline through both brain-based (e.g., de-afferentiation induced atrophy, compensatory neuroplastic changes) and social/behavioral mechanisms (e.g., social isolation, decreased behavioral activation, and increased loneliness).[14]

The obvious therapeutic implication of the above-reviewed evidence is that treatment of ARHL may help avoid these adverse outcomes, theoretically by preventing or reversing de-afferentiation induced atrophy, restoring more normative brain activation patterns, and improving social engagement. There are emerging data to suggest that restoring auditory input (with hearing aids [HAs] or cochlear implants) may improve cognitive functioning, as naturalistic assessments of neuropsychiatric status before and after hearing treatment show improvement on short- and long-term global cognition, memory tasks, and social functioning.[15–18] A large ongoing randomized controlled trial will definitively test the efficacy of an open HA (vs. successful aging health education) intervention on reducing cognitive decline in older adults with ARHL.[19] One of the few existing studies targeting depressive symptoms compared hearing treatment to a wait list control group and reported increased self-reported quality of life and cognitive function as well as decreased depressive symptoms post HA prescription.[20] However, wait list groups are in general weak controls that may result in an overestimation of treatment effects. Positive expectancies instilled by discernible changes in hearing are likely to lead to substantial placebo effects, and sham-

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controlled studies are particularly important to control for expectancy-related placebo effects in studies with depression outcomes.[21,22] In addition, interpretation of these data is limited by most studies' failure to select participants based on the presence of clinical depression, comprehensively assess cognition and depression, and measure HA compliance objectively.

Thus, there is a need for rigorously designed research to determine whether hearing remediation is effective for improving depressive symptoms and cognition. The goal of this pilot study was to test the feasibility of conducting a prospective, double blind, randomized clinical trial of full-amplification (active) vs. low-amplification (sham) HAs to treat comorbid ARHL and depression in outpatient older adults. We hypothesized that participants would comply with the experimental HA intervention (>8 hours/day device usage), that differential dropout rate would be <10% between groups, and that participants would correctly guess active vs. sham HA assignment at chance. We were also interested in obtaining preliminary information on whether treating hearing loss improves cognition and reduces depressive symptoms in this population.

METHODS

Participants

The study was conducted at the Otology and Neurotology Clinical Practice at Columbia University Medical Center (CUMC) and the Late Life Depression Research Clinic (LLDRC) at New York State Psychiatric Institute (NYSPI). It was approved by the NYSPI Institutional Review Board and registered on Clinicaltrials.gov as NCT03321006. Participants were recruited from clinicians at CUMC and through advertisements (e.g. flyers, local newspapers, CUMC RecruitMe website). All participants met eligibility criteria and signed informed consent to participate in the study.

Eligible participants were men and women ≥60 who met Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5)[23] criteria for major or persistent depressive disorder, had a 24-item Hamilton Depression Rating Scale (HRSD)[24] score ≥16, had mild to severe hearing loss with a pure-tone average (PTA) ≥30dB (average hearing threshold at 0.5, 1, 2, and 4 kHz), no HA use within the past 6 months, and were willing to and capable of providing informed consent and complying with study procedures. Participants were excluded if they had a history of psychosis, mania, bipolar disorder, substance use disorder within the past 12 months, or had current suicidal ideation. Other exclusion criteria included severe or unstable medical illness, significant retrocochlear pathology or organic lesion responsible for hearing loss, Mini-Mental State Examination score ≤ 24, or a diagnosis of probable Alzheimer's disease, Vascular Dementia, or Parkinson's Disease.

Study Design and Feasibility Measures

Participants were enrolled in a 12-week clinical trial in which they were randomly assigned to receive either active or sham HAs. The study statistician performed a computer-generated randomization schedule, which was delivered to the audiologists who provided each participant their HA devices. The audiologists were not blinded to the HA assignment but conducted identical procedures for active and sham HAs. Participants, treating clinicians,

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and depressive and cognitive outcome assessors were blinded to the HA assignment and did not have access to the randomization schedule. Active or sham HAs were added to psychiatric treatment as usual in a naturalistic study design. Based on a discussion of the clinical options and their preference, participants could continue their antidepressant medication if they were taking one, start a new medication, or participate in the study while off medications. Because this is a pilot study, feasibility, compliance and tolerability were considered the primary outcomes. Feasibility was measured by the participant attrition rate over the 12-week study, compliance was measured by median duration of HA use in hours/day, and tolerability of the study treatment was assessed using the Treatment Emergent Side Effect Scale.

Audiologic Procedures

Prior to HA fitting, all participants obtained audiological assessment performed by an audiologist at either CUMC or at an outside facility of their choosing. All audiological assessments were performed in a double walled IAC soundproof booth. Pure tone testing was performed using insert earphones and bone conducted stimuli, and pure tone average was measured as the average hearing threshold at 0.5, 1, 2, and 4 kHz in both ears. Speech reception thresholds were obtained in each ear using standard spondee words. Word recognition was assessed in each ear using recorded consonant-vowel nucleus-consonant type word list (25 words) at 40dB sound level above the participant's speech reception threshold.

Following randomization, Phonak Audeo B-R90 (Sonova, Stafa, Switzerland) hearing devices were fit at Week 0 by an audiologist. Active and sham HAs were identical in appearance, battery use, and data logging capability. Sham HAs were programmed to a hearing threshold of 10dB across all frequencies, which resulted in a small but noticeable volume increase without substantively improving the ability to discriminate speech. The hearing gain of the active devices was determined by the audiometric profile as per standard clinical practice. To assess compliance with HAs, usage rates (hours/day) were measured using data log technology built into the devices[25–26] and participants were informed that a minimum of 8 hours/day of HA usage is required to participate in the study. Participants returned for follow-up audiology visits at Weeks 2, 6, 9, and 12, which served to verify fitting and provide counseling. As all participants were new HA users, they were counseled on their hearing loss as well as proper use of the HA in order to achieve a high level of comfort with the devices.

Study Assessments

At evaluation, participants were screened for significant medical problems with a medical history and physical examination, laboratory screening, an electrocardiogram, urinalysis, and urine toxicology. Vital signs were monitored throughout the study. Structured Clinical Interview for DSM5 Disorders[27] was performed to confirm participant eligibility. Participants then returned for six psychiatric follow-up appointments at the LLRDC over the 12-week trial. At each follow-up appointment (Weeks 0, 2, 4, 6, 9, and 12), participants met with a study clinician and research assistant at LLDRC. Follow-up visits are standardized in structure and duration (45 min total). During these visits, the research assistant greeted the

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participant and conducted clinical assessments (25 min) which included the 24-item HRSD, Treatment Emergent Side Effect Scale, Inventory of Depressive Symptoms—Self Report (IDS-SR)[28], Social Adjustment Scale Self-Report[29], and Blind Assessment—Patient Version (rates participant's guess as to the HA group). At each follow-up visit, the study clinician also met the participant to review interval events and symptom change since the previous visit, inquired about compliance and tolerance of the HAs and study medications, and provided education about study progress and procedures (20 min.).

Neuropsychological and functional evaluation measures were also performed at the Weeks 0 and 12 follow-up visits. Neuropsychological assessment included the Repeatable Battery for the Assessment of Neuropsychological Status for Hearing Impaired Populations (RBANS-H), which assesses five cognitive domains (Immediate Memory, Delayed Memory, Language, Attention, and Visuospatial/Constructional).[30–33] The RBANS-H is appropriate for use in participants with hearing loss[34], as the original RBANS requires instructions and stimuli to be presented auditorily. All components of the RBANS-H are simultaneously presented orally and in written format on an external computer monitor. Coverage of executive functioning was augmented with the NIH Toolbox (Flanker Inhibitory Control and Attention Test).[35] The functional evaluation included Short Physical Performance Battery[36] to provide measures of gait, balance, and lower extremity strength and the 36-item self-report World Health Organization Disability Assessment Schedule 2.0 (WHODAS)[37] to provide a global measure of disability. The Hearing Handicap Inventory for the Elderly Screening Version (HHIE-S)[38], a 10-item questionnaire developed to assess the social and emotional effects of hearing loss, was also administered at Weeks 0 and 12. Blinding was assessed at Week 12 as the proportion of participants who correctly guessed whether they were wearing active or sham devices. All participants were eligible for travel reimbursement at up to a $25 per visit. No protocol deviations occurred during the study.

Statistical Analyses

Baseline clinical and demographic characteristics of participants were summarized as medians and interquartile ranges [IQR] for continuous variables, and proportions for categorical variables. We chose to present the medians and IQRs, as opposed to the means and SDs, as given the potential for skewed continuous variables in our small sample size. Baseline characteristics were compared between the active and sham groups using nonparametric Mann-Whitney U tests for continuous measures and Fisher Exact test tests for categorical measures, both of which are appropriate for small sample sizes.

Between-group differences in duration of HA usage per day were tested using Mann-Whitney U tests at each visit. Attrition rates and the proportion of participants experiencing adverse events were compared between groups using Fisher Exact test tests. One sample, non-parametric, proportion tests were used to determine whether the proportions of participants in each treatment group who correctly guessed their treatment assignment were significantly different from 50%. Changes (from Week 0 to Week 12) in median clinical outcome scores were compared between groups using non-parametric Mann-Whitney U tests. Mann-Whitney U and Fisher Exact tests are non-parametric hypothesis tests that are appropriate for skewed variables and/or small sample sizes.

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Additionally, we estimated the observed effect sizes for the clinical outcome scores. Since the estimates of means and SDs are not always reliable with such a small sample size, we computed a nonparametric effect size (np-ES; difference in medians divided by average IQR) between both groups. A clinically meaningful effect was defined as an np-ES of ≥0.2, with an np-ES ≥0.2 for a small effect, np-ES ≥0.5 for a moderate effect, and np-ES ≥0.8 for a large effect.

All results were produced using SAS® 9.4 and all statistical tests were two-sided with pre-selected level of significance of 5%.

RESULTS

Participant Disposition and Characteristics

Thirteen subjects participated in the 12-week trial (N=7 randomized to active and N=6 randomized to sham treatment, see Table 1). Participants in the active group were significantly younger (median [IQR] age was 66.2 [63.1 - 67.5] vs. 78.2 [70.8 – 85.4] years, p = 0.005), but there were no other differences found in baseline characteristics. Severity of hearing loss did not differ between active vs. sham groups (median [IQR] PTA was 48.1 dB [33.3 – 51.9] vs. 42.5 dB [40.6 – 53.1], respectively, p=.62).

Feasibility Outcomes

Because this was a pilot study, feasibility, compliance and tolerability were considered the primary outcomes. Feasibility was measured by the participant attrition rate and as shown in Figure 1, all 13 randomized participants completed the 12-week study, resulting in zero dropout. As shown in Table 2, the median duration of HA use was > 9 hrs/day and not different for participants randomized to active vs. sham treatment using Mann-Whitney U tests (median use 10.9 vs. 10.5 [p=.55] at Week 2; median use 10.0 vs. 10.3 [p=.79] at Week 6; median use 9.7 vs. 11.4 [p=.28] at Week 9; median use 9.3 vs. 10.7 [p=.66] at week 12). Moreover, HA utilization (hrs/day) was not different for participants taking antidepressant medications compared with those who were not (Mann-Whitney U tests for participants taking vs. not taking ADs: median use 11.1 vs. 8.0 [p=.36] at Week 2; median use 10.0 vs. 12.5 [p=.29] at Week 6; median use 11.1 vs. 9.7 [p=.99] at Week 9; median use 10.7 vs. 10.7 [p=.74] at Week 12).

Blinding was evaluated as the proportion of participants who correctly guessed whether they were wearing active or sham devices at Week 12. Rather than the anticipated proportion of 50% if full blinding were in effect, 86% of the active (p=.126, Binomial Exact test) and 83% of the sham (p=.22, Binomial Exact test) HA group guessed their treatment assignment correctly at Week 12. Tolerability was measured by treatment side effects experienced by participants and were primarily related to the antidepressant medication. They included dry mouth (3 mild, 2 severe), insomnia (1 mild, 1 severe), and drowsiness (2 severe), and the number of occurrences did not differ between HA groups.

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Neuropsychiatric Outcomes

While the feasibility results served as our primary outcome measures, we were also interested in obtaining preliminary information about neuropsychiatric outcomes. As shown in Table 3 **and** Figure 2, provision of active HAs resulted in clinically meaningful improvement in the social and emotional effects of hearing loss as measured by the HHIE-S (np-ES=.62). Clinically meaningful improvement in depressive symptoms favoring active treatment was observed on the IDS-SR (np-ES=.31). In terms of cognitive outcomes, differential numerical improvement favoring active HAs was observed on tasks testing Immediate Memory (np-ES=.25). In contrast, HRSD (np-ES=0), Delayed Memory (np-ES=.18), Language (np-ES=.06), Executive Function (Flanker task: np-ES=.33), Visuospatial/Constructional Ability (np-ES=.60) and Attention (np-ES=.16) did not demonstrate improvement. Clinically meaningful effect sizes were observed in functional improvement measured by the WHODAS (np-ES=.53), and in magnitude of social functioning measured by the SAS-SR (np-ES=.33). No clinically meaningful improvement was observed in physical functioning measured by the SPPB (np-ES=0). These improvements in hearing, depressive symptoms, immediate memory, and general functioning resulted in clinically meaningful adaptive changes.

DISCUSSION

The primary finding in this study was a double-blind randomized pilot trial of HAs as a treatment for depression and cognitive decline secondary to age-related hearing loss was highly acceptable to participants. As opposed to what is typically observed in clinical treatment with HAs[39], compliance in this study was exceedingly high, with a median usage rate of > 9 hours/day in each group that was maintained through the study, and there was zero dropout over 12 weeks. We observed small to moderate effect size improvements favoring active treatment over sham in our preliminary data on self-reported depressive symptoms, immediate memory, and both hearing-related as well as general functioning.

Given that the current treatments for both late-life depression and cognitive impairment are significantly limited in efficacy, ARHL merits further empirical attention as a causal and/or precipitating factor for the development of dementia and depression. Data from this study suggest that larger prospective randomized controlled studies of HAs for older adults with comorbid ARHL and late-life depression are feasible and that a signal of effect may exist. Our research group is currently undertaking a larger National Institute on Aging funded R21 trial of individuals with comorbid late-life depression and ARHL, and we are incorporating rigorous methodology such as compressive neuropsychiatric assessments, objective measures of HA compliance, and randomization. To obtain data on the mechanisms linking ARHL to neuropsychiatric outcomes, multimodal neuroimaging has been incorporated into this larger study.

Concealment of treatment allocation (to active or sham HAs) was incomplete in this study, as many individuals correctly guessed their treatment assignment. While blinding for a treatment with immediately apparent subjective effects such as HAs is challenging, controlling for expectancy-related placebo effects is important for studies with depression outcomes.[21,22] It is possible that providing more amplification to the sham HA group may

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improve blinding, though the degree of amplification must be balanced against dilution of a signal for active vs. sham treatment. For example, the provision of even a 10dB gain provided in the sham HA in our study may provide significant benefit to participants depending on the shape of hearing loss, especially if an individual's hearing threshold is just under "normal" for important frequencies such as that of soft consonants (i.e. 2000-4000 Hz). The magnitude and audiologic characteristics of a given individual's hearing loss are important factors and something to consider in future studies, as individuals with mild ARHL may observe a large hearing benefit from a small volume increase that would not be noticeable to individuals with severe ARHL. To improve methods of blinding in such studies, we may consider increasing the amplification to the sham HA device (e.g. to a 30dB gain) and selectively including participants with at least moderate hearing loss (e.g. PTA ≥50dB).

The findings of our study must be interpreted in light of several limitations. The small sample size achieved in this pilot study limited our ability to calculate accurate effect sizes and yielded differences between the active and sham HA groups that were unreliable. Second, the naturalistic study design limits the specific interpretations that can be made regarding the therapeutic value of HAs for depression. Nearly half of the participants in each treatment arm started a new antidepressant treatment, and while the rates of treatment initiation were not different between groups, this may have contributed to the symptomatic and functional benefits observed. Additionally, the sham HA group was significantly older, which may have influenced the depressive and cognitive outcomes. Finally, blinding of treatment assignment failed for study participants, so differential placebo effects operative between the active and sham conditions may have contributed to the results observed.

CONCLUSION

In summary, data from this first study of its kind suggest that rigorously designed clinical trials to test the efficacy of hearing treatment for depression and cognitive decline in older adults are possible. Given the promising benefits observed with active HAs vs. sham, larger studies that will be powered to determine whether hearing remediation may be an effective therapeutic strategy for late-life depression and cognitive impairment are necessary. Should future studies prove to be successful, this suggests a novel therapeutic strategy for late-life depression and cognitive impairment and may thereby mitigate their public health burden, while also contributing to the increased recognition and treatment of ARHL more generally.

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Key Points:

1. Age-related hearing loss is a prevalent condition that has been associated with the development of significant neuropsychiatric dysfunction, but there is a need for rigorously designed research to determine whether hearing remediation is effective for improving depressive symptoms and cognition.
2. We found that a double-blind sham-controlled pilot trial of hearing aids as a treatment for depression and cognitive decline was highly acceptable to participants, and we observed small to moderate improvements favoring active treatment for depressive symptoms and memory performance.
3. Given the promising benefits we observed in our study, should larger studies of hearing remediation prove to be successful, this suggests a novel therapeutic strategy for late-life depression and cognitive impairment.

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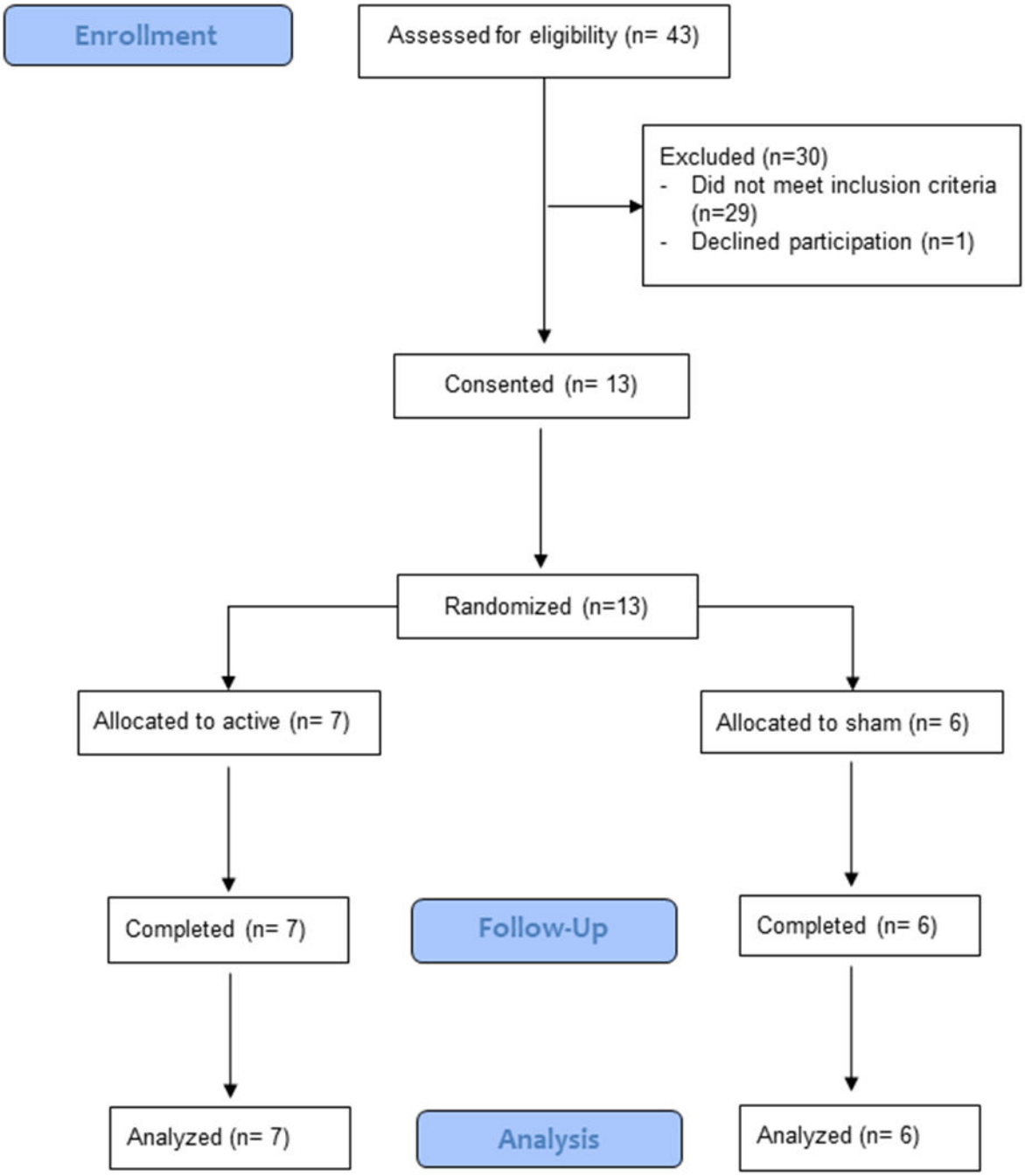

Figure 1:
CONSORT trial flow diagram. Participant flow through each stage of the randomized controlled trial (enrollment, follow-up, and data analysis).

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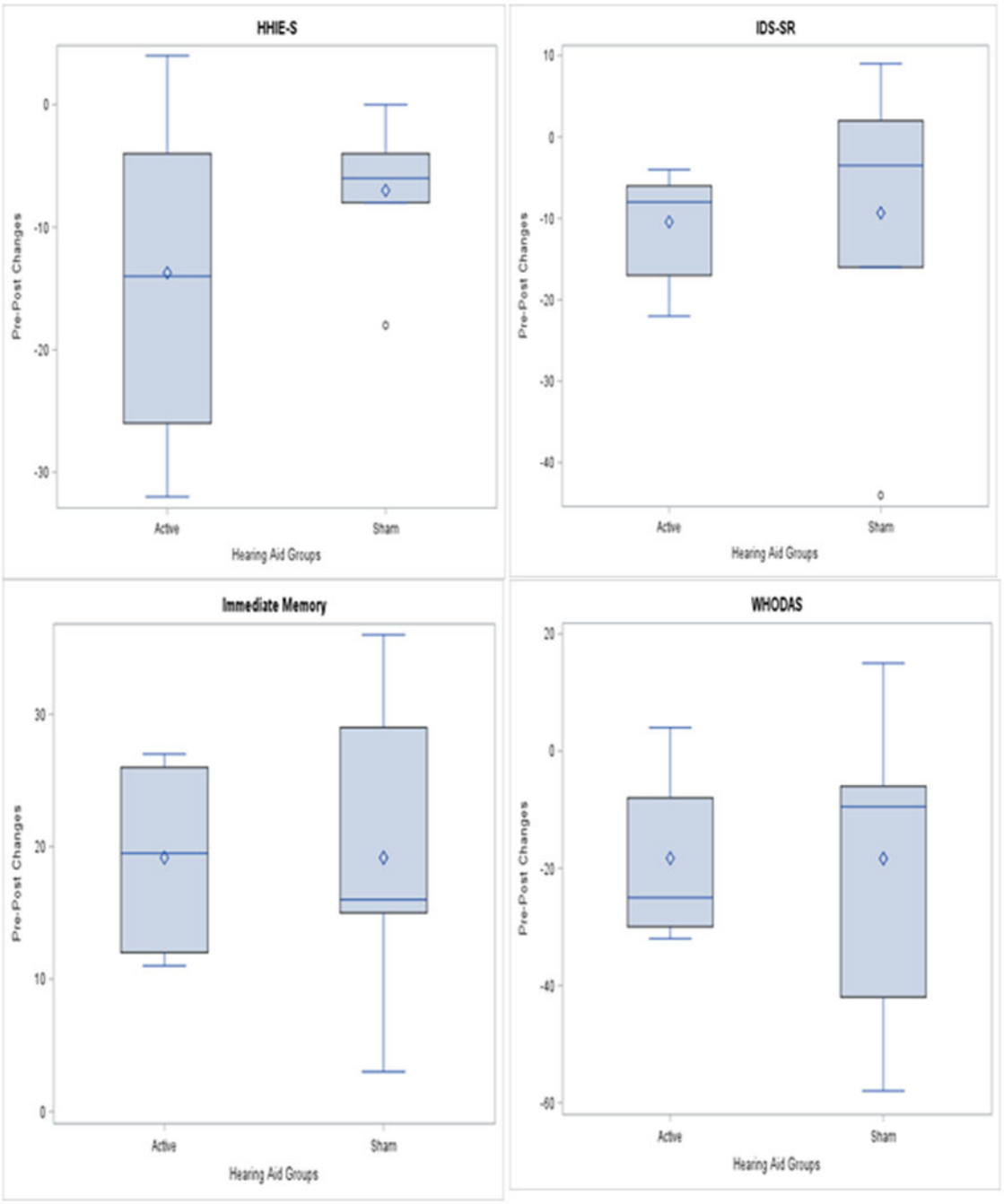

Figure 2:

Pre-Post Changes in Clinical Outcomes between Hearing Aid Groups.

Notes: Week 0 (pre-) to Week 12 (post-) change in median clinical outcome scores. HHIE-S = Hearing Handicap for the Elderly Screening Version; IDS-SR = Inventory of Depressive Symptomatology Self-Report; WHODAS = World Health Organization Disability Assessment Schedule 2.0.

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Table 1:

Baseline Characteristics for the Hearing Aid Groups

	Active	Sham	
	N = 7	N = 6	
	N (%) Median (IQR)	N (%) Median (IQR)	p-value
Gender (Male)	4 (57%)	3 (50%)	1.00
Age	66.2 (63.1 – 67.5)	78.2 (70.8 – 85.4)	0.005
Education Years	16 (12 – 18)	14.5 (13 – 17)	0.83
Race/Ethnicity			
White	4 (57%)	5 (83.3%)	
Asian	1 (14%)	0	0.39
Black/African-American	1 (14%)	1 (16.7%)	
Hispanic/Latino	1 (14%)	0	
Antidepressant (AD) Group			
+AD	5 (71%)	4 (67%)	
Started New AD	3 (43%)	3 (50%)	1.00
Remained on AD	2 (29%)	1 (16.7%)	
No AD	2 (29%)	2 (33%)	
Depression			
HRSD	20 (19-26)	18.5 (15-27)	0.67
IDS-SR	30 (23 – 36)	27.5 (23 – 30)	0.62
Cognition			
MMSE	28 (28 – 29)	27 (27 – 27)	0.21
RBANS (Total)	100 (84 – 110)	86.5 (85 – 102)	0.75
General Functioning			
WHODAS	51 (43 – 57)	48.5 (43 – 62)	1.00
SAS-SR	2.9 (1.8 – 3.0)	2.7 (1.9 – 3.0)	0.94
Hearing			
HHIE-S	34 (30 – 40)	34 (26 – 36)	0.47
Pure Tone Average (PTA)	48.1 (33.3 – 51.9)	42.5 (40.6 – 53.1)	0.62

Notes: HRSD = 24-item Hamilton Rating Scale for Depression; IDS-SR = Inventory of Depressive Symptomatology Self-Report; MMSE = Mini-Mental State Examination; WHODAS = WHO Disability Assessment Schedule 2.0; SAS-SR = Social Adjustment Scale Self-Report; RBANS (Total) = Repeatable Battery for the Assessment of Neuropsychological Status for Hearing Impaired Populations; HHIE-S = Hearing Handicap for the Elderly Screening Version.

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Table 2:

Duration of Use by Hearing Aid Group

Week	Active Usage*	Sham Usage*	Difference
	Median (IQR) Usage (N)	Median (IQR) Usage (N)	P-Value
2	10.9 (8.8-12.0), (5)	10.5 (7.2 – 11.4), (5)	0.55
6	10.0 (9.4 – 12.5), (6)	10.3 (10.0-10.3), (5)	0.79
9	9.7 (8.3-11.5), (7)	11.4 (11.1-12.0), (5)	0.28
12	9.3 (6.3-12.8), (7)	10.7 (10.7-12.0), (3)	0.66

*Median usage as measured in hours of usage per day. N = sample size varies by week as participants may have missed audiology follow-up appointments. Difference in HA usage between groups is calculated with Mann-Whitney U test.

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Table 3:

Pre-Post Changes in Clinical Outcomes between Hearing Aid Groups

	Active	Sham	
	N = 7	N = 6	
	Median (IQR)	Median (IQR)	*np-ES
Hearing			
HHIE-S	−14.0 (−26 to −4)	−6.0 (−8 to −4)	.62
Depression			
IDS-SR	−8.0 (−17 to −6)	−3.5 (−16 to 2)	.31
HRSD	−5.0 (−16 to −3)	−5.0 (−12 to 7)	.00
Cognition			
RBANS – Immediate Memory	+19.5 (12 to 26)	+16.0 (15 to 29)	.25
RBANS – Delayed Memory	+7.5 (1 to 11)	+5.5 (0 to 12)	.18
RBANS – Attention	+4.5 (−9 to 9)	+1.5 (−7 to 12)	.16
RBANS – Visuospatial/Constructional	−6.0 (−19 to −2)	+6.0 (0 to 23)	.60
RBANS – Language	+9.0 (−4 to 25)	+7.5 (−9 to 16)	.06
Flanker – Executive Function	0 (−1 to 0)	−0.5 (−2 to 0)	.33
General Functioning			
WHODAS	−25.0 (−30 to −8)	−9.5 (−42 to −6)	.53
SAS-SR	−0.32 (−0.83 to −0.09)	−0.10 (−0.67 to −0.03)	.33
SPPB	1.0 (0 to 2)	1.0 (0 to 2)	.00

Notes: Week 0 (pre-) to Week 12 (post-) change in median clinical outcome scores. HHIE-S = Hearing Handicap for the Elderly Screening Version; IDS-SR = Inventory of Depressive Symptomatology Self-Report; HRSD = 24-item Hamilton Rating Scale for Depression; RBANS = Repeatable Battery for the Assessment of Neuropsychological Status for Hearing Impaired Populations; Flanker = Flanker Inhibitory Control and Attention Test from the NIH toolbox; WHODAS = World Health Organization Disability Assessment Schedule 2.0; SAS-SR = Social Adjustment Scale Self-Report; SPPB = Short Physical Performance Battery.

*np-ES = nonparametric effect size