Study Protocol and Statistical Analysis Plan

Investigating Hearing Aid Frequency Response Curves – ID#3167

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NCT05521308

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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 study is an exploratory study in which we are evaluating various frequency gain curves for streaming and acoustic programs. Participants will be asked to rate overall preference while streaming and overall program preference in the presence of live stimuli. This clinical investigation is being conducted to determine if it is beneficial to implement new frequency gain curves for our products.

1.2 Primary and Secondary Objectives

Primary Objective

Determine if applying frequency specific gain changes to our current streaming programs are preferred by hearing aid users when compared to our current streaming program.

Secondary Objectives

- Determine if applying frequency specific gain changes to our current acoustic programs are preferred by hearing aid users when compared to our current acoustic programs.
- Determine if a proposed frequency response curves will impact speech intelligibility when compared to our current frequency response curves.

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

This clinical investigation is an interventional study and conducted at one investigation site. The investigation consists of a single group of participants that will be tested in all conditions (cross-over). When doing the streaming task, both the participant and the investigator will be blinded to the gain curves that are being compared as the software will randomize this. During the live preference ratings, participant's will be blinded to the program they are under, however the investigator will know the program as they will program the hearing aids prior to testing.

There are three gain curves that will be tested for the streaming task (Variations #1, #2, and #3) and two gain curves (Standard curve and Variation #4) that will be tested for live ratings task. Please note that changing between frequency curves is done simply by clicking a button on the hearing aid or via a mobile app. This will be done for the US matrix test and the live sound quality ratings task. For the streaming sound quality task, participants will compare pre-recorded stimuli, which have the various gain curves applied, via hearing aids. Frequency curves (i.e., interventions) can be toggled back and forth via the ratings software. Therefore, multiple gain curves (i.e. interventions) are compared simultaneously in each task (outcome measure) and participants can go back and forth between interventions during a task. This is done to allow participants to make accurate preference selections when comparing the various curves. The US matrix test is the only task in which switching back and forth during a measurement is not allowed

as it is an objective measure of speech recognition and SRT50 scores are recorded per condition tested (unaided, standard curve, and variation #4). Switching will only occur between measurements for the US Matrix test task.

Streaming Program Interventions
Variation #1
Variation #2
Variation #3
Acoustic Program and US Matrix Test Interventions
Standard Curve
Variation #4

2.2 Procedures

2.2.1 Investigation-related Procedure

Recruitment paths:

- Our internal database will be used to see if any potential participants who fit the inclusion criteria are available.
- Referrals from Hearing Healthcare Providers in the Kitchener and surrounding areas will be requested. HCPs will be contacted and provided with the recruitment materials.

Tasks

During the first appointment, participants will complete the speech in noise test and complete the live preference ratings task. During the second appointment, participants will complete the streaming preference ratings task.

Visit 1 Approximately 2 Hours	• Study consent form and related forms will be reviewed and signed. • Hearing test will be completed (including otoscopy, tympanometry, speech testing (SRT and WRS), and pure-tone threshold testing (air and bone)) • Hearing aid fitting is completed, and REM is completed. • Speech in noise task is completed. • Live preference ratings are completed
Visit 2 Approximately 2 Hours	• Streamed preference ratings are completed. • At the end of data collection, participant will be debriefed and compensated for their time

3 Statistical design and analysis

3.1 Determination of Sample Size

We will recruit 25 participants for all tasks. To obtain a power of 90% with 10% of risk of running into beta error (i.e., miss) and with 5% risk of running into alpha error (i.e. false alarm), the power analysis estimated the total sample size to be 25, leading to an actual power of 90%.

3.2 Statistical criteria of termination of trial

N/A

3.3 Planned Analyses

3.3.1 Datasets to be analyzed, analysis population

Datasets to be analyzed:

- Demographic information (e.g., hearing profiles, listening experience, hearing aid experience, age, etc.) will be analyzed
- Subjective ratings provided by participants when listening to acoustic or streaming signals
- Objective scores collected from speech in noise test

3.3.2 Primary Endpoint Analysis

The primary analysis will be the subjective ratings participants provide for the streaming task. Subjective ratings will be tallied to see which frequency response curve was preferred the most. Participants will be presented with two samples at a time and will choose which sample they prefer. For example, if Sample A was preferred over Sample B, then Sample A gets a score of 1. If Sample B was preferred over Sample A, then Sample B gets a score of 1. In some trials, if the participant does not notice a difference between the two samples, then neither sample will get a score. At the end of the task, scores will be tallied to determine which sample was preferred the most overall. There will be 3 different samples. The minimum value for the tallied score would be 0 (the sample was not preferred at all) and the maximum value would be 2 (implying that the sample was preferred in all trials in which it was involved). Higher scores mean that the sample was preferred more and lowers scores mean the sample was not preferred as much when compared to the other samples.

3.3.3 Secondary Endpoint Analysis

The secondary analysis will consist of evaluating the subjective ratings for the acoustic tasks and the objective scores for the speech in noise test. Live preference ratings will be done in a similar fashion to the streamed preference ratings, however there will only be two programs to compare. Participants will do a live paired comparison task and determine which frequency response curve they prefer when listening to various sound samples. At the end, preferences will be tallied to determine which program was preferred overall. Additionally, these ratings will be done in the sound booth as well as outside.

For the speech test, average scores across all participants will be compared to determine equivalence. Lower scores will indicate better performance.

3.3.4 Interim Analysis

N/A

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 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.