Study Protocol and Statistical Analysis Plan

Validation of Novel BTE and SP Hearing Aid Models – ID# 378

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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 validation is conducted as the final check of a novel BTE (behind-the ear) and SP (Super Power) BTE hearing aid implementation to ensure there is time to react to any critical issues prior to launch. The study (and the resulting clinical data) could support the CER which is necessary for CE submission.

1.2 Primary and Secondary Objectives

The primary objective of this study is to evaluate the sound quality of: a novel SP BTE in 7-10 participants with severe to profound hearing loss after a 6-7 week home trial; a novel BTE and its charger in 7-10 participants with hearing loss in the mild to severe range after a 3 week home trial.

The secondary objectives are to confirm the stability of the novel SP BTE and novel BTE ; stability is measured re: artifacts/ reboots/ extraneous noise in a variety of situations. Stability acceptance criteria will be considered 80% of participants indicating no unwanted/noticeable reboots or distortions during typical wearing which may include engaging in BT (Bluetooth) phone calls, streaming via a media-streaming device, etc). Objective Lab/clinic testing will include BT phone call testing.

To determine if participants (especially with severe to profound hearing loss) can operate the interactive aspects of the associated app (sliders in the manual program and the sound quality boost/adjustment buttons in the automatic program) without degrading their sound quality while wearing devices in their daily life.

To confirm that participants (especially with severe to profound hearing loss) can hear a difference between the manual program's slider settings and the automatic program's boost settings in the sound room/lab setting.

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

This is a single group, non-randomized confirmatory study with primarily a take home trial evaluation. The novel SP BTE group will be seen for 3 visits over approximately 7 weeks and the novel BTE group for 2 visits over 3 weeks.

2.2 Procedures

2.2.1 Investigation-related Procedure

Participants will be selected from our database based on their hearing loss; inclusion/exclusion criteria will be discussed . If necessary, an update of their hearing will be conducted at their first appointment in order to minimize visits to the clinic due to COVID19. When custom tips are required/involved, previously-obtained 'point clouds' will be used as appropriate to make them (e.g., earmolds).

Participants will sign the consent form and complete the demographic questionnaire prior to hearing aid fitting.

Novel SP BTE:

Visit 1 will also include pairing of aids to their smartphone and instructions; Bluetooth (BT) phone call test in clinic and app testing; Home Trial with diary and one-week email follow-up

Visit 2 will include an update of the hearing aid image and app if applicable and pairing to other accessories with instructions and demos followed by another Home Trial with diary

Visit 3 will include final questions and paperwork; devices will be returned

Novel BTE:

Visit 1 will also include pairing of aids to their smartphone and instructions; Bluetooth (BT) phone call test in clinic and app testing and pairing to other accessories; Home Trial with diary and one-week email follow-up

Visit 2 will include final questions and paperwork; devices will be returned

3 Statistical design and analysis

3.1 Determination of Sample Size

We will recruit 7-10 participants for each model of hearing aid; no statistical analysis will be performed to determine sample size.

3.2 Statistical criteria of termination of trial

n/a

3.3 Planned Analyses

3.3.1 Datasets to be analyzed, analysis population

Subjective reports will be collected primarily using Sound Quality scales from Gabrielsson et al (1988). The effects of different frequency responses on sound quality judgments and speech intelligibility. JSHR. Vol31

3.3.2 Primary Analysis

The primary analysis will be Good Subjective Ratings: Acceptance criteria is that 80% of participants provide good subjective ratings in the field. This will be done by the study manager when data are available.

3.3.3 Secondary Analysis

Acceptance criteria for stability includes 80% indicate no unwanted/noticeable reboots are distortions. This will be done by the study manager.

3.3.4 Interim Analysis

After the first week of home trial use, an email will be sent to participants to determine if they have noticed any sound quality issues that should be addressed by a firmware or software update. This information will be provided to R&D (Project Manager) to act upon.

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 and relevant tick boxes for this particular study will be noted. Participants will consent by writing their names and signature and will include the name of the researcher obtaining consent. The document will be converted into a PDF and will be uploaded into the database. The paper form will be stored in a secured cabinet only accessible by the researchers.