

Comparison of Hearing Aid Fitting Outcomes Between Self-fit and Professional Fit for MDHearing Smart Hearing Aids

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REVISED Statistical Analysis Plan

This statistical analysis plan discusses two studies: the first is a Human Factors study on the safety and usability of a subject device, the MDHearing Smart Hearing Aid; the second is a Clinical Performance study focused on examining efficacy of the subject device. Both studies recruited samples of untrained participants from the intended user population of the devices.

1. Human Factors Study

The human factors study will assess safety and usability of the subject device by providing participants with the packaged device and accompanying User Manuals and training materials. All participants will complete hands-on use scenarios and knowledge tasks with the devices in a simulated intended use environment.

1.1. Primary Endpoints

Usability will be established if the majority of participants are able to complete the use tasks, referencing the included User Manual as needed.

1.2. Secondary Endpoints

The primary safety endpoint is evaluated by tabulations of adverse events. Another aspect of safety evaluated will be participants' responses to questionnaire items about hearing health safety issues.

2. Clinical Performance Study

The clinical performance study will use a randomized, controlled field trial to examine safety and effectiveness of the subject device, comparing hearing aid outcomes for self-fitting of the device to professional-fitting of the same device.

2.1. Primary Endpoints

The primary endpoint is user-reported (subjective) aided benefit with the subject devices. This endpoint is met if the self-fit group demonstrates significantly non-inferior aided benefit to the professional-fit group as assessed with two standard questionnaires: 1) Abbreviated Profile of Hearing Aid Benefit (APHAB), and 2) 12-item short form of the Speech, Spatial, and Qualities of Hearing scale (SSQ12).

2.2. Safety Endpoint

The primary safety endpoint is evaluated by tabulations of adverse events.

2.3. Secondary Endpoints and Other Effectiveness Measures

The Clinical study will have the following secondary endpoints: speech-in-noise (objective) aided benefit, self-fit user satisfaction, appropriateness (or validity) and reliability of self-fitting method, and robustness of the personalization process to estimate hearing sensitivity for self-fitting using the MDHearing app.

Objective benefit will be considered acceptable if self-fit users have significantly non-inferior benefit scores for speech in noise performance on the QuickSIN compared with the professionally-fit group.

Quick SIN will be performed at two presentation levels: 70 dB HL and Most Comfortable Loudness Level (MCL).

Self-fit participants' satisfaction with sound quality, cost of devices, and ease of device use is evaluated by questionnaire. Sound quality and device cost is considered satisfactory if a majority of respondents are "satisfied" or "very satisfied" according to questionnaire responses; ease of use is considered satisfactory if a majority of questionnaire responses indicate that the hearing aids were easy to operate or that they were able to operate the devices.

The reliability and validity endpoints for in-lab hearing aid performance testing are probe-microphone measures of hearing aid output in the ear canal. The self-fitting method is considered to be reliable if average mean absolute differences (MAD) in the real ear aided response (REAR) measured from 500-4000 Hz after each experimental trial (or run) of user-based self-fitting is 5 dB or less with significance testing. The REAR of professionally-selected hearing aid settings achieved as part of the initial fitting of the hearing aids for professional-fit group participants will be evaluated for proximity to NAL-NL2 prescriptive targets at the respective test frequencies, and amplification will be deemed adequate for the intended user population (adults with mild to moderate hearing loss) if a subjectively close approximation to targets, on average, is achieved.

Participants' hearing levels in each ear from 500-6000 Hz as measured in a quiet room using the MDHearing app installed on a smartphone or tablet (i.e., the personal profile) is compared to their "gold standard" audiometric pure tone thresholds obtained by a clinician using an audiometer in a double-walled sound-treated booth to evaluate the robustness of the personalization process for estimating hearing sensitivity using the MDHearing app; this endpoint will be met if the average difference between personal profile and audiogram is within 10 dB, with a 95% confidence interval.

3. Software

All analyses will be performed using an established statistical computing software (MATLAB, R, JMP).

4. Data Collection

Due to the COVID-19 pandemic, it is understood some subjects may not be able to attend their appointments as scheduled. In that case, subjects will be scheduled as soon as they are able to safely attend appointments. Missing data will be noted as such.

5. Data Use

Human factors endpoints will be used to determine if the current user manual and/or MDHearing app need to be adjusted to ensure user success and safe operation of the devices.