Official Title of the study: Longitudinal Outcomes of Hearing Aids

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Study Protocol

Longitudinal Outcomes of Hearing Aids

1 Background

Hearing aids (HAs) have been shown to improve communication ability, hearing-specific quality of life, and social and emotional function. Additionally, HAs have the potential to reduce cognitive decline in older adults at increased risk. Despite these benefits, HA adoption rates remain quite low. The reasons for this low HA adoption rate are multidimensional, with one widely cited reason being the financial and physical barriers to accessing traditional HA fitting services and amplification devices.

In recent years, the over-the-counter (OTC) service-delivery model has emerged as an alternative to traditional HAs. OTC HAs enable users to self-determine hearing loss and self-fit the device without professional support. While previous research exists on the short-term outcomes of OTC HAs, there is no evidence on the long-term outcomes of OTC HAs and whether these outcomes worsen, improve, or remain stable over time.

2 Purpose

To explore the trajectory of long-term outcomes of OTC HAs over a period of twelve weeks.

3 Research Design

3.1 Overview

This study is an observational study. Participants will use OTC HAs for twelve weeks. Outcomes will be measured at the first week, sixth week, and twelfth week post-HA use.

3.2 Intervention

OTC Group: In this group, preset-based OTC HAs, simulated using commercially available HAs, will be provided to subjects. Subjects will take the full initiative and responsibility for learning and using the HAs without assistance from audiologists.

3.3 Sample size

Because this is an exploratory study, no power analysis is conducted to determine the sample size. Based on prior research experience, it is estimated that approximately 34 participants are needed to see the trend of long-term HA outcomes.

3.4 Randomization and blinding

All participants will be assigned to the OTC group. Therefore, blinding will not be necessary.

3.5 Participant eligibility criteria

3.5.1 Inclusion: Inclusion Criteria:

- Adults between 55 and 85 years old
- Adult-onset, bilateral, mild-to-moderate sensorineural hearing loss

3.5.2 Exclusion Criteria:

- Non-native speaker of English

3.6 Outcome measures

3.6.1 Primary outcome

3.6.1.1 Glasgow Hearing Aid Benefit Profile (GHABP)

The GHABP is a questionnaire that measures hearing aid users' listening experience in four situations (TV listening, small conversation in quiet, conversation in noise, and group conversation). The score ranges from 0 (no benefit) to 5 (lots of benefit). The score at 1-week, 6-week and 12-week post intervention is the primary outcome. Participants will complete this questionnaire at 1-week, 6-week, and 12-week post-intervention based on their experience with the study device.

3.6.2 Secondary outcomes

3.6.2.1 Hearing Handicap Inventory for the Elderly (HHIE) or Hearing Handicap Inventory for Adults (HHIA)

The HHIE and HHIA are questionnaires designed to measure subject's 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). Participants will complete this questionnaire at 1-week, 6-week, and 12-week post-intervention based on their experience with the study device.

3.6.2.2 Hearing Aid Satisfaction Survey (HASS)

The HASS is a questionnaire developed to measures subject's perceived hearing aid satisfaction. The score ranges from 0 (low satisfaction) to 10 (high satisfaction). Participants will complete this questionnaire at 1-week, 6-week, and 12-week post-intervention based on their experience with the study device.

3.6.2.3 Willingness-to-pay (WTP)

WTP estimates the extent to which (in dollars) a subjects, at a maximum, is willing to pay out-of pocket for the amplification devices and the associated services used in the study. Participants will complete this questionnaire at 6-week, and 12-week post-intervention based on their experience with the study device.

3.6.2.4 World Health Organization's Disability Assessment Schedule 2.0 (WHODAS 2.0)

The WHODAS is a questionnaire designed to measure quality of life. The summary score ranges from 0 (No disability) to 100 (Full disability). Participants will complete this questionnaire at 1-week, 6-week, and 12-week post-intervention based on their experience with the study device.

3.6.2.5 Satisfaction With Amplification in Daily Life (SADL)

The SADL is a questionnaire designed to measures subject's perceived hearing aid satisfaction. The score ranges from 1 (low satisfaction) to 7 (high satisfaction). Participants will complete this questionnaire at 1-week, 6-week, and 12-week post-intervention based on their experience with the study device.

3.6.2.6 Connected Speech Test (CST)

The CST is a speech recognition test designed to simulate daily speech communication. The score ranges from 0 (understand no speech) to 100 (understand all speech). Participants will complete this test in the laboratory at 1-week, 6-week, and 12-week post-intervention with the study device.

3.7 Statistical analysis

Because this is an exploratory study, no statistical analysis will be conducted.

3.8 Adverse events

Adverse events will be monitored for each subject during their participation in the study, which averaged 12 weeks from the time the participants entered the study.