Study Protocol and Statistical Analysis Plan

Using Headphone Presentation to Investigate Compression Strategy Modifications in Hearing Aids for Moderate-to-severe Hearing Loss – ID# 365

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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

The insight on general and individual preferences of fast and slow compression time constants generated in this study will be used to propose compression parameters for new hearing aids, which will be investigated in an in-person follow-up study.

1.2 Primary and Secondary Objectives

The primary objective of this study is to identify the most preferred compression setting for various acoustic scenes in experienced hearing aid users with moderate-to-severe hearing loss by subjectively rate recorded stimuli presented through headphones.

The secondary objective is to investigate potential benefit of a modifier for these compression settings by analyzing trends in individual preferences and their potential dependencies, such as hearing loss, acoustic scenes and previous amplification strategies.

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

This is a randomized, double-blinded, cross-over, remote study with participants serving as self-controls and the current default compression setting as well as a competitor's hearing aid as comparator. An unaided recording will be provided as reference.

2.2 Procedures

2.2.1 Investigation-related Procedure

The study is conducted remotely, so a potential participant's eligibility will be determined based on audiograms on file. If the study site doesn't have a participant's audiogram on file, the potential participant can request their HCP to release an audiogram to a study site.

After successful completion of the screening call, participants will sign the consent form and complete the demographic questionnaire over the phone. Afterwards, they will receive a package with a tablet and headphones and will get on another call with the researcher to conduct the subjective rating via an online sound survey tool.

The subjective rating will include rating of reverberation, sound source separation, sound source localization, overall preference ranking and an A/B test for preference. The stimuli consist of speech in quiet, speech in noise, reverberant speech, and music recorded with different hearing aids and hearing aid settings (hearing aids set to fast and slow compression settings, default

compression setting, a competitor's hearing aid and unaided), post-processed for headphone presentation and incorporated in an online sound survey.

3 Statistical design and analysis

3.1 Determination of Sample Size

We will recruit up to 28 participants, including up to 6 pilot participants. Previous research with subjective ratings has repeatedly shown that data collected with 15-25 participants can yield significant results. Since participants do not need to visit the research site, participants will be recruited from both locations as available.

Statistical criteria of termination of trial

If results for sound quality ratings are significant after 15 participants completed the rating, we will consider terminating the data collection.

3.2 Planned Analyses

3.2.1 Datasets to be analyzed, analysis population

- Analysis population: 15-25 participants
- Evaluation group: rating per setting
- Data sets: subjective ratings
- Additional analyses:
    - individual preferences and their potential dependencies, such as hearing loss, acoustic scenes and previous amplification strategies
    - correction for repeated measures.

3.2.2 Primary Endpoint Analysis

Automatic data analysis is available in the survey tool and will be used throughout the data collection for interim analysis. The study manager will analyze the collected data set in R Statistics after the data collection completed. Microsoft Excel may be used for arranging data and plotting data sets.

3.2.3 Secondary Endpoint Analysis

The study manager will analyze the collected data set in R Statistics after the data collection completed.

Subgroup analyses:

- Hearing loss: H_0: There is no significant difference in sound quality ratings among all tested conditions depending on hearing loss degree.
- Acoustic scenes: H_0: There is no significant difference in sound quality ratings among all tested conditions depending on acoustic scene.
- Previous amplification strategies: H_0: There is no significant difference in sound quality ratings among all tested conditions depending on previous amplification strategy of participants.

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3.2.4 Interim Analysis

Automatic data analysis is available in the survey tool and will be used throughout the data collection for interim analysis. Data will be adjusted for repeated measures.

3.3 Handling of missing data and drop-outs

Drop-outs will be replaced if possible (depending on participant availability and schedule). Smaller data sets will be analyzed if the data is complete for sub-sets of the investigation.