Investigations of Ear Tip Performance, Perceptions, and Experiences (IETPPE)

NCT05725824

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PROTOCOL

General Procedures

Participants completed three phases: Listening Session #1, Earmold Fabrication, and a Listening Session #2. See **Figure 4.2**. The primary distinction among listeners was the material-type of earmold they received first. There are three material-types and thus three groups that participants could be initially assigned to. All participants received and were tested with each of the three material-type groups. Earmolds were connected to the same Unitron T-Stride M behind-the-ear hearing aid.

Figure 4. 1 *Participant-study flow chart for RCT study.*

Specific Procedures

Listening Session #01

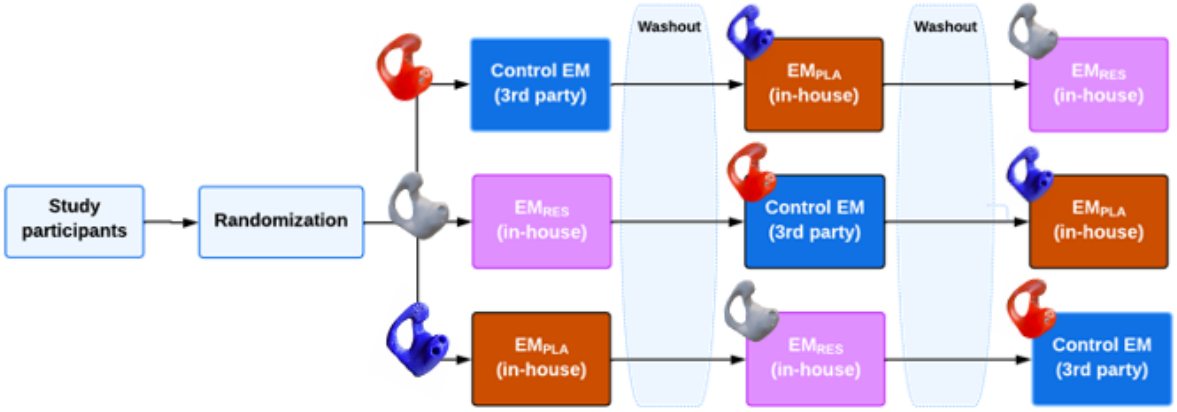
Participants completed intake questionnaires that included questions about hearing health history, demographics, and study eligibility information. At this stage, researchers also informed participants of procedures, risks, and benefits of the study. If participants met eligibility criteria up to this point, they underwent conventional audiologic testing to evaluate hearing and ear function following best-practices for audiology. Otoscopy, a visual exam of the ear, was used to ensure patent ear canals, normal appearing tympanic membrane, and normally aerated middle

ear. Air conduction and bone conduction pure tone audiometry were used to establish hearing thresholds from 250 to 8000Hz, bilaterally. Normal hearing was considered thresholds equal or less than 25 dB HL. If participants met audiometric candidacy, a custom ear impression was made of one of their ears using a common, clinically used, two-part impression material.

Randomization

Each participant was made three earmolds for a single ear. The main difference between participants was the material-type of earmold that they received first. All participants were eventually fit with and underwent testing with each earmold material-type. Participants were randomly assigned to one of three arms, using a 1:1 allocation ratio, each with a different initial material type. The three material-type groups included a control group (EM_{CTRL}) made by a professional manufacturer, and two in-house study groups that were 3D printed using Resin (EM_{RES}) and PLA (EM_{PLA}). See **Figure 4.3**. Randomization was completed *a priori* via a list generated by a custom Microsoft Excel script. This script randomly sequenced three blocks of ten numbers equally containing values from 1 to 3. Once participants were deemed eligible, they were automatically assigned the next value on the randomized list, from 1 to 3, indicating which arm of the study they were allocated to.

Figure 4. 2 *Workflow study diagram across material-type groups*



Earmold Fabrication Period

After completing Listening Session #01, ear impressions were digitally scanned and edited using commercially available 3D editing software. The physical ear canal impression was then sent to a third-party earmold manufacturer. Each participant was made three earmolds, for an overall total of 90 earmolds. For each individual, one earmold was created using a *third- party* manufacturer with the traditional service delivery pathway and two earmolds were created *in-house* with the novel service-delivery pathway using local 3D printers. The *third-party* earmold served as the control earmold. The *in-house* earmolds were made from two different material-types and served as the study earmolds. To control for style of earmolds, all earmolds were made in a skeleton style with a sound bore that accommodates size #13T tubing and a separate select-a-vent (SAV).

Listening Session #02

Once all earmolds were fabricated and received, participants were scheduled for Listening Session #02. This stage involved collecting objective acoustic measurements and subjective perceptual ratings while wearing each of the earmolds. A stock Unitron T-stride M behind-the-ear hearing aid was programmed to simulate a flat, mild, sensorineural hearing loss at

40 dB HL from octave frequencies between 250 to 8000Hz. The hearing aid was programmed and fit to NAL-NL2 targets for these threshold values. All advanced hearing aid programming and features were disabled. The same hearing aid was used across all participants. Participants underwent objective and subjective measures three times, once for the *third-party* control earmold and twice for each *in-house* study earmold. Each material-type condition was separated by a short 10 minute washout period, during which participants completed a self-assessment questionnaire.

ANALYSIS PLAN

The alpha level of statistical significance was set at .05 for all statistical analyses. The main statistical analysis included a one-way, within group, repeated measures analysis of variance (RM-ANOVA) to compare the effect of 3D printed material across outcome measures. Assumption testing for normality, outliers, and sphericity were utilized. Outliers were assessed on an individual basis, using Cook's D and a strict cutoff of 0.5. Sphericity was evaluated using Mauchly's test for Sphericity with a criteria of .05. If sphericity was violated, then both Geisser & Greenhouse and Huynh Feldt correction factors were used, with the latter being used when epsilon was greater than .075. Pairwise t-tests with Bonferroni correction were used for planned comparisons.