Study Protocol and Statistical Analysis Plan

Investigating Hearing Aid Frequency Response Curves - ID# 12792

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NCT05828017

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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 exploratory study evaluates a series of proposed frequency gain curves, comparing them to our current frequency gain curve across various hearing aid programs and configurations (both acoustic and streaming). Participants were asked to rate speech clarity, noise intrusion, comfort, and overall preference in the presence of live stimuli. Additionally, they were asked to rank two proposed streaming frequency response curves alongside our current standard streaming curve. SRT50 scores were also collected using the US Matrix test task. The aim of this clinical investigation is to assess whether the proposed gain offsets provide benefits for hearing aid users in different listening environments.

1.2 Primary Objective

The primary objective of this study was to evaluate whether participants with moderate to severe sensorineural hearing loss (SNHL) prefer a newly proposed frequency gain curve (Variation #1) compared to our current frequency response curve, when fitted with different hearing aid programs or under various hearing aid settings. Testing was conducted in a controlled lab environment, where participants listened to a range of stimuli to assess which program they preferred and how they rated each program based on various sound quality metrics.

1.3 Secondary Objectives

One secondary objective of this study was to assess whether two newly proposed streaming frequency response curves (Variation #2 and Variation #3) are preferred by hearing aid users compared to our current streaming frequency response curve, across various musical genres and speech stimuli.

Another secondary objective was to evaluate the impact of the proposed frequency response curve (Variation #1) on speech performance in noise, specifically by comparing SRT50 scores to those obtained with the current frequency response curve. Participants will complete a standardized test (OLSA – US Matrix test) in noise within a sound booth, under three conditions: a program with the proposed frequency response curve, a program with the current frequency response curve, and an unaided condition (without hearing aids).

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

This clinical investigation was an interventional study conducted at two investigation sites. The study involved a single group of participants who were tested under all conditions in a crossover design. During the live preference ratings, participants were blinded to the program they were using, although the investigator was aware of the program, as they programmed the hearing aids prior to testing. For the streaming sound quality task, participants wore headphones, and both participants and investigators were blinded to the program being rated.

The table below indicates the various programs that each participant evaluated.

Programs	Interventions
Acoustic Programs	
Program 1	Standard Frequency Response Curve
Program 1	Proposed Frequency Response Curve - Variation #1
Program 2	Standard Frequency Response Curve
Program 2	Proposed Frequency Response Curve - Variation #1
Program 3	Standard Frequency Response Curve
Program 3	Proposed Frequency Response Curve - Variation #1
Program 4	Standard Frequency Response Curve
Program 4	Proposed Frequency Response Curve - Variation #1
Streaming Programs	
Program 5	Current Streaming Frequency Response Curve – Variation #2
Program 5	Proposed Streaming Frequency Response Curve - Variation #3
Program 5	Proposed Streaming Frequency Response Curve - Variation #4
US Matrix Test Task Programs	
Program 1	Standard Frequency Response Curve
Program 1	Proposed Frequency Response Curve - Variation #1
Unaided	No hearing devices

Acoustic Task:

Participants were seated in the center of a 12-loudspeaker array, positioned at azimuths of 0°, 30°, 60°, 90°, 120°, 150°, 180°, 210°, 240°, 270°, 300°, and 330° in a sound-treated room. The 12 speakers were used to render ambisonic audio scenes. While immersed in these scenes, participants were asked to toggle between two frequency response curves: the standard curve and the proposed frequency response curve – Variation #1 – using an iPhone.

Participants were then asked to rate the following attributes for each program:

1. Which program resulted in increased noise intrusion?
2. Which program provided better speech clarity?
3. Which program offered greater comfort?
4. Which program did they prefer overall?

The responses were tallied for further analysis. This process was repeated for four different hearing aid programs, where the frequency response curves were compared but not the programs themselves. In other words, ratings from one hearing aid program were not compared with those from another.

Streaming Task:

Participants were asked to wear headphones while listening to three versions of the same pre-recorded stimulus: the Current Streaming Frequency Response Curve (Variation #2), the Proposed Streaming Frequency Response Curve (Variation #3), and the Proposed Streaming Frequency Response Curve (Variation #4). This process was repeated with multiple different stimuli. After listening to each version for each stimulus, participants were asked to rank them from most preferred to least preferred, with one version ranked in between. Responses were recorded on a laptop, and the rankings for each curve were tallied and compared at the end for further analysis.

US Matrix Test Task:

Participants were seated at the center of an 8-loudspeaker array positioned at azimuths of 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° within a sound-treated room. Noise was presented from all speakers, except the one at 0° azimuth, while speech was presented from the front speaker at 0°. Participants were asked to repeat sentences they heard while wearing hearing aids programmed with either the Standard Frequency Response Curve or the Proposed Frequency Response Curve – Variation #1, or while wearing no hearing aids at all. A total of 20 sentences were presented for each condition. At the end of the experiment, a dB SNR (signal-to-noise ratio) score was calculated for each condition and used for further analysis.

2.1.2 Investigation-related Procedure

Recruitment paths:

- Our internal database was accessed to see if any potential participants who fit the inclusion criteria are available.
- Referrals from hearing healthcare providers in the Kitchener and surrounding area were requested.

Tasks

Appointment tasks are listed in the table below.

Tasks per appointment visit.

Visit 1	Visit 2	Visit 3
• The visit will last approximately 2 hours. • Participants will come in and will be asked to complete the following: • 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)) • Earmold impressions taken	• The visit will last approximately 2 hours. • Participants will come in and will be asked to complete the following: • Earmolds are fit to participants and hearing aids are programmed • Real ear measurements taken • Live sound quality and preference ratings task is completed.	• The visit will last approximately 2 hours. • Participants will come in and will be asked to complete the following: • US Matrix test conducted • Streaming sound quality ratings task completed • At the end of data collection, participant will be debriefed and compensated for their time.

2.2 Determination of Sample Size

Our previous study (ID – 3167, NCT05521308) evaluated similar hearing aids programs (e.g., the current program vs. the proposed programs) and had a similar study design. Therefore, we have determined that a sample size of 20-25 participants, which is the sample we used for the previous study - ASQ study (SRF-3167), is sufficient for our purposes.

2.3 Statistical criteria of termination of trial

n/a

2.4 Planned Analyses

2.4.1 Datasets to be analyzed, analysis population

Datasets to be analyzed:

- Demographic / health care data information – age, sex, hearing thresholds
- Subjective ratings provided by participants when listening to acoustic or streaming signals
- Objective scores collected from speech in noise test

2.4.2 Primary Endpoint Analysis

The primary analysis focused on the subjective responses provided by participants during the acoustic task, comparing their experiences under different frequency response curves, hearing aid programs, and sound scenes. Scores for all 20 participants were tallied for the final analysis. Higher scores indicated a greater preference for a particular frequency response curve, while lower scores indicated a lesser preference. Additionally, the mean number of times participants preferred each frequency response curve (intervention) or rated the two interventions as equal in sound quality was calculated, based on the four sound quality attributes: comfort, noise intrusiveness, speech clarity (when applicable).

The analysis proceeded as follows:

1. **Chi-Square Analysis (First Step)**: A chi-square test was conducted to compare the three means

(the mean number of times the standard curve was chosen, the mean number of times Variation #1 was chosen, and the mean number of times participants rated the sound quality as "same"). This test aimed to determine whether participants perceived a difference between the two curves by not selecting the "same" option.

2. **Chi-Square Analysis (Second Step)**: Another chi-square test was conducted to compare the two means (the mean number of times the standard curve was chosen versus the mean number of times Variation #1 was chosen). This test assessed whether there was a preference between the two curves.

This process was repeated for each hearing aid program

2.4.3 Secondary Endpoint Analysis

The secondary analysis focused on the subjective sound quality ratings provided by participants during the streaming task. Participants were asked to rank three stimuli in order of overall preference and sound quality, with each stimulus corresponding to one of the three frequency response curves being tested (Variations #2, #3, or #4). The analysis involved calculating the mean number of times each curve was ranked as the highest, lowest, and middle choice across all stimuli.

The analysis proceeded as follows:

1. **Chi-Square Analysis (First Step)**: A chi-square test was conducted at each ranking level (highest, middle, and lowest) to determine how each frequency response variation was ranked.
2. **Chi-Square Analysis (Second Step)**: Two additional chi-square tests were run at each ranking level to compare how the proposed frequency response curves (Variations #3 and #4) were ranked against Variation #1.

In total, 9 chi-square analyses were performed for this task.

For the speech-in-noise tests, the average SRT50 scores across all participants were compared to determine equivalence. Lower SRT50 scores indicate better performance.

1. **One-Way ANOVA**: A one-way ANOVA was conducted to assess the impact of the different interventions (standard curve, Variation #1, and unaided) on the SRT50 scores.
2. **Post-Hoc Analyses**: Post-hoc pairwise comparisons were conducted following the ANOVA, where one intervention was excluded at a time to assess differences between the remaining interventions.

2.4.4 Interim Analysis

N/A

3 Informed consent process

3.1 Process for obtaining informed consent

Participants were 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 consented by initialing, signing, and dating the consent form in the respective fields. The name of the researcher obtaining consent was also noted. This document was converted into a PDF and was uploaded into the study folder. The paper form was stored in a secured cabinet and only accessible to the researchers.