Study Protocol and Statistical Analysis Plan

Lab Evaluation of Novel Hearing Aid Coupling Method - ID# 1082

January 30, 2024

NCT05377359

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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 was an exploratory study in which we evaluated a novel coupling method that allows us to take advantage of both open and closed fittings in a single solution and compared this to traditional coupling methods. The various coupling methods were evaluated using two outcome measures: streaming sound quality and situational preference.

1.2 Primary Objective

The primary objective of this study was to determine if participants with mild to moderately-severe SNHLs find an improvement in streaming sound quality under the novel coupling method (state 1) when compared to the novel coupling method (state 2). Additionally, streaming sound quality of the novel coupling method was compared to traditional open and vented domes.

1.3 Secondary Objectives

The secondary objective of this study was to determine how overall preference ratings for streamed stimuli in realistic noise changes when using novel coupling methods while in different states and while the hearing aid mic is on and off.

2 Design of the clinical investigation

2.1 General

2.1.1 Design Type

This study was a single-blinded, single group interventional study where stimulus presentation order was randomized between participants. All participants were subject to each test condition (cross-over). There was no control group. Participants and investigators were always blinded to the programs that were being rated during testing.

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

Primary Objective	Novel Coupling Method – State 1
	Novel Coupling Method – State 2
	Open Domes
	Vented Domes
Secondary Objective	Novel Coupling Method – State 1 – Mic Off
	Novel Coupling Method – State 1 – Mic On
	Novel Coupling Method – State 2 – Mic Off
	Novel Coupling Method – State 2 – Mic On

2.2 Procedures

2.2.1 Investigation-related Procedure

Recruitment paths:

- Western University's internal database was accessed to see if any potential participants who fit the inclusion criteria were available.
- Referrals from hearing healthcare providers in the London and surrounding area were requested.
- Self-referral from clinical investigation postings.

Tasks:

Appointment tasks are listed in the table below.

Tasks per appointment visit.

Visit 1	Visit 2
• The visit would last approximately 2 hours. • Participants were asked to complete the following: o Review and sign study consent form and related forms o Hearing test was completed (including otoscopy, tympanometry, speech testing (SRT and WRS), and pure-tone threshold testing (air and bone))	• The visit would last approximately 2 hours. • Participants were asked to complete the following: o Streaming sound quality task (primary objective) o Situational preference task (secondary objective)

2.3 Determination of Sample Size

Sample size was estimated based on a previous version of the study in which the primary outcome was speech in noise recognition. Sample size was estimated using GPower software, for repeated measures ANOVA (Faul et al., 2007; Faul et al., 2009). Past studies in this area have typically used about 20 participants. It should be noted that as a post-market exploration study, a formal sample size estimation for the sound quality evaluation is not mandatory.

2.4 Statistical criteria of termination of trial

n/a

2.5 Planned Analyses

2.5.1 Datasets to be analyzed, analysis population

Datasets to be analyzed:

- Demographic information (e.g., hearing profiles, hearing aid experience, age, etc.) will be analyzed.
- Sound Quality: Subjective ratings (fullness, sharpness, overall preference) (1-100)
- Situational Preference: Subjective ratings (overall preference) (1-100)

2.5.2 Primary Endpoint Analysis

Sound quality ratings were analyzed using ratings on a scale from 1-100. Ratings were transformed to rationalized arcsine units (Studebaker, 1985). Transformed scores were inspected for normality by visual inspection of histogram data, and protected against departures from sphericity using Greenhouse-Geisser corrections to degrees of freedom. Scores were analyzed using a 3x4 repeated measures analysis of

variance (RM-ANOVA) with stimulus (classical, pop, speech) and condition (state 1, state 2, open dome, closed dome) as the within-subjects factors. Significant effects were located using pairwise comparisons with Bonferroni corrections.

2.5.3 Secondary Endpoint Analysis

Situational preference data were analyzed using a 2x2x2 RM-ANOVA with condition (state 1, state 2), microphone state (on vs. off), and stimulus (music, speech) as within-subjects factors. Data and analysis followed the same treatment procedures as for the sound quality data. A separate RM-ANOVA was run for when participants were focusing on the stream and for focusing on the external environment. Planned contrasts included: comparison of conditions and or microphone states across stimuli, and comparison of conditions and or microphone states within each stimulus. Comparisons between stimuli were not of interest.

2.5.4 Interim Analysis

N/A

3   Informed consent process

3.1   Process for obtaining informed consent.

Participants are presented with the Letter of Information (LOI) by email, mail, or in person. They are provided time to review the LOI. They are permitted to ask any questions they have about the information in the LOI. They will then sign the letter of information. A member of the study staff will also sign the LOI. A copy of the LOI is provided to the participant.

Faul, F., Erdfelder, E., Lang, A.-G., & Buchner, A. (2007). G*Power 3: A flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior Research Methods, 39, 175-191.

Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. Behavior Research Methods, 41, 1149-1160.

Studebaker, G. A. (1985). A "rationalized" arcsin transform. Journal of Speech and Hearing Research, 28, 455-462.