Study Protocol and Statistical Analysis Plan

Evaluation of the Clinical benefit of the hearing aids tinnitus feature – ID# 481

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1 Objectives and hypotheses of the clinical investigation

1.1 Purpose of the clinical investigation claims for clinical performance, effectiveness or safety of the investigational device that are to be verified

This clinical study was conducted with commercially available hearing devices to verify the clinical benefit of a haring aids tinnitus feature. The study (and the resulting clinical data) could support the CER for claims purposes.

1.2 Primary and Secondary Objectives

The primary objective of this study is to evaluate the clinical benefit of a noiser feature for tinnitus relief in 30 participants with mild to moderate sensorineural hearing loss and chronic bothersome tinnitus.

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

This is a randomized, cross-over confirmatory study with participants serving as self-controls. Tinnitus Functional Index questionnaire (TFI) will be the outcome measurer, administered at baseline (before study intervention), and after each study condition. Baseline TFI will be compared to that after each study condition.

There are two intervention conditions (duration of 4 weeks each): amplification-only, and amplification+noiser, followed by the same period (4 weeks) of intervention withdrawal.

The outcome measurer (TFI) will be administered before and after each study condition.

2.2 Procedures

2.2.1 Investigation-related Procedure

Participants will be recruited from the overall population based on their hearing loss and tinnitus intrusion levels; Inclusion criteria include: mild to moderate sensorineural hearing loss, chronic (3+months) bothersome tinnitus (determined by TFI equal or greater than 20 points at baseline), confirmed tinnitus stability with 2 consecutive TFI measures of at least 2 weeks apart, minimum age of 18 years old, no previous experience with hearing aid amplification. Participants will undergo a screening session to confirm study eligibility.

Participants will sign the consent form and complete the demographic questionnaire prior to being assigned randomly to their first intervention condition with a hearing aid fitting (with or without a masking noiser).

Visit 1: hearing screening, demographic information collection, first TFI screening.

Visit 2: between 2 and 4 weeks after the 1st visit, to verify tinnitus stability (via 2nd TFI measurement). If TFI confirms stable Tinnitus condition, participant will be randomly assigned to one intervention condition and can be fit with hearing aids on the same session.

Visit 3: TFI administration, and second intervention condition set up

Visit 4: TFI administration and devices will be returned

Visit 5: TFI administration

3 Statistical design and analysis

3.1 Determination of Sample Size

We will recruit 30 participants in total;

3.2 Statistical criteria of termination of trial

n/a

3.3 Planned Analyses

3.3.1 Datasets to be analyzed, analysis population

TFI scores will be analysed before and after each intervention condition within study participants.

3.3.2 Primary Analysis

Repeated Measures ANOVA will be used to detect significant effects with amplification-only and amplification+noiser as fixed effects variables, and participants as a random effects variable. Post-hoc pairwise t-tests will identify further differences.

3.3.3 Interim Analysis

Within 48 of each intervention condition set up time, and again at 2 weeks after each intervention condition set up, the study team will contact each participant to address any questions or issues they may have, and an office visit will be offered if needed.

4 Informed consent process

4.1 Process for obtaining informed consent

Participants are required to sign a consent form prior to participation in the study. The consent form will be provided at the time of their first appointment. Participants are asked to review the entirety of the form and ask questions about the content in the form, if any. Participants consent by writing their names and signature.