Official Title of the study: Impact of Hearing Aid Intervention on Individuals with Cognitive Disorders

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Study Protocol

Impact of Hearing Aid Intervention on Individuals with Cognitive Disorders

1 Background

Age-related hearing loss is common among older adults, affecting about two-thirds of those aged 70 and older. Given that (1) neuropsychiatric symptoms of dementia may be worsened by communication difficulties from hearing loss, and (2) hearing aids (HAs) effectively improve communication and reduce psychosocial impacts in older adults without dementia, it seems reasonable to use HAs for individuals with Alzheimer's Disease and related dementias (ADRD).

However, ADRD pathology may affect central auditory pathways, raising concerns about the effectiveness of HAs, which primarily improve peripheral audibility. Currently, no high-quality evidence confirms or refutes the benefits of HA intervention in reducing communication difficulties, dementia-related symptoms, or caregiver burden in adults with ADRD.

Additionally, the best service model for providing HAs to this population remains unclear. Customized HAs fitted by audiologists using best practices may offer optimal outcomes, but implementing these services for adults with ADRD is challenging. Alternatively, recent research suggests that low-cost, pre-programmed, non-customized amplification devices may provide reasonable outcomes at a lower cost. However, no high-quality studies have rigorously evaluated the outcomes, value, or candidacy of different HA service-delivery models for older adults with ADRD.

2 Purpose

This pilot study aims to evaluate the feasibility of procedures for a future clinical trial assessing the impact of hearing aid interventions on older patients with ADRD. The collected data will help refine hypotheses, conduct a power analysis, and finalize the research protocol for the clinical trial. To ensure participants have wide range of cognitive functions, eligible participants include those with mild cognitive impairment (MCI) and ADRD.

3 Research Design

3.1 Overview

This study employs a randomized controlled trial design. Participants are randomly assigned to one of three intervention groups: Audiologist-based, service-only, and device-only groups (explained below). Patient outcomes are measured at the sixth week post-intervention.

3.2 Intervention

- Audiologist-Based Group: In this group, HAs are fitted by audiologists using established procedures.

- Service-Only Group: This intervention group is designed to explore the contribution of amplification devices in HA intervention. In this intervention group, audiological services (e.g., counselling and education) plus HAs that provide minimum amplification will be provided.
- Device-Only Group: This intervention group is designed to explore the contribution of amplification devices in HA intervention. The patient participants in this intervention group will have minimum services regarding the pre-fitting, selection, and orientation of the HAs.

3.3 Sample size

Because this is a pilot study, no power analysis is conducted to determine the sample size. It was expected to enroll approximately 30 participants.

3.4 Randomization and blinding

Simple randomization is used to assign participants to the three groups with equal probability. Blinding is not feasible.

3.5 Participant eligibility criteria

3.5.1 Inclusion: Inclusion Criteria:

- Adults between 55 and 85 years old
- Adult-onset mild-to-moderate sensorineural hearing loss
- Montreal Cognitive Assessment (MoCA) score lower than 25 points

3.5.2 Exclusion Criteria:

- Non-native speaker of English
- Prior hearing aid experience

3.6 Outcome measures

3.6.1 Primary outcome

3.6.1.1 Hearing aid benefit as measured by the International Outcomes Inventory for Hearing Aids (IOI-HA)

The IOI-HA is a questionnaire designed to assess the benefits of hearing aids from the user's perspective. The score ranges from 1 (less benefit) to 5 (more benefit). Participants complete this measure at 6 weeks post-intervention.

3.6.1.2 Change of daily activity as measured by the Lawton Instrumental Activities of Daily Living Scale (IADL)

The IADL was developed to assess independent living skills, such as feeding, dressing, and food preparation. The score ranges from 0 (low function) to 8 (high function). Participants complete this measure pre-intervention and at 6 weeks post-intervention. The change in scores between pre- and post-intervention are reported, with score changes ranging from +8 (indicating a benefit from hearing aids) to -8 (indicating a detrimental effect of hearing aids).

3.6.1.3 Change of caregiver burden as measured by the "Zarit Burden Interview" (ZBI)

Caregiver burden are measured using the ZBI, which is a 22-item questionnaire. The score ranges from 0 (little or no burden) to 88 (severe burden). This measure is completed pre-intervention and at 6 weeks post-intervention. The change in scores between pre- and post-intervention are reported, with score changes ranging from -88 (indicating a benefit from hearing aids) to +88 (indicating a detrimental effect of hearing aids).

3.6.2 Secondary outcomes

3.6.2.1 Change of Hearing Handicap Measured by Hearing Handicap Inventory for the Elderly (HHIE) or Hearing Handicap Inventory for Adults (HHIA)

The HHIE and HHIA are questionnaires designed to measure perceived hearing handicap. For subjects order and younger 65 years old, the HHIE and HHIA will be used, respectively. The score ranges from 0 (no handicap) to 100 (more handicap) (i.e., lower scores mean less handicap). Participants will complete this questionnaire pre-intervention and at 6 weeks post-intervention. The change in scores between pre- and post-intervention are reported, with score changes ranging from -100 (indicating a benefit from hearing aids) to +100 (indicating a detrimental effect of hearing aids).

3.6.2.2 Change of quality of life as measured by the Alzheimer's Disease-Related Quality of Life (ADRQL)

The ADRQL was developed to assess health related quality of life in people with Alzheimer's disease using assessments from family caregivers or professional staff. The score ranges from 0 (worst situation) to 100 (best situation). Participants complete this measure pre-intervention and at 6 weeks post-intervention. The change in scores between pre- and post-intervention are reported, with score changes ranging from +100 (indicating a benefit from hearing aids) to -100 (indicating a detrimental effect of hearing aids).

3.6.2.3 Change of depression as measured using the Geriatric Depression Scale (GDS)

The GDS a self-report measure of depression in older adults. The short form of the GDS has 15 items. The score ranges from 0 (no depression) to 15 (more depression). Participants complete this measure pre-intervention and at 6 weeks post-intervention. The change in scores between pre- and post-intervention are reported, with score changes ranging from -15 (indicating a benefit from hearing aids) to +15 (indicating a detrimental effect of hearing aids).

3.7 Statistical analysis

As this is a pilot study, no inferential statistical analyses will be performed. Only descriptive analyses will be conducted.

3.8 Adverse events

Adverse events are monitored for each subject during their participation in the study, which averaged 7 weeks from the time the participants entered the study.