Study Protocol and Statistical Analysis Plan

A Study to Compare Patient Perceptions of Two Different Hearing Aid Processing Philosophies

Version 1.0

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Protocol Title

1 Background

Hearing aid brands vary in their DSP (Digital Signal Processing) strategies. For example, there are philosophical differences in processing when there is uncertainty of target location. One processing strategy aligns with a front facing target, whereas another aligns with the absence of a target in these situations. Despite the investigations regarding the different processing strategies, research has been limited as to how different populations perceive these different strategies in their daily life. Previous data gives insight to the different strategies in lab environments and simulated acoustic environments, but there is substantial need to investigate how these findings relate to the real world, which this study seeks to accomplish through the use of a home trial comparison.

2 Objectives

The primary objective of this study is to investigate whether individuals with moderate to severe hearing loss perceive a difference between Brand A and Brand B devices in their daily life.

3 Description of the investigational device

The investigational devices are intended for consumers with hearing loss, and provide amplification for soft, medium, and loud inputs using varying methods of compression and features. The devices will be used as intended for this investigation.

4 Design of the clinical investigation

This interventional study uses a within-subject, single blinded design with three conditions: Condition one consists of study hearing aid set A, condition two is study hearing aid set B, and condition three is study hearing aid set C. Sets A and C are the same hearing aids but will be different color casings. Twenty participants are planned.

5 Risks and benefits of the investigational device and clinical Investigation

Hearing aids enable people to hear sounds again, which could not be heard previously due to a hearing loss. The benefit of a compensated hearing loss results in a facet of multiple benefits which can be measured in different dimensions.

One of the main benefits of hearing aids is that they may enable people with a hearing loss to better and easier hear speech again, which is a fundamental ability to communicate and inter- act with others (e.g. family and friends, colleagues at work) in different listening situations in daily life.

The investigation carries risks typical to the standard of care for fitting and placing hearing aids in the ear. When placing a dome in the auditory canal, there is the risk of discomfort to the participant. There are risks of skin sensitivity to the material of the devices inserted into the auditory canal and behind the ear (pinna).

The risks of this study are minimal as the procedures are within the scope of practice of the

research audiologists. The participants may notice an improvement in hearing as compared to their own devices, or they may prefer their own devices to the study devices. The primary endpoint of subjective questionnaires and calculation of the Net Promoter Score will provide evidence for the perceived similarities or differences between the two study devices, as well as any preference for either device.

6 Endpoints

- SSQ (Speech Spatial Qualities) Questionnaire: Subjective ratings from 0 to 10 on various aspects of hearing aid performance in daily life, hearing speech in a variety of situations and contexts, spatial hearing, and overall qualities of hearing.
- Hearing Aid Satisfaction Score: Subjective ratings on overall satisfaction of devices. Ratings range from Very Satisfied (5) to Very Dissatisfied (1) for a number of hearing aid features, as well as performance in various listening situations.

7 Inclusion and Exclusion Criteria

Inclusion criteria for participant selection:

1. Experienced (6+ months) Phonak hearing aid users
2. N3-N4 binaural sensorineural hearing loss
3. Age 18 years and older

Exclusion criteria:

1. Conditions which may cause fluctuations in hearing (i.e. Meniere's)
2. Unable to tolerate the physical fit of RIC device with standard fit domes
3. Unable or unwilling to wear study devices for specified period of time, or inability to be seen for 4 study visits

8 Measurements and procedures

This study has a total of four visits.

Visit 1	Visit 2 (following Home Trial #1)	Visit 3 (following Home Trial #2)	Visit 4 (following Home Trial #3)
-Sound Quality Questionnaire for own devices -Hearing Aid Satisfaction survey for own devices -Three sets of hearing aids programmed for participant -Participant leaves with set A for home trial #1	-Sound Quality Questionnaire for Set A -Hearing Aid Satisfaction survey for Set A -Participant returns Set A and is sent home with Set B for home trial #2	-Sound Quality Questionnaire for Set B -Hearing Aid Satisfaction survey for Set B -Participant returns Set B and is sent home with Set A (Participant is told this is set C) for home trial #3	-Sound Quality Questionnaire for Set A -Hearing Aid Satisfaction survey for Set A -Participant returns set A and exits study

9 Statistical design and analysis

Fifteen to twenty participants are needed to determine significant differences between the study set A device and study set B device algorithms and sound quality. As the null

hypothesis (no difference will be detected) is the expected outcome, a smaller number of participants is acceptable. As this is an exploratory study, no a priori power analysis has been done.

Data collection will terminate once the acceptable number of participants has been recruited and have completed all three trials. As this is an observational study and done for internal purposes only, there is no statistical criteria for termination.

There are no planned objective tests for this study, therefore, all data collected will be subjective and qualitative in nature. Responses will be collected as question, response, and anonymous participant ID.

Responses to the subjective questionnaires will be analyzed using a repeated measures ANOVA test. The mean scores for each subsection of the sound quality questionnaire will be analyzed between the three test devices for all participants. The mean scores of each subsection of the sound quality questionnaire will also be analyzed between the three sets of study devices for all participants. Repeated measures ANOVA will also be used to determine if there are any individual differences between the brands. Aggregate data and individual HASS data will be analyzed using repeated measures ANOVA.

10 Investigation Duration

The expected duration of participation is six weeks.

11 Data Handling and Management

Study data is recorded both with paper and with electronic Case Report Forms (p/eCRF). For each enrolled study participant a CRF is maintained. All CRFs are kept current to reflect the subject's status at each phase during the course of study. Participants cannot be identified in the CRF by name or initials and birth date but an appropriate coded identification is used. All study team members are authorized for the CRF entries and it is assured that anyauthorized person can be identified both for pCRFs and eCRFs. If pCRFs are used, the investigator's acronym as well as the subject ID is filled in and data are entered into an electronic file for analysis by the respective investigator and data get monitored by the assigned monitor. In case of a self-evident corrections, either the subject does it by himself or the investigator undertakes the correction by crossing out the word/sentence with a single horizontal line and by adding the correction including his personal identifier and the date.

All paper data will be stored in a locked filing cabinet at the Phonak Audiology Research Cen- ter (PARC). All electronic data files will be encrypted and stored on secure research computers. All identifying data will be stored at PARC.

The identifiable data kept at PARC will be destroyed as soon as the final analyses have been completed. The de-identified data will be kept for seven years after the publication of results. When the data are destroyed, paper records will be shredded by services provided at PARC. Electronic data will be encrypted as de-identified NOAH packages, where applicable, to be shared with Sonova Switzerland.

12 Amendments to the CIP

Amendments to the CIP, if necessary, will be updated with justification in this document.

13 Deviations from clinical investigation plan

Deviations from the CIP to protect the rights, safety and well-being of human participants under emergency circumstances may proceed without prior approval of the sponsor and theEC– such deviations will be documented and reported to the sponsor representative (Study Man- ager) and the EC as soon as possible. Apart from that the investigator is not allowed to deviate from this CIP unless that deviation does not influence the investigation data.

Each deviation from the CIP will be documented including date of protocoldeviation, name of investigator, participant ID, affected visit (if applicable), reason for deviation and anticipated influence on investigation data. Each deviation needs to be reported to the Sponsor (= Study Manager) and depending on the severity, also to the IRB.

14 Device accountability

The PI or authorized designee keep records documenting the following in a written process:

- Names of participants who received, used, returned, or disposed of device
- Date of receipt, identification, and quantity of each investigational device (batch/serial number or unique code)
- Expiry date (if applicable)
- Date(s) of use
- Participant identification
- Date on which the device was returned (if applicable)
- Date of return of unused, expired, or malfunctioning investigational devices (if applicable)
- Date and documentation of disposal of devices as per sponsor instructions(if applicable)

15 Informed consent process

At the beginning of the first appointment, investigators will hand the consent form to the participant in a private setting and grant sufficient time to read the whole form. The consent form contains detailed information about incentives and reimbursement. Any questions will be an- swered and the participant will be given sufficient time to decide whether or not they want to participate in the study. After the participant signed two copies of the consent form, the re- searcher will sign both copies as well and provide one copy to the participant.
In case of changes to the procedures described in the consent form, the participant will be informed at the beginning of an appointment. Informed Consent will only be obtained by investigation participants who can provide informed consent themselves before enrollment.

16 Adverse events, adverse device effects and device deficiencies

Device deficiencies and all **adverse events (AE)** including all **serious adverse events (SAE)** are collected, fully investigated and documented in the source document and appropriate case report form (CRF) during the entire investigation period, i.e. from participant's informed con- sent until the last protocol-specific procedure, including a safety follow-up period (ISO_14155, 2020). Documentation includes dates of event, treatment, resolution, assessment of serious- ness and causal relationship to device and/or investigation procedure.
Information on AEs is systematically collected during the regular investigation visits, and phone calls (if applicable).

The causality assessment of the SAE will be conducted according to MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.

The reporting of Serious Adverse Events and Device Deficiencies follows the Regulation (EU) 2017/745 and the MDCG 2020-10/1 Safety Reporting in Clinical Investigations of Medical Devices under Regulation (EU) 2017/745.

17 Vulnerable Populations

The investigation does not include any vulnerable populations.

18 Suspension or premature termination of the clinical investigation

The clinical investigation will be suspended or prematurely terminated if a study device malfunctions or if the participants or researchers are exposed to safety risks other than those outlined in this document. These events may include but are not limited to natural disaster, widespread outbreak of illness, compromised structure of the investigation site, etc.

There is a blinding code kept electronically with the study materials. This code can be used to link the participant with their study ID, if needed.

According to the FDA, follow-up is required for participants who experience serious adverse events. Follow-up will be conducted by the study manager until the nature of the event is resolved.

19 Publication policy

The clinical investigation will be registered in clinicaltrials.gov, a publicly accessible database, as required by US law.

The results of the clinical investigation will be documented as an internal report only.