

Statistical Analysis Plan (SAP) – Primary Analysis (APHAB)

Project: Evaluation of Unilateral vs Bilateral Hearing Aids for the Treatment of Age-related Hearing Loss

IRB Number: Pro00106077

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Investigator Agreement

- ☐ All statistical analyses included in an abstract or manuscript should reflect the work of the biostatistician(s) listed on this SAP. No changes or additional analyses should be made to the results or findings without discussing with the project biostatistician(s).
- ☐ All biostatisticians on this SAP should be given sufficient time to review the full presentation, abstract, manuscript, or grant and be included as co-authors on any abstract or manuscript resulting from the analyses.
- ☐ If substantial additional analysis is necessary or the aims of the project change, a new SAP will need to be developed.
- ☐ Publications resulting from this SAP are supported in part by the Duke CTSA and must cite grant number UL1TR002553 and be submitted to PubMed Central.
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Activity Log

10.07.2021 Moved 6 month APHAB outcomes to separate SAP and edited based on feedback/comments in the 09.21.2021_SBP SAP.
11.01.2021 Added written models
01.20.2022 Edited document based on discussions
07.20.2022 Stratified Table 1 by randomization
11.17.2022 Added additional details to variables
12.15.2022 Edited based on discussions
06.28.2023 Refined ITT language
05.31.2024 Updated audiogram data information
07.11.2024 Added specific subgroup analysis (mild vs moderate)
09.30.2024 Added APHAB subscale change scores, specified primary analysis as “completers” analysis, changed benefit scores to change scores (3m-baseline), updated variable names, added information about adjusted models/subgroup models
10.28.2024 Added ineligible (missing) definition to binary APHAB change score in Section 3.2, date of data lock

11.13.2024 Moved tables to different order, removed tables for analyses we are not doing/created a subsection describing which analyses we are not doing, updated heterogeneity of treatment effects to only mention variables of interest, added variables of interest for multiple imputation

Acronyms	APHAB	Abbreviated Profile of Hearing Aid Benefit
	MoCA	Montreal Cognitive Assessment
	EC scale	Ease of Communication
	BN scale	Background Noise
	RV scale	Reverberation
	AV scale	Aversiveness

1 Study Overview

Background/Introduction: The overall goal of the project is to determine the benefit of unilateral or bilateral hearing aid fittings in adults with mild-to-moderate age-related hearing loss. This will address the lack of high-quality evidence supporting bilateral hearing aids over unilateral hearing aids. This project will use a randomized controlled trial with two treatment arms: a bilateral hearing aid fitting group and a unilateral hearing aid fitting group.

1.1 Primary Aims

- Compare the APHAB change scores between the two arms (bilateral hearing aid and unilateral hearing aid) at the end of month 3. The primary hypothesis is that bilateral hearing aids are superior to the unilateral hearing aids with respect to the overall patient-reported benefit.

1.2 Secondary Aims

- Compare the APHAB change scores between the two arms at the end of month 3 while adjusting for covariates
- Compare the APHAB change scores between the two arms at the end of month 3 with subgroup analyses
- Sensitivity analysis with missing data
- Analyze APHAB binary response at 3 months
- Create descriptives for the 4 APHAB subscales in unaided (baseline) and aided conditions (3 month) for each arm

2 Study Population

2.1 Inclusion Criteria

- 50+ years of age
- Mild to moderate, symmetrical SNHL (symmetrical: < 20 dB between ears on average from 500-4000 Hz)
- Open-mindedness to unilateral or bilateral amplification
- No prior hearing aid experience
- Adequate literacy to complete questionnaires
- Willing to purchase study-specific hearing aid(s)

2.2 Exclusion Criteria

- Concerns for middle ear pathology
- Concerns for retrocochlear pathology
- Severe tinnitus as the reason for seeking amplification
- Co-morbid condition that would interfere with study (e.g., dementia, blindness, neurologic pathology)
- History of fluctuating hearing loss

2.3 Data Acquisition

Fill in all relevant information:

Study design	Randomized controlled trial with 2 arms (bilateral hearing aid, unilateral hearing aid) Note: Randomization was stratified by clinical site.
Data source/how the data were collected	Screening information pulled from EHR data Baseline surveys captured via in-person interview and recorded in REDCap
Contact information for team member responsible for data collection/acquisition	All data access is through [REDACTED]. Questions on data validity will go to PI: Sherri Smith (Sherri.smith@duke.edu)
Date or version (if downloaded, provide date)	Date of data pull (locked data): 10/17/2024
Data transfer method and date	Direct data extraction from REDCap
Where dataset is stored	REDCap Extracted data and analytic datasets will be stored in a secure drive on the CRU folder. Path name: \\duhs-vclin-nc1\dusom_biostats_fs\Data\BiostatsCore\CRU\Head and Neck\Smith\PCORI_Pro00106077\Data pulls

Notes: Additional variable details for all variables can be found in the “PCORI Variable Details” Excel file. Scoring details for APHAB can be found in “PCORI Scoring 20240923”.

Description:

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Primary Outcome(s)

Outcome	Description	Variables and Source	Specifications
APHAB Change Score	Difference in aided APHAB scores at month 3 and unaided scores at baseline	aphab_change	Scale score – will need to calculate global communication scores at baseline (unaided) and 3 months (aided), subtract (3 months – baseline) A lower score on APHAB is better.

			<p>Rescore variables and multiply by 100</p> <ul style="list-style-type: none"> • 1 = 0.99 • 2 = 0.87 • 3 = 0.75 • 4 = 0.50 • 5 = 0.25 • 6 = 0.12 • 7 = 0.01 <p>Reverse score questions 1, 9, 11, 16, 19, 21</p> <p>Global score: mean of variables in the EC, BN, RV subscale scores (excludes questions 3, 8, 13, 17, 20, 22)</p> <p>Note: APHAB has 4 subscales and a global communication scale. The study is powered based on the benefit score on the global communication scale (August 2019 draft – APHAB SD of 25 with different levels of Cohen’s D).</p>
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3.2 Secondary Outcome(s)

Outcome	Description	Variables and Source	Specifications
APHAB change score – binary, 3 months	Responders vs non-responders for primary APHAB outcome	<p>Decrease of 25 units: use aphab_change_responder</p> <p>Decrease of 15 units: use aphab_change_responder_15</p>	<p>Patients with a decrease of at least 25 units (or 15 units for the sensitivity analysis) on the APHAB scale at month 3 will be considered “responders.” Patients not returning or who do not have a score at 3 months will be considered “non-responders.” Patients with a baseline score < 25 (or < 15) are ineligible (missing).</p> <p>Binary (25 unit decrease):</p> <ul style="list-style-type: none"> • Missing if baseline score <25 • 1 if aphab_change <=-25

			<ul style="list-style-type: none"> • 0 else Binary (15 unit decrease); <ul style="list-style-type: none"> • Missing if baseline score <15 • 1 if aphab_change <=-15 • 0 else
APHAB – 4 subscales	EC, BN, RV, AV scales at both baseline and 3 months, as well as change scores	Baseline variables: aphab_ec_base aphab_bn_base aphab_rv_base aphab_av_base 3-month variables: aphab_ec_3m aphab_bn_3m aphab_rv_3m aphab_av_3m Change scores: aphab_ec_change aphab_bn_change aphab_rv_change aphab_av_change	Rescore variables and multiply by 100 <ul style="list-style-type: none"> • 1 = 0.99 • 2 = 0.87 • 3 = 0.75 • 4 = 0.50 • 5 = 0.25 • 6 = 0.12 • 7 = 0.01 Reverse score questions 1, 9, 11, 16, 19, 21 EC: mean of questions 4, 10, 12, 14, 15, 23 BN: mean of questions 1, 6, 7, 16, 19, 24 RV: mean of questions 2, 5, 9, 11, 18, 21 AV: mean of questions 3, 8, 13, 17, 20, 22

3.3 Additional Variables of Interest

Variable	Description	Variables and Source	Specifications
Randomization assignment	Hearing aid assignment	assign	Binary 1: unilateral 2: bilateral
Clinical site	Which site - Duke or Vanderbilt?	which_site Character version: which_site_ch	Binary 1: Vanderbilt 2: Duke
Gender		gender Character version: gender_ch	Categorical <ul style="list-style-type: none"> • 1: male • 2: female • 3: other • 99: declined
Age	Age at baseline (years)	age_base	Continuous

		Baseline visit is baseline_date	Years from baseline_date to dob Baseline visit is defined as apha_base_date if non-missing, otherwise use date_moca
Race		race Character version: race_ch	Categorical <ul style="list-style-type: none"> • 1: African American/Black • 2: White/Caucasian • 3: Asian • 4: Native American/Alaska Native • 5: Native Hawaiian/Pacific Islander • 6: More than one race • 99: Declined <p>If cell counts are less than 10 for a given category, we may not report the exact cell count.</p> <p>NIH racial categories: -American Indian/Alaska Native -Asian or Asian American -Black or African American -Native Hawaiian/Pacific Islander -White</p>
Ethnicity		ethnicity Character version: ethnicity_ch	Categorical <ul style="list-style-type: none"> • 1: Hispanic or Latino • 2: Not Hispanic or Latino • 999: Declined <p>If cell counts are less than 10 for a given category, we may not report the exact cell count.</p>
Income	Personal Income Last Year	income Character version: income_ch	Categorical <ul style="list-style-type: none"> • 0: \$0 • 1: \$1 to \$9999 • 2: \$10,000 to \$24,999 • 3: \$25,000 to \$49,999 • 4: \$50,000 to \$74,999

			<ul style="list-style-type: none"> • 5: \$75,000 to \$99,999 • 6: \$100,000 to \$149,999 • 7: \$150,000 or greater • 999: Prefer not to answer <p>We will also simplify this to below median/above median/prefer not to answer for heterogeneity of treatment effects</p>
Hearing Aid Health Insurance Benefits		benefits Character version: benefits_ch	Categorical <ul style="list-style-type: none"> • 0: No • 1: Yes • 998: Not Sure
Marital Status		marital Character version: marital_ch	Categorical <ul style="list-style-type: none"> • 1: married • 2: widowed • 3: divorced • 4: separated • 5: never married • 999: prefer not to answer
Living arrangements		living Character version: living_ch	Categorical <ul style="list-style-type: none"> • 1: alone • 2: with spouse • 3: with spouse and others • 888: other • 999: prefer not to answer
Education		education Character version: education_ch	Categorical <ul style="list-style-type: none"> • 1: less than high school • 2: high school • 3: some college • 4: 4-year degree • 5: graduate degree • 888: other • 999: prefer not to answer
Baseline Date Quarter		baseline_quarter	Categorical Put baseline date into quarters
Cognition (Screened via MoCA)	Adjusted MoCA score	total_moca	Continuous, 0-30 moca31 is a modifier for high school education

			<p>If moca31=0, then total moca score is the sum of moca1 through moca30</p> <p>If moca31=1, then total moca score is the minimum of 30 and the sum of moca1 through moca 31</p>
Audiogram Data	<p>Frequencies: 250, 500, 750, 1000, 1500, 2000, 3000, 4000, 6000, 8000, 12000</p> <p>Create a “complete” audiogram using screening and baseline data</p>	<p>Right ear (numeric):</p> <p>audio_r_250_unaided audio_r_500_unaided audio_r_750_unaided audio_r_1000_unaided audio_r_1500_unaided audio_r_2000_unaided audio_r_3000_unaided audio_r_4000_unaided audio_r_6000_unaided audio_r_8000_unaided audio_r_12000_unaided</p> <p>Left ear (numeric):</p> <p>audio_l_250_unaided audio_l_500_unaided audio_l_750_unaided audio_l_1000_unaided audio_l_1500_unaided audio_l_2000_unaided audio_l_3000_unaided audio_l_4000_unaided audio_l_6000_unaided audio_l_8000_unaided audio_l_12000_unaided</p> <p>NR flags right ear:</p> <p>audio_r_250_unaided_nr audio_r_500_unaided_nr audio_r_750_unaided_nr audio_r_1000_unaided_nr audio_r_1500_unaided_nr audio_r_2000_unaided_nr audio_r_3000_unaided_nr audio_r_4000_unaided_nr audio_r_6000_unaided_nr audio_r_8000_unaided_nr audio_r_12000_unaided_nr</p> <p>NR flags left ear:</p> <p>audio_l_250_unaided_nr audio_l_500_unaided_nr</p>	<p>Will create a “complete” audiogram by combining baseline and screening visit audiograms – baseline visit takes priority over screening visit.</p> <p>Variables are originally stored as character – can have responses like “NA”, “NR”, “DNT”. Convert to numeric. If we have any responses like this, set to missing.</p> <p>If “NR” – create a flag for each frequency and each ear to be 1 (0 else)</p>

		audio_l_750_unaided_nr audio_l_1000_unaided_nr audio_l_1500_unaided_nr audio_l_2000_unaided_nr audio_l_3000_unaided_nr audio_l_4000_unaided_nr audio_l_6000_unaided_nr audio_l_8000_unaided_nr audio_l_12000_unaided_nr	
Degree of Hearing Loss – Pure Tone Average	PTA in better ear	Right ear: pta_right Left ear: pta_left Better ear: pta_better	We will use the pure tone average in the better ear. Take the average at frequencies 500, 1000, 2000, 4000 in both ears. The lower average is the better ear.
Hearing loss classification		hearing_loss_class	Binary <ul style="list-style-type: none"> Mild: pta_better <= 40 Moderate pta_better > 40

4 Statistical Analysis Plan

Analysis: To be completed by December 31, 2024

4.1 Demographic and Clinical Characteristics (“Table 1”)

Analysis: This will be descriptive. As appropriate, we will present the mean with standard deviation (SD), median with interquartile range (IQR), and ranges (min and max), or frequency with percentage (see Table 1). Categorical variables may be collapsed into fewer categories. If cell counts are less than 10 for variables that could identify patients (e.g., race, ethnicity), we may not report the exact cell count. We may consider stratifying this table by clinical site as well.

Table 1: Patient Characteristics at Baseline

	Unilateral (N=XXX)	Bilateral (N=XXX)	Total (N=XXX)
Clinical Site			
Duke	XXX (%)	XXX (%)	XXX (%)
Vanderbilt	XXX (%)	XXX (%)	XXX (%)
Gender			
Female	XXX (%)	XXX (%)	XXX (%)
Male	XXX (%)	XXX (%)	XXX (%)
Other	XXX (%)	XXX (%)	XXX (%)
Age at Baseline Visit			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX

Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
Race			
American Indian/Alaska Native	XXX (%)	XXX (%)	XXX (%)
Asian	XXX (%)	XXX (%)	XXX (%)
Black or African American	XXX (%)	XXX (%)	XXX (%)
White	XXX (%)	XXX (%)	XXX (%)
More than one race	XXX (%)	XXX (%)	XXX (%)
Native Hawaiian/Pacific Islander	XXX (%)	XXX (%)	XXX (%)
Declined	XXX (%)	XXX (%)	XXX (%)
Ethnicity			
Hispanic or Latino	XXX (%)	XXX (%)	XXX (%)
Not Hispanic or Latino	XXX (%)	XXX (%)	XXX (%)
Declined	XXX (%)	XXX (%)	XXX (%)
Personal Income Last Year			
\$0	XXX (%)	XXX (%)	XXX (%)
\$1 to \$9999	XXX (%)	XXX (%)	XXX (%)
\$10,000 to \$24,999	XXX (%)	XXX (%)	XXX (%)
\$25,000 to \$49,999	XXX (%)	XXX (%)	XXX (%)
\$50,000 to \$74,999	XXX (%)	XXX (%)	XXX (%)
\$75,000 to \$99,999	XXX (%)	XXX (%)	XXX (%)
\$100,000 to \$149,999	XXX (%)	XXX (%)	XXX (%)
\$150,000 or greater	XXX (%)	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)	XXX (%)
Personal Income Last Year (Categorical)			
Below Median	XXX (%)	XXX (%)	XXX (%)
Above Median	XXX (%)	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)	XXX (%)
Hearing Aid Health Insurance Benefits			
No	XXX (%)	XXX (%)	XXX (%)
Yes	XXX (%)	XXX (%)	XXX (%)
Not sure	XXX (%)	XXX (%)	XXX (%)
Marital Status			
Married	XXX (%)	XXX (%)	XXX (%)
Widowed	XXX (%)	XXX (%)	XXX (%)
Divorced	XXX (%)	XXX (%)	XXX (%)
Separated	XXX (%)	XXX (%)	XXX (%)
Never married	XXX (%)	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)	XXX (%)
Living Arrangements			
Alone	XXX (%)	XXX (%)	XXX (%)
With spouse	XXX (%)	XXX (%)	XXX (%)

With spouse and others	XXX (%)	XXX (%)	XXX (%)
Other	XXX (%)	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)	XXX (%)
Education			
Less than high school	XXX (%)	XXX (%)	XXX (%)
High school	XXX (%)	XXX (%)	XXX (%)
Some college	XXX (%)	XXX (%)	XXX (%)
4-year degree	XXX (%)	XXX (%)	XXX (%)
Graduate degree	XXX (%)	XXX (%)	XXX (%)
Other	XXX (%)	XXX (%)	XXX (%)
Quarter of Baseline Visit			
2021 Q2	XXX (%)	XXX (%)	XXX (%)
2021 Q3	XXX (%)	XXX (%)	XXX (%)
2021 Q4	XXX (%)	XXX (%)	XXX (%)
...	XXX (%)	XXX (%)	XXX (%)
Total MoCA Score			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
Pure Tone Average in Better Ear**			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
Hearing Loss Classification in Better Ear			
Mild	XXX (%)	XXX (%)	XXX (%)
Moderate	XXX (%)	XXX (%)	XXX (%)
(report generated on XXXXXXX)			
**Average value for frequencies of 500, 1000, 2000, 4000 Hz			

We will create a table for clinical characteristics (Supplemental Table 1) which will be given to Sherri Smith in order to create an audiogram that follows the standards of the field.

Supplemental Table 1: Clinical Characteristics at Baseline

	Unilateral (N=XXX)	Bilateral (N=XXX)	Total (N=XXX)
Right Ear: 250 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 500 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 750 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 1000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 1500 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 2000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 3000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 4000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 6000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 8000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Right Ear: 12000 Hz			

N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 250 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 500 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 750 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 1000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 1500 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 2000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 3000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 4000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 6000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 8000 Hz			
N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX
Left Ear: 12000 Hz			

N	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
NR Values	XXX	XXX	XXX

(report generated on XXXXXXX)

4.2 Describe APHAB Global Score Distributions and Responder Status

We will describe the distribution of APHAB global score at baseline (unaided) and 3 months (aided), along with the change score and responder status (both definitions) by hearing aid assignment in Table 2.

Table 2: APHAB Global Score Distributions and Responder Status			
	Unilateral (N=XXX)	Bilateral (N=XXX)	Total (N=XXX)
APHAB Global Score (Baseline)			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
APHAB Global Score (3 Months)			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
APHAB Change Score			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
APHAB Responder (25 Units)*			
No	XXX (%)	XXX (%)	XXX (%)
Yes	XXX (%)	XXX (%)	XXX (%)
Ineligible to Drop 25 Units	XXX	XXX	XXX
APHAB Responder (15 Units)*			
No	XXX (%)	XXX (%)	XXX (%)
Yes	XXX (%)	XXX (%)	XXX (%)
Ineligible to Drop 15 Units	XXX	XXX	XXX

4.3 Primary aim: compare APHAB scores between the two arms

Compare the APHAB change scores between the two arms (bilateral hearing aid and unilateral hearing aid) at the end of month 3 vs baseline.

Analysis: This will be done for all randomized patients who have both baseline and 3 month scores (a “completers” analysis). The primary analysis will be performed by linear regression and include randomized assignment and clinical site as covariates.

$$APHAB \text{ change score} = \beta_0 + \beta_1 * \text{treatment} + \beta_2 * \text{site}$$

Table 3: Linear Regression Beta Estimates Outcome Modelled: APHAB Change Score			
Covariate	Beta	95% C.I.	P-Value*
Hearing Aid Assignment (Reference: Bilateral)			
Unilateral	XXX	(XXX , XXX)	XXX
Clinical Site (Reference: Duke)			
Vanderbilt	XXX	(XXX , XXX)	XXX
*Using XXX statistic			

4.4 Heterogeneity of Treatment Effects Analysis for APHAB scores

Compare APHAB change scores between the two arms at the end of month 3 vs baseline while adjusting for interaction terms between treatment and each variable of interest.

Analysis: This will be done for all randomized patients who have both baseline and 3 month scores (“completers”). The primary analysis will be performed by linear regression and include randomized assignment, clinical site, a given variable of interest (denoted by S), and interactions between treatment and the variable of interest, with separate models fit for each variable of interest. The two variables of interest that decided to investigate are income group (simplified version – below median, above median, prefer not to answer) and hearing loss classification (mild, moderate). Interactions will be tested at the 0.15 level. If the overall test for the interaction is significant, forest plots will be constructed to examine the heterogeneity of treatment effect and formal treatment by factor interaction terms tested in the models. The general model structure is:

$$APHAB \text{ change score} = \beta_0 + \beta_1 * \text{treatment} + \beta_2 * \text{site} + \beta_S * S + \beta_{ST} * S * \text{treatment}$$

Table 4: Linear Regression Beta Estimates for Variable S Model Outcome Modelled: APHAB Change Score			
Covariate	Beta	95% C.I.	P-Value*
Hearing Aid Assignment (Reference: Bilateral)			
Unilateral	XXX	(XXX , XXX)	XXX
Clinical Site (Reference: Duke)			
Vanderbilt	XXX	(XXX , XXX)	XXX
Variable S	XXX	(XXX, XXX)	XXX
HA Assignment*Variable S	XXX	(XXX, XXX)	XXX

4.5 Sensitivity analyses for APHAB scores

If more than 5% of randomized patients have missing APHAB scores at 3 months, we will use multiple imputation in an intent to treat sensitivity analysis.

Analysis 1: An imputation model via linear regression will be developed based on available data and will include initial APHAB scores, treatment, baseline characteristics, and possible interactions of these variables with treatment. The specific variables of interest to include are: treatment, site, income group, and baseline APHAB. A total of 1000 datasets with imputations of APHAB score reduction will be generated using this model. Each dataset will be analyzed using linear regression models as described in section 4.3. The combined results will be reported and will take the variability of multiple imputations into account.

Analysis 2: The characteristics from the participants with completed data will be compared to those with missing APHAB data with the use of a “Table 1”. We may also include treatment randomization in this table.

Table 5: Patient Characteristics for Missing and Non-Missing APHAB

	Missing APHAB (N=XXX)	Not Missing APHAB (N=XXX)	Total (N=XXX)
Assignment			
Unilateral	XXX (%)	XXX (%)	XXX (%)
Bilateral	XXX (%)	XXX (%)	XXX (%)
Clinical Site			
Duke	XXX (%)	XXX (%)	XXX (%)
Vanderbilt	XXX (%)	XXX (%)	XXX (%)
Gender			
Female	XXX (%)	XXX (%)	XXX (%)
Male	XXX (%)	XXX (%)	XXX (%)
Other	XXX (%)	XXX (%)	XXX (%)
Age at Baseline Visit			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
Race			
American Indian/Alaska Native	XXX (%)	XXX (%)	XXX (%)
Asian	XXX (%)	XXX (%)	XXX (%)
Black or African American	XXX (%)	XXX (%)	XXX (%)
White	XXX (%)	XXX (%)	XXX (%)
More than one race	XXX (%)	XXX (%)	XXX (%)
Native Hawaiian/Pacific Islander	XXX (%)	XXX (%)	XXX (%)
Declined	XXX (%)	XXX (%)	XXX (%)
Ethnicity			

Hispanic or Latino	XXX (%)	XXX (%)	XXX (%)
Not Hispanic or Latino	XXX (%)	XXX (%)	XXX (%)
Declined	XXX (%)	XXX (%)	XXX (%)
Personal Income Last Year			
\$0	XXX (%)	XXX (%)	XXX (%)
\$1 to \$9999	XXX (%)	XXX (%)	XXX (%)
\$10,000 to \$24,999	XXX (%)	XXX (%)	XXX (%)
\$25,000 to \$49,999	XXX (%)	XXX (%)	XXX (%)
\$50,000 to \$74,999	XXX (%)	XXX (%)	XXX (%)
\$75,000 to \$99,999	XXX (%)	XXX (%)	XXX (%)
\$100,000 to \$149,999	XXX (%)	XXX (%)	XXX (%)
\$150,000 or greater	XXX (%)	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)	XXX (%)
Personal Income Last Year (Categorical)			
Below Median	XXX (%)	XXX (%)	XXX (%)
Above Median	XXX (%)	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)	XXX (%)
Hearing Aid Health Insurance Benefits			
No	XXX (%)	XXX (%)	XXX (%)
Yes	XXX (%)	XXX (%)	XXX (%)
Not sure	XXX (%)	XXX (%)	XXX (%)
Marital Status			
Married	XXX (%)	XXX (%)	XXX (%)
Widowed	XXX (%)	XXX (%)	XXX (%)
Divorced	XXX (%)	XXX (%)	XXX (%)
Separated	XXX (%)	XXX (%)	XXX (%)
Never married	XXX (%)	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)	XXX (%)
Living Arrangements			
Alone	XXX (%)	XXX (%)	XXX (%)
With spouse	XXX (%)	XXX (%)	XXX (%)
With spouse and others	XXX (%)	XXX (%)	XXX (%)
Other	XXX (%)	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)	XXX (%)
Education			
Less than high school	XXX (%)	XXX (%)	XXX (%)
High school	XXX (%)	XXX (%)	XXX (%)
Some college	XXX (%)	XXX (%)	XXX (%)
4-year degree	XXX (%)	XXX (%)	XXX (%)
Graduate degree	XXX (%)	XXX (%)	XXX (%)
Other	XXX (%)	XXX (%)	XXX (%)
Quarter of Baseline Visit			
2021 Q2	XXX (%)	XXX (%)	XXX (%)

2021 Q3	XXX (%)	XXX (%)	XXX (%)
...	XXX (%)	XXX (%)	XXX (%)
Total MoCA Score			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
Pure Tone Average in Better Ear			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
Hearing Loss Classification			
Mild	XXX (%)	XXX (%)	XXX (%)
Moderate	XXX (%)	XXX (%)	XXX (%)
(report generated on XXXXXXXX)			

Analysis 3: We will report the rate of dropout in each of the two groups and look at the potential imbalances in dropouts between randomized interventions. We will report clinically meaningful differences. Given the size of the study, the ability to detect MNAR is small.

4.6 Analyze APHAB binary response at 3 months

Patients with a decrease of at least 25 units on the APHAB scale at month 3 compared to baseline unaided APHAB will be defined as “responders.” Patients who do not meet this criterion of 25 units, do not return, or do not have a score at month 3 will be defined as “non-responders.” If there are any patients with unaided APHAB scores of less than 25, these patients will be excluded as they are not eligible to drop 25 units.

Analysis 1: This will be done for all randomized patients who are eligible, including those missing APHAB change scores. This analysis will be performed by logistic regression and include randomized assignment and clinical site as covariates.

$$\text{Binary APHAB change score} = \beta_0 + \beta_1 * \text{treatment} + \beta_2 * \text{site}$$

Table 6: Logistic Regression OR Estimates

Outcome Modelled: Binary APHAB Change Score Response (25 Unit)

Covariate	OR	95% C.I.	P-Value*
Hearing Aid Assignment (Reference: Bilateral)			
Unilateral	XXX	(XXX , XXX)	XXX
Clinical Site (Reference: Duke)			
Vanderbilt	XXX	(XXX , XXX)	XXX

*Using XXX statistic

Analysis 2 (heterogeneity of treatment effects): This analysis will be performed by logistic regression and include randomized assignment, clinical site, a given variable of interest (denoted by S), and interactions between treatment and the variable of interest, with separate models fit for each variable of interest. The two variables of interest that decided to investigate are income group (simplified version – below median, above median, prefer not to answer) and hearing loss classification (mild, moderate). Interactions will be tested at the 0.15 level. If the overall test for the interaction is significant, forest plots will be constructed to examine the heterogeneity of treatment effect and formal treatment by factor interaction terms tested in the models. The general model structure is:

$$\text{Binary APHAB change score} = \beta_0 + \beta_1 * \text{treatment} + \beta_2 * \text{site} + \beta_S * S + \beta_{ST} * S * \text{treatment}$$

We will report the joint test p-value for the interaction term. If significant, we will report odds ratios and 95% confidence intervals.

Table 7 Logistic Regression OR Estimates for Variable S Model Outcome Modelled: Binary APHAB Change Score Response (25 Unit)			
Covariate	OR	95% C.I.	P-Value*
Hearing Aid Assignment (Reference: Bilateral)			
Unilateral	XXX	(XXX , XXX)	XXX
Clinical Site (Reference: Duke)			
Vanderbilt	XXX	(XXX , XXX)	XXX
Variable S	XXX	(XXX, XXX)	XXX
HA Assignment*Variable S	XXX	(XXX, XXX)	XXX
*Using XXX statistic			

Analyses 3-4: repeat analyses 1-2 of this section, but define responders as having a decrease of at least 15 units.

$$\text{Binary APHAB change score} = \beta_0 + \beta_1 * \text{treatment} + \beta_2 * \text{site}$$

Table 8 Logistic Regression OR Estimates Outcome Modelled: Binary APHAB Change Score (15 Unit)			
Covariate	OR	95% C.I.	P-Value*
Hearing Aid Assignment (Reference: Bilateral)			
Unilateral	XXX	(XXX , XXX)	XXX
Clinical Site (Reference: Duke)			
Vanderbilt	XXX	(XXX , XXX)	XXX
*Using XXX statistic			

$$\text{Binary APHAB change score} = \beta_0 + \beta_1 * \text{treatment} + \beta_2 * \text{site} + \beta_S * S + \beta_{ST} * S * \text{treatment}$$

Table 9 Logistic Regression OR Estimates for Variable S Model Outcome Modelled: Binary APHAB Change Score (15 Unit)			
Covariate	Beta	95% C.I.	P-Value*

Hearing Aid Assignment (Reference: Bilateral)			
Unilateral	XXX	(XXX , XXX)	XXX
Clinical Site (Reference: Duke)			
Vanderbilt	XXX	(XXX , XXX)	XXX
Variable S	XXX	(XXX, XXX)	XXX
HA Assignment*Variable S	XXX	(XXX, XXX)	XXX
*Using XXX statistic			

4.7 Describe APHAB Subscales

We will describe the distribution of the 4 APHAB subscales (EC, BN, RV, AV) at baseline (unaided) and 3 months (aided) by hearing aid assignment, along with the change scores graphically and in a Table (Table 10).

Table 10: APHAB Subscale Distributions			
	Unilateral (N=XXX)	Bilateral (N=XXX)	Total (N=XXX)
APHAB EC Subscale (Baseline)			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
APHAB EC Subscale (3 Months)			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
APHAB EC Subscale Change Score			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
APHAB BN Subscale (Baseline)			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX

APHAB BN Subscale (3 Months)

N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX

APHAB BN Subscale Change Score

N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX

APHAB RV Subscale (Baseline)

N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX

APHAB RV Subscale (3 Months)

N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX

APHAB RV Subscale Change Score

N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX

APHAB AV Subscale (Baseline)

N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX

APHAB AV Subscale (3 Months)

N	XXX	XXX	XXX
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Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
APHAB AV Subscale Change Score			
N	XXX	XXX	XXX
Missing	XXX	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX	XXX - XXX
(report generated on XXXXXXXX)			

4.8 Initially planned analyses that we will not do

We had initially planned to conduct adjusted analyses for the outcomes of global change score and both responder definitions. After reviewing cell counts of demographics at baseline and discussion, we decided that there are no variables of interest to include in an adjusted model.

Statistical Analysis Plan (SAP) – Secondary (3-Month) Outcomes and Descriptives

Project: Evaluation of Unilateral vs Bilateral Hearing Aids for the Treatment of Age-related Hearing Loss

IRB Number: Pro00106077

Investigator(s): Sherri Smith, AuD, PhD

Biostatistician(s): Kayla Kilpatrick, PhD, Sarah Peskoe, PhD, Frank Rockhold, PhD

Original Creation Date: 12.15.2021

Version Date: 09.30.2024

Investigator Agreement

- ☐ All statistical analyses included in an abstract or manuscript should reflect the work of the biostatistician(s) listed on this SAP. No changes or additional analyses should be made to the results or findings without discussing with the project biostatistician(s).
- ☐ All biostatisticians on this SAP should be given sufficient time to review the full presentation, abstract, manuscript, or grant and be included as co-authors on any abstract or manuscript resulting from the analyses.
- ☐ If substantial additional analysis is necessary or the aims of the project change, a new SAP will need to be developed.
- ☐ Publications resulting from this SAP are supported in part by the Duke CTSA and must cite grant number UL1TR002553 and be submitted to PubMed Central.
- ☐ I have reviewed the SAP and understand that any changes must be documented.

Acknowledged by: Click or tap here to enter text.

Date: Click or tap to enter a date.

Activity Log

11.16.2023 Split secondary outcomes SAP into multiple SAPs
05.31.2024 Added additional variables
07.11.2024 Resolved some questions about variables (see SAP dated 20240531 and Overview of All Planned Analysis dated 20240620)
07.25.2024 Moved GHABP from the GHABP/EMA SAP to this SAP
09.30.2024 Updated variable names, resolved comments from previous SAP dated 20240725)

Acronyms

APHAB	Abbreviated Profile of Hearing Aid Benefit
EMA	Ecological Momentary Assessment
GHABP	Glasgow Hearing Aid Benefit Profile
IOI-HA	International Outcomes Inventory for Hearing Aids
SADL	Satisfaction with Amplification in Daily Life
SSQ	Speech Spatial Qualities
HHIE	Hearing Handicap Inventory for Elderly

1 Study Overview

Background/Introduction: The overall goal of the project is to determine the benefit of unilateral or bilateral hearing aid fittings in adults with mild-to-moderate age-related hearing loss. This will address the lack of high-quality evidence supporting bilateral hearing aids over unilateral hearing aids. This project will use a randomized controlled trial with two treatment arms: a bilateral hearing aid fitting group and a unilateral hearing aid fitting group.

1.1 Aims for Secondary Outcomes

- Compare all outcomes between the two arms (bilateral hearing aid and unilateral hearing aid) at 3 months. The primary hypothesis is that bilateral hearing aids are superior to the unilateral hearing aids with respect to the overall patient-reported benefit.
- Descriptive tables for additional clinical variables at baseline and 3-months by assigned treatment
- Plots of hearing aid fit by assigned treatment

2 Study Population

2.1 Inclusion Criteria

- 50+ years of age
- Mild to moderate, symmetrical SNHL (symmetrical: < 20 dB between ears on average from 500-4000 Hz)
- Open-mindedness to unilateral or bilateral amplification
- No prior hearing aid experience
- Adequate literacy to complete questionnaires
- Willing to purchase study-specific hearing aid(s)

2.2 Exclusion Criteria

- Concerns for middle ear pathology
- Concerns for retrocochlear pathology
- Severe tinnitus as the reason for seeking amplification
- Co-morbid condition that would interfere with study (e.g., dementia, blindness, neurologic pathology)
- History of fluctuating hearing loss

2.3 Data Acquisition

Fill in all relevant information:

Study design	Randomized controlled trial with 2 arms (bilateral hearing aid, unilateral hearing aid) Note: Randomization was stratified by clinical site.
Data source/how the data were collected	Screening information pulled from EHR data Baseline surveys captured via in-person interview and recorded in REDCap
Contact information for team member responsible for data collection/acquisition	All data access is through [REDACTED]. Questions on data validity will go to PI: Sherri Smith (Sherri.smith@duke.edu)
Date or version (if downloaded, provide date)	10.17.2024
Data transfer method and date	Direct data extraction from REDCap
Where dataset is stored	REDCap

	<p>Extracted data and analytic datasets are stored on a secure drive in the CRU folder: \\duhs-vclin-nc1\dusom_biostats_fs\Data\BiostatsCore\CRU\Head and Neck\Smith\PCORI_Pro00106077\Data pulls</p>
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Notes: Additional variable details for all variables can be found in the “PCORI Variable Details” Excel file. Scoring details can be found in “PCORI Scoring 20240923”.

For GHABP:

6 total scenarios, 4 standard, 2 user-nominated. Standard scenarios:

1. LISTENING TO THE TELEVISION WITH OTHER FAMILY OR FRIENDS WHEN THE VOLUME IS ADJUSTED TO SUIT OTHER PEOPLE
2. HAVING A CONVERSATION WITH ONE OTHER PERSON WHEN THERE IS NO BACKGROUND NOISE
3. CARRYING ON A CONVERSATION IN A BUSY STREET OR SHOP
4. HAVING A CONVERSATION WITH SEVERAL PEOPLE IN A GROUP

Unaided questions:

1. Does this situation happen in your life?
2. How much difficulty do you have in this situation?
3. How much does any difficulty in this situation worry, annoy or upset you?

Aided/EMA questions:

1. Did this situation happen in the past few weeks? (GHABP aided) OR Did this situation happen in the last three hours? (EMA)
2. In this situation, with your hearing aid, how much does any difficulty in this situation worry, annoy or upset you? NOTE: **this question is non-standard for the aided GHABP**. We will report on this in a descriptive table but will not include in analyses.
3. In this situation, what proportion of the time do you wear your hearing aid?
4. In this situation, how much does your hearing aid help you?
5. In this situation, with your hearing aid, how much difficulty do you now have?
6. For this situation, how satisfied are you with your hearing aid?

Description:

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Outcome(s)

Outcome	Description	Variables and Source	Specifications
IOI-HA	Note: this is measured only at 3 and 6 months	Total score: ioiha_total_3m	<p>Total score: sum responses to questions 1-7 (should be on a range between 1-5).</p> <p>Item 8 is self-perceived hearing difficulty used for normative purposes</p>

			<p>(currently not used as part of total score)</p> <p>This is initially coded as 0 to 4 in REDCap – changed to 1-5</p> <p>Currently, we're treating IOI-HA total score as continuous, but this may need to be treated as ordinal.</p> <p>Higher scores are better</p>
SADL	<p>Note: this is measured only at 3 and 6 months.</p> <p>Note: the "sister" questionnaire at baseline is ECHO</p>	<p>Global score: sadl_global_3m</p> <p>Positive effect subscale: sadl_positive_effect_3m</p> <p>Service cost subscale: sadl_service_cost_3m</p> <p>Negative features subscale: sadl_negative_features_3m</p> <p>Personal image subscale: sadl_personal_image_3m</p>	<p>Questions 1 – 15 are used. This is scored from 1-7 (or reversed for questions 2, 4, 7, 13).</p> <p>There are 4 subscales: Positive Effect, Service & Cost, Negative Features, Personal Image. For each subscale, the average score is calculated.</p> <p>For the global score, this is the mean of the scores for all items (excluding questions 11 and 14 if applicable).</p> <p>Higher scores are better (higher satisfaction).</p> <p>See PCORI Scoring file for more details</p>
SSQ	<p>Note: this is measured at baseline, 3 months, and 6 months.</p>	<p>Change score: ssq_change</p> <p><u>Baseline:</u></p> <p>Overall score: ssq_overall_base</p> <p>Speech/hearing subscale: ssq_speech_hearing_base</p> <p>Spatial/hearing subscale: ssq_spatial_hearing_base</p>	<p>3 subscales: Speech is questions 1 – 14 (corresponds to the "pt1" variables). Spatial is 17 questions (corresponds to the "pt2" variables). Qualities is 18 questions (correspond to the "pt3" variables).</p>

		<p>Qualities of hearing subscale: ssq_qualities_of_hearing_base</p> <p><u>3-Months:</u> Overall score: ssq_overall_3m</p> <p>Speech/hearing subscale: ssq_speech_hearing_3m</p> <p>Spatial/hearing subscale: ssq_spatial_hearing_3m</p> <p>Qualities of hearing subscale: ssq_qualities_of_hearing_3m</p>	<p>Overall score: mean of the items.</p> <p>For instances where people mark NA and a value, if the value is 50, set as NA. If a value other than 50, use that value.</p> <p>We will also create a change score as the difference in the overall score between 3 months and baseline (3 months – baseline)</p> <p>Higher scores are better</p>
HHI-E	Note: this is measured at baseline, 3 months, and 6 months	<p>Change score: hhie_change</p> <p><u>Baseline:</u> Total score: hhie_total_base</p> <p>Situational subscale: hhie_situational_base</p> <p>Emotional subscale: hhie_emotional_base</p> <p><u>3-Months:</u> Total score: hhie_total_3m</p> <p>Situational subscale: hhie_situational_3m</p> <p>Emotional subscale: hhie_emotional_3m</p>	<p>Yes = 4 points, Sometimes = 2 points, and No = 0 points.</p> <p>Total scale score = sum of all 25 items</p> <p>Situational subscale: questions 1, 3, 6, 8, 10, 11 13, 15, 16, 19, 21, 23</p> <p>Emotional subscale: questions 2, 4, 5, 7, 9, 12, 14, 17, 18, 20, 22, 24, 25</p> <p>We will also create a change score as the difference in the total scale score between 3 months and baseline (3 months – baseline)</p> <p>Lower scores are better</p>
GHABP Aided	Aided: 3 months	<p>Question 2 average, 4 standard scenarios: ghabp_q2_4block_3m</p> <p>Question 3 average, 4 standard scenarios: ghabp_q3_4block_3m</p>	<p>For questions 3-6 (IF they answer yes to question 1), doing this separately by question:</p> <ol style="list-style-type: none"> 1. Subtract 1, multiply by 25, average answer to question across

		<p>Question 4 average, 4 standard scenarios: ghabp_q4_4block_3m</p> <p>Question 5 average, 4 standard scenarios: ghabp_q5_4block_3m</p> <p>Question 6 average, 4 standard scenarios: ghabp_q6_4block_3m</p>	<p>4 standard scenarios</p> <p>Note: ignore current question 2 for analyses as it is non-standard but report on this in a descriptive table</p> <p>There are 6 scenarios (4 standard, 2 user-nominated)</p> <p>Note that question 1 just asks if this scenario has happened – participants are only included in the averages if they answer “yes”</p> <p>Higher/lower scores are better depending on question</p>
Speech and Noise Test	<p>Baseline (unaided) and 3-months (aided)</p> <p>Speech and noise 0 degrees (collocated)</p> <p>Speech left, noise right</p> <p>Noise left, speech right</p>	<p>Baseline: sin_collocated_base sin_right_base sin_left_base</p> <p>3-Months: sin_collocated_3m sin_right_3m sin_left_3m</p> <p>Change: sin_collocated_change sin_r_change sin_l_change</p> <p>May also want change scores for speech to aided side and speech to unaided side</p>	<p>Continuous</p> <p>Change scores: 3m-baseline for each of collocated, speech left/noise right, noise left/speech right</p> <p>Positive values for unaided/aided variables indicate speech is louder than noise; negative indicate speech is under the noise</p> <p>For unilateral assigned, also have speech to aided side (advantage) and speech to unaided side (disadvantage).</p> <p>Speech to aided (advantage):</p> <ul style="list-style-type: none"> • If assigned R, this is noise left, speech right

			<ul style="list-style-type: none"> If assigned L, this is speech left, noise right <p>Speech to unaided (disadvantage):</p> <ul style="list-style-type: none"> If assigned R, this is speech left, noise right If assigned L, this is noise left, speech right <p>Lower scores are better</p>
Auditory Working Memory	<p>Unaided and Aided (3 months)</p> <p>Recognition, judgement, recall</p>	<p>Change scores: warrm_recog_change warrm_recall_change</p> <p><u>Baseline:</u> warrm_recog_base warrm_recall_base warrm_judge_base</p> <p><u>3-Months:</u> warrm_recog_3m warrm_recall_3m warrm_judge_3m</p>	<p>Continuous</p> <p>Sum questions 2-6 for each tasks (recognition, judgement, recall) separately and get a % correct (out of 20)</p> <p>Construct change scores as difference between 3 months and baseline for recognition and recall.</p> <p>Judgement is more of a sanity check (<90% means they probably aren't engaged)</p> <p>Higher scores are better</p>
Hours of Hearing Aid Use	<p>Multiple time periods (every scheduled visit and unscheduled follow ups)</p> <p>Only reporting 3-month values here</p> <p>Right and left ears separately</p>	<p>Right ear: r_avg_hrs_3m r_avg_hrs_3m_na (if right HA is NA)</p> <p>Left ear: l_avg_hrs_3m l_avg_hrs_3m_na</p>	<p>How many hours on average the right/left HA was worn.</p> <p>NA variables: value of 1 if that HA was NA</p>

3.2 Additional Variables of Interest

Variable	Description	Variables and Source	Specifications
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Randomization assignment	hearing aid assignment	assign	Binary 1: unilateral 2: bilateral
Clinical site	Which site - Duke or Vanderbilt?	which_site Character version: which_site_ch	Binary 1: Vanderbilt 2: Duke
GHABP Unaided	Unaided: baseline	Question 2 average, 4 standard scenarios: ghabp_q2_4block_base Question 3 average, 4 standard scenarios: ghabp_q3_4block_base	For questions 2 and 3 (IF they answer yes to question 1), doing this separately by question: 1. Subtract 1, multiply by 25, average answer to question across 4 standard scenarios There are 6 scenarios (4 standard, 2 user-nominated) Note that question 1 just asks if this scenario has happened – participants are only included in the averages if they answer “yes” Lower scores are better for both questions
ECHO	Baseline only Note: this is the “sister” questionnaire to SADL (aided)	Global score: echo_global_base Positive effect subscale: echo_positive_effect_base Service cost subscale: echo_service_cost_base Negative features subscale: echo_negative_features_base Personal image subscale: echo_personal_image_base	Questions 1 – 15 are used. This is scored from 1-7 (or reversed for questions 2, 4, 7, 13). There are 4 subscales: Positive Effect, Service & Cost, Negative Features, Personal Image. For each subscale, the average score is calculated. For the global score, this is the mean of the scores for all items (excluding question 11 if applicable).

			<p>Higher scores are better (higher expectations).</p> <p>See PCORI Scoring file for more details</p>
TFI	<p>Tinnitus Functional Index</p> <p>Only at baseline</p>	<p>Yes/no: tfiyn</p> <p>Number of TFI questions missing: tfi_num_miss</p> <p>TFI invalid flag: tfi_invalid</p> <p>TFI overall score: tfi_overall_score</p>	<p>Non-missing if tfiyn=1</p> <p>Overall score: sum all valid answers, divide by the number of questions with valid answers, multiply by 10</p> <p>If more than 7 items are omitted, the overall score is not valid.</p> <p>8 subscales but only reporting overall score</p> <p>Lower scores are better</p> <p>See PCORI Scoring file for more details</p>
Binaural loudness summation	<p>Baseline only</p> <p>CSL level right</p> <p>CSL level left</p> <p>CSL level both</p>	<p>binaural_r_base</p> <p>binaural_l_base</p> <p>binaural_both_base</p>	Continuous
Dichotic digit test	<p>Baseline only</p> <p>Right ear directed</p> <p>Left ear directed</p> <p>Free recall both ears</p> <p>Right ear free recall</p> <p>Left ear free recall</p>	<p>dichotic_r_base</p> <p>dichotic_l_base</p> <p>dichotic_free_both_base</p> <p>dichotic_free_r_base</p> <p>dichotic_free_l_base</p>	Continuous
Hearing Aid Fitting information	<p>Was RealEar performed?</p> <p>Which WRECD was used?</p>	<p>hafitrealear</p> <p>re_wrecd</p> <p>Ear fit</p> <p>Numeric: hafitwhich</p> <p>Character: ear_fit_ch</p>	<p>Yes/no for RealEar performed – these should all be “yes” for the initial fitting</p>

	Which ear was fit?		<p>Average/measured for WRECD – these should all be “average” at initial fitting</p> <p>Ear fit: 1=right 2=left 3=both</p>
HA fit audiogram – real ear	<p>65 dB SPL target</p> <p>65 dB SPL output</p> <p>UCL SPL</p> <p>MPO</p> <p>Report on differences between target and output, UCL and MPO</p> <p>R and L ears (may only have 1 if unilateral)</p> <p>250 Hz</p> <p>500 Hz</p> <p>750 Hz</p> <p>1000 Hz</p> <p>1500 Hz</p> <p>2000 Hz</p> <p>3000 Hz</p> <p>4000 Hz</p> <p>6000 Hz</p> <p>8000 Hz</p>	<p>Right ear:</p> <p>r_250_targ_out_fit</p> <p>r_250_ucl_mpo_fit</p> <p>r_500_targ_out_fit</p> <p>r_500_ucl_mpo_fit</p> <p>r_750_targ_out_fit</p> <p>r_750_ucl_mpo_fit</p> <p>r_1000_targ_out_fit</p> <p>r_1000_ucl_mpo_fit</p> <p>r_1500_targ_out_fit</p> <p>r_1500_ucl_mpo_fit</p> <p>r_2000_targ_out_fit</p> <p>r_2000_ucl_mpo_fit</p> <p>r_3000_targ_out_fit</p> <p>r_3000_ucl_mpo_fit</p> <p>r_4000_targ_out_fit</p> <p>r_4000_ucl_mpo_fit</p> <p>r_6000_targ_out_fit</p> <p>r_6000_ucl_mpo_fit</p> <p>r_8000_targ_out_fit</p> <p>r_8000_ucl_mpo_fit</p> <p>Left ear:</p> <p>l_250_targ_out_fit</p> <p>l_250_ucl_mpo_fit</p> <p>l_500_targ_out_fit</p> <p>l_500_ucl_mpo_fit</p> <p>l_750_targ_out_fit</p> <p>l_750_ucl_mpo_fit</p> <p>l_1000_targ_out_fit</p> <p>l_1000_ucl_mpo_fit</p> <p>l_1500_targ_out_fit</p> <p>l_1500_ucl_mpo_fit</p> <p>l_2000_targ_out_fit</p> <p>l_2000_ucl_mpo_fit</p> <p>l_3000_targ_out_fit</p> <p>l_3000_ucl_mpo_fit</p> <p>l_4000_targ_out_fit</p> <p>l_4000_ucl_mpo_fit</p> <p>l_6000_targ_out_fit</p> <p>l_6000_ucl_mpo_fit</p> <p>l_8000_targ_out_fit</p> <p>l_8000_ucl_mpo_fit</p>	<p>Take absolute value of the difference between target and output</p> <p>Take difference UCL - MPO</p> <p>Do plots of averages by HA configuration for each ear</p>

Assigned HA 3 Month audiogram (real ear)	65 dB SPL target	Right ear:	Take absolute value of the difference between target and output
	65 dB SPL output	r_250_targ_out_3m	
	UCL SPL	r_250_ucl_mpo_3m	
	MPO	r_500_targ_out_3m	
		r_500_ucl_mpo_3m	Take difference UCL - MPO
		r_750_targ_out_3m	
		r_750_ucl_mpo_3m	
		r_1000_targ_out_3m	
	R and L ears (may only have 1 if unilateral)	r_1000_ucl_mpo_3m	
		r_1500_targ_out_3m	Do plots of averages by HA configuration for each ear
		r_1500_ucl_mpo_3m	
		r_2000_targ_out_3m	
		r_2000_ucl_mpo_3m	
	250 Hz	r_3000_targ_out_3m	
	500 Hz	r_3000_ucl_mpo_3m	
	750 Hz	r_4000_targ_out_3m	
	1000 Hz	r_4000_ucl_mpo_3m	
	1500 Hz	r_6000_targ_out_3m	
	2000 Hz	r_6000_ucl_mpo_3m	
	3000 Hz	r_8000_targ_out_3m	
	4000 Hz	r_8000_ucl_mpo_3m	
	6000 Hz		
	8000 Hz	Left ear:	
		l_250_targ_out_3m	
		l_250_ucl_mpo_3m	
		l_500_targ_out_3m	
		l_500_ucl_mpo_3m	
		l_750_targ_out_3m	
		l_750_ucl_mpo_3m	
		l_1000_targ_out_3m	
		l_1000_ucl_mpo_3m	
		l_1500_targ_out_3m	
		l_1500_ucl_mpo_3m	
		l_2000_targ_out_3m	
		l_2000_ucl_mpo_3m	
		l_3000_targ_out_3m	
		l_3000_ucl_mpo_3m	
		l_4000_targ_out_3m	
		l_4000_ucl_mpo_3m	
		l_6000_targ_out_3m	
		l_6000_ucl_mpo_3m	
		l_8000_targ_out_3m	
		l_8000_ucl_mpo_3m	

4 Statistical Analysis Plan

Analysis: To be completed by December 31, 2024.

4.1 Aim: compare all outcomes between the two arms

Compare the outcomes between the two arms (bilateral hearing aid and unilateral hearing aid) at 3 months.

Analysis: This will be reported for patients who have 3-month scores ("completers"). The primary analysis will be performed using either t-tests or Kruskal Wallis tests depending on whether or not the outcome

distributions appear to be normally distributed. The total score for each survey at 3 months or the benefit score will be used as the outcomes. For GHABP, we will compare the four standard questions (averaged and standardized) for the 4 standard scenarios between the two arms at 3 months for patients who answer “yes” to the first question (if the scenario happens).

The null hypothesis is that the means of the outcomes for the two treatment groups are the same.

$$H_0: \mu_{unilateral} = \mu_{bilateral}$$

Table 1: Distributions of 3-Month Outcomes or Benefit Scores by Assigned Treatment Group			
	Unilateral (N=XXX)	Bilateral (N=XXX)	P-Value*
GHABP Aided: In this situation, what proportion of the time do you wear your hearing aid?			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
GHABP Aided: In this situation, how much does your hearing aid help you?			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
GHABP Aided: In this situation, with your hearing aid, how much difficulty do you now have?			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
GHABP Aided: For this situation, how satisfied are you with your hearing aid?			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
SADL Global Score			XXX
N	XXX	XXX	

Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
HHI-E Change Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
IOI-HA Total Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
SSQ Change Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
Speech and Noise Test: 0 Degrees (Co-located) Change Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
Auditory Working Memory - Recognition Change Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
Auditory Working Memory - Recall Change Score			
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	

Average Hours of Hearing Aid Use			XXX
At 3-Month Visit: Right Ear			
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
Average Hours of Hearing Aid Use			XXX
At 3-Month Visit: Left Ear			
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
*T-test/Kruskal Wallis			

We will create boxplots or other figures displaying the distributions of these outcomes by randomization. These figures may supplement or replace Table 1 above.

4.2 Aim: descriptive tables/plots for additional variables

Analysis: we will describe or plot the distributions of additional variables at baseline, hearing aid fit, or 3 month visit as appropriate by assigned treatment. For GHABP, the two unaided (baseline) questions and the one aided (3-month) question (averaged and standardized) will only include patients who answered “yes” to the first question (if the scenario happens). These will be reported across the 4 standard scenarios.

Table 2: Distributions of Clinical Variables by Assigned Treatment

	Unilateral (N=XXX)	Bilateral (N=XXX)
GHABP Unaided: How much difficulty do you have in this situation?		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
GHABP Unaided: How much does any difficulty in this situation worry, annoy or upset you?		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

GHABP Aided: In this situation, with your hearing aid, how much does any difficulty in this situation worry, annoy, or upset you?

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

ECHO Global Score (Baseline)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

ECHO Positive Effect Subscale (Baseline)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

ECHO Service Cost Subscale (Baseline)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

ECHO Negative Features Subscale (Baseline)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

ECHO Personal Image Subscale (Baseline)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

SADL Positive Effect Subscale (3 Months)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

SADL Service Cost Subscale (3 Months)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

SADL Negative Features Subscale (3 Months)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

SADL Personal Image Subscale (3 Months)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

HHI-E Total Score (Baseline)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

HHI-E Total Score (3-Month)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

HHI-E Situational Subscale (Baseline)

N	XXX	XXX
Missing	XXX	XXX

Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
HHI-E Situational Subscale (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
HHI-E Emotional Subscale (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
HHI-E Emotional Subscale (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Tinnitus Presence (Baseline)		
No	XXX (XXX%)	XXX (XXX%)
Yes	XXX (XXX%)	XXX (XXX%)
Missing	XXX (XXX%)	XXX (XXX%)
TFI Overall Score (Baseline)		
N	XXX	XXX
Not Applicable (Answered No to Presence)	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SSQ Overall Score (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SSQ Overall Score (3-Month)		
N	XXX	XXX

Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SSQ Speech/Hearing Subscale (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SSQ Speech/Hearing Subscale (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SSQ Spatial/Hearing Subscale (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SSQ Spatial/Hearing Subscale (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SSQ Qualities of Hearing Subscale (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SSQ Qualities of Hearing Subscale (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)

Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Binaural Loudness Summation:		
Right (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Binaural Loudness Summation:		
Left (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Binaural Loudness Summation:		
Both (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Dichotic Digits: Right Ear		
Directed (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Dichotic Digits: Left Ear Directed		
(Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Dichotic Digits: Free Recall Both		
(Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX

Range	XXX - XXX	XXX - XXX
Dichotic Digits: Free Recall Right (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Dichotic Digits: Free Recall Left (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Speech and Noise Test: 0 Degrees (Co-located) Score (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Speech and Noise Test: 0 Degrees (Co-located) Score (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Speech and Noise Test: Speech Left, Noise Right Score (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Speech and Noise Test: Speech Left, Noise Right Score (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)

Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Speech and Noise Test: Speech Left, Noise Right Change Score		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Speech and Noise Test: Noise Left, Speech Right Score (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Speech and Noise Test: Noise Left, Speech Right Score (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Speech and Noise Test: Noise Left, Speech Right Change Score		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Auditory Working Memory - Recognition Score (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Auditory Working Memory - Recognition Score (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)

Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Auditory Working Memory - Recall Score (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Auditory Working Memory - Recall Score (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Auditory Working Memory - Judgement Score (Baseline)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Auditory Working Memory - Judgement Score (3-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

We will plot the average absolute difference between target and output at each frequency for each ear by assigned hearing aid configuration for both the hearing aid fit and 3-month visits (with visits either grouped together in the same plot or plotted separately). We will also do this for the average difference between MPO and UCL at each frequency.

5 Future Plans

There are additional items we may wish to explore in the future, at which point a new SAP will be developed. Ideas include looking at:

- Additional GHABP measures
- EMA surveys
- Mask questions

- Additional hearing aid hours of use
- Unscheduled visits

Statistical Analysis Plan (SAP) – Secondary (6-Month) Outcomes and Descriptives

Project: Evaluation of Unilateral vs Bilateral Hearing Aids for the Treatment of Age-related Hearing Loss

IRB Number: Pro00106077

Investigator(s): Sherri Smith, AuD, PhD

Biostatisticians: Rebecca North, PhD, Kayla Kilpatrick, PhD, Sarah Peskoe, PhD, Frank Rockhold, PhD

Original Creation Date: 01.07.2025

Version Date: 01.07.2025

Investigator Agreement

- ☐ All statistical analyses included in an abstract or manuscript should reflect the work of the biostatistician(s) listed on this SAP. No changes or additional analyses should be made to the results or findings without discussing with the project biostatistician(s).
- ☐ All biostatisticians on this SAP should be given sufficient time to review the full presentation, abstract, manuscript, or grant and be included as co-authors on any abstract or manuscript resulting from the analyses.
- ☐ If substantial additional analysis is necessary or the aims of the project change, a new SAP will need to be developed.
- ☐ Publications resulting from this SAP are supported in part by the Duke CTSA and must cite grant number UL1TR002553 and be submitted to PubMed Central.
- ☐ I have reviewed the SAP and understand that any changes must be documented.

Acknowledged by: Click or tap here to enter text.

Date: Click or tap to enter a date.

Activity Log

Acronyms	APHAB	Abbreviated Profile of Hearing Aid Benefit
	IOI-HA	International Outcomes Inventory for Hearing Aids
	SADL	Satisfaction with Amplification in Daily Life
	SSQ	Speech Spatial Qualities
	HHIE	Hearing Handicap Inventory for Elderly

1 Study Overview

Background/Introduction: The overall goal of the project is to determine the benefit of unilateral or bilateral hearing aid fittings in adults with mild-to-moderate age-related hearing loss. This will address the lack of high-quality evidence supporting bilateral hearing aids over unilateral hearing aids. This project will use a randomized controlled trial with two treatment arms: a bilateral hearing aid fitting group and a unilateral hearing aid fitting group.

1.1 Aims for Secondary Outcomes

- Compare all outcomes between the two arms (bilateral hearing aid and unilateral hearing aid) at 6 months. *The primary hypothesis is that bilateral hearing aids are superior to the unilateral hearing aids with respect to the overall patient-reported benefit.*
 - Descriptive tables for additional clinical variables at 6-months by assigned treatment
 - Plots of APHAB Global score and change from baseline by assigned treatment
- Compare all outcomes at 6 months by final configuration choice
- Compare all outcomes at 6 months by switching status relative to baseline

2 Study Population

2.1 Inclusion Criteria

- 50+ years of age
- Mild to moderate, symmetrical SNHL (symmetrical: < 20 dB between ears on average from 500-4000 Hz)
- Open-mindedness to unilateral or bilateral amplification
- No prior hearing aid experience
- Adequate literacy to complete questionnaires
- Willing to purchase study-specific hearing aid(s)

2.2 Exclusion Criteria

- Concerns for middle ear pathology
- Concerns for retrocochlear pathology
- Severe tinnitus as the reason for seeking amplification
- Co-morbid condition that would interfere with study (e.g., dementia, blindness, neurologic pathology)
- History of fluctuating hearing loss

2.3 Data Acquisition

Fill in all relevant information:

Study design	Randomized controlled trial with 2 arms (bilateral hearing aid, unilateral hearing aid) Note: Randomization was stratified by clinical site.
Data source/how the data were collected	Screening information pulled from EHR data Baseline surveys captured via in-person interview and recorded in REDCap
Contact information for team member responsible for data collection/acquisition	All data access is through [REDACTED]. Questions on data validity will go to PI: Sherri Smith (Sherri.smith@duke.edu)
Date or version (if downloaded, provide date)	10.28.2024
Data transfer method and date	Direct data extraction from REDCap
Where dataset is stored	REDCap Extracted data and analytic datasets are stored on a secure drive in the CRU folder: \\duhs-vclin-nc1\dusom_biostats_fs\Data\BiostatsCore\CRU\Head and Neck\Smith\PCORI_Pro00106077\Data pulls

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Notes: Additional variable details for all variables can be found in the “PCORI Variable Details” Excel file. Scoring details can be found in “PCORI Scoring 20240923”.

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Outcome(s)

Outcome	Description	Variables and Source	Specifications
APHAB Change Score	Difference in aided APHAB scores at month 6 and unaided scores at baseline	aphab_global_change_6m (constructed in analytic script)	<p>Scale score – will need to calculate global communication scores at baseline (unaided) and 3 months (aided), subtract (3 months – baseline)</p> <p>A lower score on APHAB is better.</p> <p>Rescore variables and multiply by 100</p> <ul style="list-style-type: none"> • 1 = 0.99 • 2 = 0.87 • 3 = 0.75 • 4 = 0.50 • 5 = 0.25 • 6 = 0.12 • 7 = 0.01 <p>Reverse score questions 1, 9, 11, 16, 19, 21</p> <p>Global score: mean of variables in the EC, BN, RV subscale scores (excludes questions 3, 8, 13, 17, 20, 22)</p> <p>Note: APHAB has 4 subscales and a global communication scale. The study is powered based on the benefit score on the global communication scale (August 2019 draft – APHAB SD of 25 with different levels of Cohen’s D).</p>
APHAB change score – binary, 6 months	Responders vs non-responders for primary APHAB outcome	<p>Decrease of 25 units: aphab_responder25_6m</p> <p>Decrease of 15 units: aphab_responder15_6m</p> <p>(Constructed in analytic script)</p>	<p>Patients with a decrease of at least 25 units (or 15 units for the sensitivity analysis) on the APHAB scale at month 6 will be considered “responders.”</p> <p>Patients not returning or who do not have a score at 6</p>

			<p>months will be considered “non-responders.” Patients with a baseline score < 25 (or < 15) are ineligible (missing).</p> <p>Binary (25 unit decrease):</p> <ul style="list-style-type: none"> • Missing if baseline score <25 • 1 if aphab_global_change_6m <=-25 • 0 else <p>Binary (15 unit decrease);</p> <ul style="list-style-type: none"> • Missing if baseline score <15 • 1 if aphab_global_change_6m <=-15 • 0 else
APHAB – 4 subscales	EC, BN, RV, AV scales at 6 months and change score relative to baseline	6-month variables: aphab_ec_6m aphab_bn_6m aphab_rv_6m aphab_av_6m	<p>Rescore variables and multiply by 100</p> <ul style="list-style-type: none"> • 1 = 0.99 • 2 = 0.87 • 3 = 0.75 • 4 = 0.50 • 5 = 0.25 • 6 = 0.12 • 7 = 0.01 <p>Reverse score questions 1, 9, 11, 16, 19, 21</p> <p>EC: mean of questions 4, 10, 12, 14, 15, 23</p> <p>BN: mean of questions 1, 6, 7, 16, 19, 24</p> <p>RV: mean of questions 2, 5, 9, 11, 18, 21</p> <p>AV: mean of questions 3, 8, 13, 17, 20, 22</p>
IOI-HA	Total score Note: this is measured only at 3 and 6 months	ioiha_total_6m	<p>Total score: sum responses to questions 1-7 (should be on a range between 1-5).</p> <p>Item 8 is self-perceived hearing difficulty used for normative purposes (currently not used as part of total score)</p>

			<p>This is initially coded as 0 to 4 in REDCap – changed to 1-5</p> <p>Currently, we’re treating IOI-HA total score as continuous, but this may need to be treated as ordinal.</p> <p>Higher scores are better</p>
SADL	<p>Note: this is measured only at 3 and 6 months.</p> <p>Note: the “sister” questionnaire at baseline is ECHO</p>	<p>Global score: sadl_global_6m</p> <p>Positive effect subscale: sadl_positive_effect_6m</p> <p>Service cost subscale: sadl_service_cost_6m</p> <p>Negative features subscale: sadl_negative_features_6m</p> <p>Personal image subscale: sadl_personal_image_6m</p>	<p>Questions 1 – 15 are used. This is scored from 1-7 (or reversed for questions 2, 4, 7, 13).</p> <p>There are 4 subscales: Positive Effect, Service & Cost, Negative Features, Personal Image. For each subscale, the average score is calculated.</p> <p>For the global score, this is the mean of the scores for all items (excluding questions 11 and 14 if applicable).</p> <p>Higher scores are better (higher satisfaction).</p> <p>See PCORI Scoring file for more details</p>
SSQ	<p>Note: this is measured at baseline, 3 months, and 6 months.</p>	<p>Change score (constructed in analytic script): ssq_overall_change_6m</p> <p><u>Baseline:</u> Overall score: ssq_overall_base</p> <p>Speech/hearing subscale: ssq_speech_hearing_base</p> <p>Spatial/hearing subscale: ssq_spatial_hearing_base</p> <p>Qualities of hearing subscale: ssq_qualities_of_hearing_base</p> <p><u>6-Months:</u> Overall score: ssq_overall_6m</p>	<p>3 subscales: Speech is questions 1 – 14 (corresponds to the “pt1” variables). Spatial is 17 questions (corresponds to the “pt2” variables). Qualities is 18 questions (correspond to the “pt3” variables).</p> <p>Overall score: mean of the items.</p> <p>For instances where people mark NA and a value, if the value is 50, set as NA. If a value other than 50, use that value.</p> <p>We will also create a change score as the difference in the overall score between 6 months and baseline (6 months – baseline)</p>

		<p>Speech/hearing subscale: ssq_speech_hearing_6m</p> <p>Spatial/hearing subscale: ssq_spatial_hearing_6m</p> <p>Qualities of hearing subscale: ssq_qualities_of_hearing_6m</p>	Higher scores are better
HHI-E	Note: this is measured at baseline, 3 months, and 6 months	<p>Change score (constructed in analytic script): hhie_total_change_6m</p> <p><u>Baseline:</u> Total score: hhie_total_base</p> <p>Social/Situational subscale: hhie_situational_base</p> <p>Emotional subscale: hhie_emotional_base</p> <p><u>6-Months:</u> Total score: hhie_total_6m</p> <p>Social/Situational subscale: hhie_situational_6m</p> <p>Emotional subscale: hhie_emotional_6m</p>	<p>Yes = 4 points, Sometimes = 2 points, and No = 0 points.</p> <p>Total scale score = sum of all 25 items</p> <p>Social/Situational subscale: questions 1, 3, 6, 8, 10, 11 13, 15, 16, 19, 21, 23</p> <p>Emotional subscale: questions 2, 4, 5, 7, 9, 12, 14, 17, 18, 20, 22, 24, 25</p> <p>We will also create a change score as the difference in the total scale score between 6 months and baseline (6 months – baseline)</p> <p>Lower scores are better</p>

3.2 Additional Variables of Interest

Variable	Description	Variables and Source	Specifications
Randomization assignment	hearing aid assignment	assign	Binary 1: unilateral 2: bilateral
Clinical site	Which site - Duke or Vanderbilt?	which_site Character version: which_site_ch	Binary 1: Vanderbilt 2: Duke
Switch configuration at 6 months	Patients are given the opportunity to switch configuration at 3 months and make a final configuration	ha_switch_assign_6m	Binary: 1: Switched configuration 0: Didn't switch Switched configuration is defined as unilateral to bilateral or vice versa (do not count

	choice at 6 months		switching unilateral to a different ear as a switch) Switched configuration also includes switching from 1 or 2 to 0
6-month final choice configuration	Patients are given to opportunity to make a final choice of hearing aid configuration at 6 months	ha_final_choice_6m Character version: ha_final_choice_6m_ch	Categorical: <ul style="list-style-type: none"> • Right • Left • Both • None • Missing

4 Statistical Analysis Plan

Deadline: To be completed by January 24, 2025.

4.1 Aim: compare all outcomes between the two assigned treatment arms

Compare the outcomes between the two assigned treatment arms (bilateral hearing aid and unilateral hearing aid) at 6 months.

Analysis: This will be reported for patients who have 6-month scores (“completers”). The analysis will be performed using either t-tests or Kruskal Wallis tests depending on whether or not the outcome distributions appear to be normally distributed for continuous outcomes. The total score for each survey at 6 months or the benefit score will be used as the outcomes. The Chi-Square test will be used for the APHAB Responder outcomes, with patient counts and relative frequencies reported.

The null hypothesis is that the means of the outcomes for the two treatment groups are the same.

$$H_0: \mu_{unilateral} = \mu_{bilateral}$$

Table 1: Distributions of 6-Month Outcomes or Benefit Scores by Assigned Treatment Group

	Unilateral (N=XXX)	Bilateral (N=XXX)	P-Value*
APHAB Global Change Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
APHAB Responder (25 Units)**			XXX
No	XXX (%)	XXX (%)	
Yes	XXX (%)	XXX (%)	
Ineligible to Drop 25 Units	XXX	XXX	
APHAB Responder (15 Units)**			XXX
No	XXX (%)	XXX (%)	
Yes	XXX (%)	XXX (%)	

Ineligible to Drop 15 Units	XXX	XXX	
SADL Global Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
HHI-E Change Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
IOI-HA Total Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	
SSQ Change Score			XXX
N	XXX	XXX	
Missing	XXX	XXX	
Mean (SD)	XXX (XXX)	XXX (XXX)	
Median	XXX	XXX	
Q1, Q3	XXX, XXX	XXX, XXX	
Range	XXX - XXX	XXX - XXX	

*T-test/Kruskal Wallis or Chi-Square test

**Denominator for percentages does not include patients ineligible to drop 'x' units

We will also describe the distributions of additional variables at 6-month visit as appropriate by assigned treatment (subscales and total scores where change score was reported above). We will also create boxplots for APHAB Global total score and change score by randomization. These figures may supplement Table 1 above.

Table 2: Distributions of Clinical Variables by Assigned Treatment

	Unilateral (N=XXX)	Bilateral (N=XXX)
APHAB Global Total Score (6 Months)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
APHAB EC Subscale (6 Months)		
N	XXX	XXX
Missing	XXX	XXX

Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
APHAB EC Subscale Change Score		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
APHAB BN Subscale (6 Months)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
APHAB BN Subscale Change Score		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
APHAB RV Subscale (6 Months)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
APHAB RV Subscale Change Score		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
APHAB AV Subscale (6 Months)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
APHAB AV Subscale Change Score		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)

Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SADL Positive Effect Subscale (6 Months)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SADL Service Cost Subscale (6 Months)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SADL Negative Features Subscale (6 Months)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
SADL Personal Image Subscale (6 Months)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
HHI-E Total Score (6-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
HHI-E Social/Situational Subscale (6-Month)		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

HHI-E Emotional Subscale (6-Month)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

SSQ Overall Score (6-Month)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

SSQ Speech/Hearing Subscale (6-Month)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

SSQ Spatial/Hearing Subscale (6-Month)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

SSQ Qualities of Hearing Subscale (6-Month)

N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

4.2 Aim: Compare 6-month outcomes by 6-month final choice of HA configuration

Compare the outcomes between the two HA configuration choice groups (bilateral hearing aid and unilateral hearing aid) at 6 months.

Analysis: Similar analysis and table as in Aim 1, Table 1, but with columns defined by 6-month HA configuration choice [Table 3].

4.3 Aim: Compare 6-month outcomes by 6-month configuration switching status relative to baseline

Compare the outcomes between the two groups (switched or did not switch from assigned HA configuration) at 6 months.

Analysis: Similar analysis and table as in Aim 1, Table 1, but with columns defined by 6-month HA switching status relative to baseline [Table 4].

4.4 Initially planned analyses that we will not do

We had initially planned to estimate repeated measures mixed models for all outcomes gathered at baseline, 3-months, and 6-months with randomized treatment assignment as the covariate of interest. However, given the propensity for participants to switch hearing aid configurations at 3-months and that there are only 2 follow-up timepoints, we deemed it more appropriate to look at the outcomes cross-sectionally rather than longitudinally.

5 Future Plans

There are additional items we may wish to explore in the future, at which point a new SAP will be developed. Ideas include looking at:

- Additional Glasgow Hearing Aid Benefit Profile measures
- Mask questions
- Additional hearing aid hours of use
- Unscheduled visits

Statistical Analysis Plan (SAP) – EMAs

Project: Evaluation of Unilateral vs Bilateral Hearing Aids for the Treatment of Age-related Hearing Loss

IRB Number: Pro00106077

Investigator(s): Sherri Smith, AuD, PhD

Biostatisticians: [REDACTED]

Original Creation Date: 02.18.2022

Version Date: 12.02.2024

Investigator Agreement

- ☐ All statistical analyses included in an abstract or manuscript should reflect the work of the biostatistician(s) listed on this SAP. No changes or additional analyses should be made to the results or findings without discussing with the project biostatistician(s).
- ☐ All biostatisticians on this SAP should be given sufficient time to review the full presentation, abstract, manuscript, or grant and be included as co-authors on any abstract or manuscript resulting from the analyses.
- ☐ If substantial additional analysis is necessary or the aims of the project change, a new SAP will need to be developed.
- ☐ Publications resulting from this SAP are supported in part by the Duke CTSA and must cite grant number UL1TR002553 and be submitted to PubMed Central.
- ☐ I have reviewed the SAP and understand that any changes must be documented.

Acknowledged by: Click or tap here to enter text.

Date: Click or tap to enter a date.

Activity Log

02.18.2022 Created SAP for GHABP and EMA outcomes
02.21.2022 Added details to analysis
03.14.2022 Updated based on discussion
01.26.2023 Add additional details to variables and updates reflective of changes made in other SAPs
05.31.2024 Moved 6-month data to Future Plans section
12.02.2024 Removed GHABP and moved user-nominated scenarios to Future Plans section

Acronyms

APHAB	Abbreviated Profile of Hearing Aid Benefit
EMA	Ecological Momentary Assessment
GHABP	Glasgow Hearing Aid Benefit Profile
IOI-HA	International Outcomes Inventory for Hearing Aids
SADL	Satisfaction with Amplification in Daily Life
SSQ	Speech Spatial Qualities
HHIE	Hearing Handicap Inventory for Elderly

1 Study Overview

Background/Introduction: The overall goal of the project is to determine the benefit of unilateral or bilateral hearing aid fittings in adults with mild-to-moderate age-related hearing loss. This will address the lack of high-quality evidence supporting bilateral hearing aids over unilateral hearing aids. This project will use a randomized controlled trial with two treatment arms: a bilateral hearing aid fitting group and a unilateral hearing aid fitting group.

1.1 Aim

- Compare EMA outcome between the two arms across all responses to the 4 standard scenarios, looking at the time periods from baseline to 3 months and 3 months to 6 months.

2 Study Population

2.1 Inclusion Criteria

- 50+ years of age
- Mild to moderate, symmetrical SNHL (symmetrical: < 20 dB between ears on average from 500-4000 Hz)
- Open-mindedness to unilateral or bilateral amplification
- No prior hearing aid experience
- Adequate literacy to complete questionnaires
- Willing to purchase study-specific hearing aid(s)

2.2 Exclusion Criteria

- Concerns for middle ear pathology
- Concerns for retrocochlear pathology
- Severe tinnitus as the reason for seeking amplification
- Co-morbid condition that would interfere with study (e.g., dementia, blindness, neurologic pathology)
- History of fluctuating hearing loss

2.3 Data Acquisition

Fill in all relevant information:

Study design	Randomized controlled trial with 2 arms (bilateral hearing aid, unilateral hearing aid) Note: Randomization was stratified by clinical site.
Data source/how the data were collected	Screening information pulled from EHR data Baseline surveys captured via in-person interview and recorded in REDCap
Contact information for team member responsible for data collection/acquisition	All data access is through [REDACTED]. Questions on data validity will go to PI: Sherri Smith (Sherri.smith@duke.edu)
Date or version (if downloaded, provide date)	10.17.2024
Data transfer method and date	Direct data extraction from REDCap
Where dataset is stored	REDCap Extracted data and analytic datasets are stored on a secure drive in the CRU folder: \\duhs-vclin-

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Outcome(s)

Outcome	Description	Variables and Source	Specifications
GHABP Unaided	GHABP is measured at baseline (unaided)	<p>GHABP unaided: ghabun1a – ghabun6c</p> <p>3 total questions for each of 6 scenarios (4 standard, 2 user-nominated)</p> <p>First question just asks if this scenario has happened – ONLY include those who say yes to this</p>	<p>For questions 2 and 3 (IF they answer yes to question 1), doing this separately by question:</p> <ol style="list-style-type: none"> 1. Subtract 1, multiply by 25, average answer to question across 4 standard scenarios 2. Subtract 1, multiply by 25, average answer to question across 2 user-nominated scenarios 3. Subtract 1, multiply by 25, average answer to question across all 6 scenarios. <p>For self-nominated goals, people may write in “NA”, “N/A”, “Na”, “None”, “Not applicable” – these should be ignored (set to missing)</p>
GHABP Aided	GHABP is measured at 3 months (aided)	<p>GHABP aided: ghaba1a_v1 – ghaba6f_v1</p> <p>6 total questions for each of 6 scenarios (4 standard, 2 user-nominated)</p> <p>First question just asks if this scenario has happened – ONLY include those who say yes to this</p>	<p>For questions 3-6 (IF they answer yes to question 1), doing this separately by question:</p> <ol style="list-style-type: none"> 1. Subtract 1, multiply by 25, average answer to question across 4 standard scenarios 2. Subtract 1, multiply by 25, average answer to question across 2 user-nominated scenarios 3. Subtract 1, multiply by 25, average answer to question across all 6 scenarios. <p>Note: ignore current question 2 as it is non-standard</p>

			<p>For self-nominated goals, people may write in “NA”, “N/A”, “Na”, “None”, “Not applicable” – these should be ignored (set to missing). Note: we will need to keep track of these baseline goals in case people answer “yes” at the later timepoints.</p>
EMA	<p>EMA are surveys (same questions as GHABP) sent 5 times a day for a week. Have these in two time periods: before 3 months and after 3 months. These time periods will be kept separate.</p>	<p>EMA variables: for Duke, these are ghaba1a – ghaba6f. For Vanderbilt, these are ghaba1a_v2 – ghaba6f_v2. Have EMA “events” EMA 1a – EMA 7e for survey before 3 months. Have EMA “events” EMA 8a – EMA 14e for surveys after 3 months (before 6 months)</p> <p>6 total questions for each of 6 scenarios (4 standard, 2 user-nominated)</p> <p>First question just asks if this scenario has happened – ONLY include those who say yes to this</p>	<p>Several pieces here. First, for questions 3-6 (IF they answer yes to question 1), subtract 1 and multiply by 25.</p> <p>Then interested in 2 cases:</p> <ol style="list-style-type: none"> 1. Look at answer to all question X’s over ALL scenarios for blocks of scenarios below 2. For question X, look at answer to all question X’s within a given scenario for the 4 standard scenarios <p>Blocks of scenarios:</p> <ol style="list-style-type: none"> 1. 4 standard scenarios 2. 2 user-nominated scenarios 3. All 6 scenarios. <p>Note: ignore current question 2 as it is non-standard</p> <p>For self-nominated goals, people may write in “NA”, “N/A”, “Na”, “None”, “Not applicable” – these should be ignored (set to missing). Note: we will need to keep track of these baseline goals in case people answer “yes” at the later timepoints.</p>

Notes: 6 total scenarios, 4 standard, 2 user-nominated. Standard scenarios:

1. LISTENING TO THE TELEVISION WITH OTHER FAMILY OR FRIENDS WHEN THE VOLUME IS ADJUSTED TO SUIT OTHER PEOPLE
2. HAVING A CONVERSATION WITH ONE OTHER PERSON WHEN THERE IS NO BACKGROUND NOISE

3. CARRYING ON A CONVERSATION IN A BUSY STREET OR SHOP
4. HAVING A CONVERSATION WITH SEVERAL PEOPLE IN A GROUP

Unaided questions:

1. Does this situation happen in your life?
2. How much difficulty do you have in this situation?
3. How much does any difficulty in this situation worry, annoy or upset you?

Aided/EMA questions:

1. Did this situation happen in the past few weeks? (GHABP aided) OR Did this situation happen in the last three hours? (EMA)
2. In this situation, with your hearing aid, how much does any difficulty in this situation worry, annoy or upset you? (NOTE: ignore this question as it is non-standard)
3. In this situation, what proportion of the time do you wear your hearing aid?
4. In this situation, how much does your hearing aid help you?
5. In this situation, with your hearing aid, how much difficulty do you now have?
6. For this situation, how satisfied are you with your hearing aid?

3.2 Additional Variables of Interest

Variable	Description	Variables and Source	Specifications
Randomization assignment	hearing aid assignment	Baseline visit: assign	Binary 1: unilateral 2: bilateral
Clinical site	Which site - Duke or Vanderbilt?	Baseline visit: which_site	Binary 1: Vanderbilt 2: Duke

4 Statistical Analysis Plan

Analysis: To be completed by December 31, 2024

4.1 Descriptive Characteristics for EMA Surveys

Analysis: We will present the mean with standard deviation (SD), median with interquartile range (IQR), and ranges (min and max) for number of EMA surveys completed. The 0-3-month period and 3-6-month period will be done separately, stratified by baseline assignment and 3M choice, respectively.

Table 1: EMA Summaries

Number of EMA Surveys Completed Before 3 Months	Assigned Unilateral (N=XXX)	Assigned Bilateral (N=XXX)
N	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX
Number of EMA Surveys Completed After 3 Months	3M Choice – Unilateral (N=XXX)	3M Choice – Bilateral (N=XXX)
N	XXX	XXX

Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX, XXX	XXX, XXX
Range	XXX - XXX	XXX - XXX

4.2 Aim: compare EMA surveys between the two arms in the period between baseline and 3 months, and between 3M choice groups between 3 months and 6 months

For question X, we want to look at the answers to all question X's over the 4 standard scenarios.

Analysis: This will be done using intent-to-treat for patients who have EMA surveys and answer "yes" to the first question (if the scenario happens). The primary analysis will be performed by linear mixed effects models with covariates clinical site and assigned treatment/3M choice, with a separate model for each question. The overall average of within-person means will be reported by treatment arm/3M choice, as well as T-test p-values from the fitted models for the treatment arm/3M choice covariate, where a p-value < 0.05 would indicate a difference in average response between treatment arms/3M choices.

Table 4: Repeated Measures ANOVA Comparing EMA Surveys Across Scenarios in Unilateral and Bilateral Groups

Question & Scenarios	Assigned Unilateral (Overall Mean)	Assigned Bilateral (Overall Mean)	P-Value*
0-3 Months			
1. In this situation, what proportion of the time do you wear your hearing aid?	XXX	XXX	XXX
2. In this situation, how much does your hearing aid help you?	XXX	XXX	XXX
3. In this situation, with your hearing aid, how much difficulty do you now have?	XXX	XXX	XXX
4. For this situation, how satisfied are you with your hearing aid?	XXX	XXX	XXX
3-6 Months	3M Choice: Unilateral	3M Choice: Bilateral	P-Value*
1. In this situation, what proportion of the time do you wear your hearing aid?	XXX	XXX	XXX
2. In this situation, how much does your hearing aid help you?	XXX	XXX	XXX
3. In this situation, with your hearing aid, how much difficulty do you now have?	XXX	XXX	XXX
4. For this situation, how satisfied are you with your hearing aid?	XXX	XXX	XXX

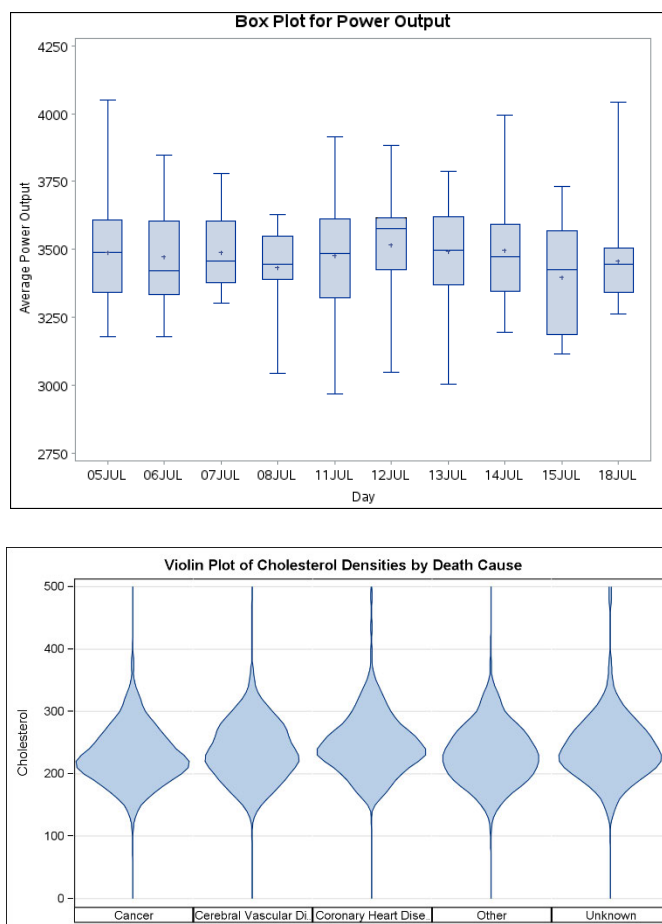
*Using T-test statistic

4.3 Aim: compare EMA surveys between the two arms in the period between baseline and 3 months, and between 3M choice groups between 3 months and 6 months

For question X, we want to look at the answers to all question X's within a given scenario for the 4 standard scenarios.

Analysis: This will be descriptive. We will use boxplots, violin plots, or another type of plot to describe these scenarios. For each of the 4 standard scenarios, we will display the distributions of the answers to each of the 4 questions for both unilateral and bilateral hearing aid groups (i.e., 1 plot per question with two boxes per scenario for each of the 4 scenario/treatment combos).

Examples of what boxplots and violin plots look like (violin plots can be more informative about the distribution of data because they show the density as well):



5 Future Plans

There are additional items we may wish to explore in the future, at which point a new SAP will be developed. In particular, we may explore EMA responses for the 2 user-nominated scenarios or all 6 scenarios.

Statistical Analysis Plan (SAP) – Hearing Aid Choice and Switching

Project: Evaluation of Unilateral vs Bilateral Hearing Aids for the Treatment of Age-related Hearing Loss

IRB Number: Pro00106077

Investigator(s): Sherri Smith, AuD, PhD

Biostatisticians: [REDACTED]

Original Creation Date: 11.16.2023

Version Date: 11.26.2024

Investigator Agreement

- ☐ All statistical analyses included in an abstract or manuscript should reflect the work of the biostatistician(s) listed on this SAP. No changes or additional analyses should be made to the results or findings without discussing with the project biostatistician(s).
- ☐ All biostatisticians on this SAP should be given sufficient time to review the full presentation, abstract, manuscript, or grant and be included as co-authors on any abstract or manuscript resulting from the analyses.
- ☐ If substantial additional analysis is necessary or the aims of the project change, a new SAP will need to be developed.
- ☐ Publications resulting from this SAP are supported in part by the Duke CTSA and must cite grant number UL1TR002553 and be submitted to PubMed Central.
- ☐ I have reviewed the SAP and understand that any changes must be documented.

Acknowledged by: Click or tap here to enter text.

Date: Click or tap to enter a date.

Activity Log

11.16.2023 Created SAP for outcomes related to hearing aid choice and switching
06.03.2024 Added additional variables, moved questions related to data collected after 3 months to the Future Plans section
07.11.2024 Resolved some comments, added details about potential covariates
07.25.2024 Moved 6-month APHAB into this SAP
10.02.2024 Resolved some comments after discussion (see previous SAP for more details), updated variable names/descriptions
11.26.2024 Resolved some comments after discussion, revised model for identifying associations between baseline covariates and 3M switching or 6M final choice

Acronyms

APHAB	Abbreviated Profile of Hearing Aid Benefit
EMA	Ecological Momentary Assessment
GHABP	Glasgow Hearing Aid Benefit Profile
IOI-HA	International Outcomes Inventory for Hearing Aids

1 Study Overview

Background/Introduction: The overall goal of the project is to determine the benefit of unilateral or bilateral hearing aid fittings in adults with mild-to-moderate age-related hearing loss. This will address the lack of high-quality evidence supporting bilateral hearing aids over unilateral hearing aids. This project will use a randomized controlled trial with two treatment arms: a bilateral hearing aid fitting group and a unilateral hearing aid fitting group.

1.1 Hearing Aid Switching Aims

- Explore if treatment assignment influences switching configuration at 3 months
- Explore what predicts switching at 3 months
- Describe patient characteristics for switchers vs. non-switchers
- Describe APHAB data (subscales and global score) over time within subgroups of individuals

2 Study Population

2.1 Inclusion Criteria

- 50+ years of age
- Mild to moderate, symmetrical SNHL (symmetrical: < 20 dB between ears on average from 500-4000 Hz)
- Open-mindedness to unilateral or bilateral amplification
- No prior hearing aid experience
- Adequate literacy to complete questionnaires
- Willing to purchase study-specific hearing aid(s)

2.2 Exclusion Criteria

- Concerns for middle ear pathology
- Concerns for retrocochlear pathology
- Severe tinnitus as the reason for seeking amplification
- Co-morbid condition that would interfere with study (e.g., dementia, blindness, neurologic pathology)
- History of fluctuating hearing loss

2.3 Data Acquisition

Fill in all relevant information:

Study design	Randomized controlled trial with 2 arms (bilateral hearing aid, unilateral hearing aid) Note: Randomization was stratified by clinical site.
Data source/how the data were collected	Screening information pulled from EHR data Baseline surveys captured via in-person interview and recorded in REDCap

Contact information for team member responsible for data collection/acquisition	All data access is through [REDACTED]. Questions on data validity will go to PI: Sherri Smith (Sherri.smith@duke.edu)
Date or version (if downloaded, provide date)	10.17.2024
Data transfer method and date	Direct data extraction from REDCap
Where dataset is stored	REDCap Extracted data and analytic datasets are stored on a secure drive in the CRU folder: \\duhs-vclin-nc1\dusom_biostats_fs\Data\BiostatsCore\CRU\Head and Neck\Smith\PCORI_Pro00106077\Data pulls

Notes:

Description:
[insert]

3 Outcomes, Exposures, and Additional Variables of Interest

3.1 Outcome(s)

Outcome	Description	Variables and Source	Specifications
Switch configuration at 3 months	Patients are given the opportunity to switch configurations at 3 months.	ha_switch_3m	Binary: 1: Switched configuration 0: Didn't switch Switched configuration is defined as unilateral to bilateral or vice versa (do not count switching unilateral to a different ear as a switch) Switched configuration also includes switching from 1 or 2 to 0
APHAB Global Score	Global communication score at baseline, 3 months, 6 months	aphab_global_base aphab_global_3m aphab_global_6m	Rescore variables and multiply by 100 <ul style="list-style-type: none"> 1 = 0.99 2 = 0.87 3 = 0.75 4 = 0.50 5 = 0.25 6 = 0.12 7 = 0.01 Reverse score questions 1, 9, 11, 16, 19, 21

			<p>Global score: mean of variables in the EC, BN, RV subscale scores (excludes questions 3, 8, 13, 17, 20, 22)</p> <p>Also potentially used in other models as a covariate</p>
APHAB – 4 subscales	EC, BN, RV, AV scales at baseline, 3 months, 6 months	<p>aphab_ec_base aphab_ec_3m aphab_ec_6m</p> <p>aphab_bn_base aphab_bn_3m aphab_bn_6m</p> <p>aphab_rv_base aphab_rv_3m aphab_rv_6m</p> <p>aphab_av_base aphab_av_3m aphab_av_6m</p>	<p>Rescore variables and multiply by 100</p> <ul style="list-style-type: none"> • 1 = 0.99 • 2 = 0.87 • 3 = 0.75 • 4 = 0.50 • 5 = 0.25 • 6 = 0.12 • 7 = 0.01 <p>Reverse score questions 1, 9, 11, 16, 19, 21</p> <p>EC: mean of questions 4, 10, 12, 14, 15, 23</p> <p>BN: mean of questions 1, 6, 7, 16, 19, 24</p> <p>RV: mean of questions 2, 5, 9, 11, 18, 21</p> <p>AV: mean of questions 3, 8, 13, 17, 20, 22</p> <p>Also potentially used in prediction models as covariates</p>

3.2 Additional Variables of Interest

Variable	Description	Variables and Source	Specifications
Randomization assignment	hearing aid assignment	assign	Binary 1: unilateral 2: bilateral
Clinical site	Which site - Duke or Vanderbilt?	which_site Character version: which_site_ch	Binary 1: Vanderbilt 2: Duke
3 month chosen treatment	Hearing aid configuration at 3 months	ha_config_3m	Categorical <ul style="list-style-type: none"> • Right • Left • Both

			<ul style="list-style-type: none"> • None • Missing
Gender		gender Character version: gender_ch	Categorical <ul style="list-style-type: none"> • 1: male • 2: female • 3: other • 99: declined
Age	Age at baseline (years)	age_base Baseline visit is baseline_date	Continuous Years from baseline_date to dob Baseline visit is defined as apha_base_date if non-missing, otherwise use date_moca
Race		race Character version: race_ch	Categorical <ul style="list-style-type: none"> • 1: African American/Black • 2: White/Caucasian • 3: Asian • 4: Native American/Alaska Native • 5: Native Hawaiian/Pacific Islander • 6: More than one race • 99: Declined <p>If cell counts are less than 10 for a given category, we will not report the exact cell count.</p> <p>NIH racial categories:</p> <ul style="list-style-type: none"> -American Indian/Alaska Native -Asian or Asian American -Black or African American -Native Hawaiian/Pacific Islander -White
Ethnicity		ethnicity	Categorical <ul style="list-style-type: none"> • 1: Hispanic or Latino

		Character version: ethnicity_ch	<ul style="list-style-type: none"> • 2: Not Hispanic or Latino • 999: Declined <p>If cell counts are less than 10 for a given category, we will not report the exact cell count.</p>
Income	Personal Income Last Year	income Character version: income_ch	Categorical <ul style="list-style-type: none"> • 0: \$0 • 1: \$1 to \$9999 • 2: \$10,000 to \$24,999 • 3: \$25,000 to \$49,999 • 4: \$50,000 to \$74,999 • 5: \$75,000 to \$99,999 • 6: \$100,000 to \$149,999 • 7: \$150,000 or greater • 999: Prefer not to answer
Hearing Aid Health Insurance Benefits		benefits Character version: benefits_ch	Categorical <ul style="list-style-type: none"> • 0: No • 1: Yes • 998: Not Sure
Marital Status		marital Character version: marital_ch	Categorical <ul style="list-style-type: none"> • 1: married • 2: widowed • 3: divorced • 4: separated • 5: never married • 999: prefer not to answer
Living arrangements		living Character version: living_ch	Categorical <ul style="list-style-type: none"> • 1: alone • 2: with spouse • 3: with spouse and others • 888: other • 999: prefer not to answer
Education		education Character version: education_ch	Categorical <ul style="list-style-type: none"> • 1: less than high school • 2: high school • 3: some college • 4: 4-year degree

			<ul style="list-style-type: none"> • 5: graduate degree • 888: other • 999: prefer not to answer
Baseline Date Quarter		baseline_quarter	Categorical Put baseline date into quarters
Cognition (Screened via MoCA)	Adjusted MoCA score	total_moca	Continuous, 0-30 moca31 is a modifier for high school education If moca31=0, then total moca score is the sum of moca1 through moca30 If moca31=1, then total moca score is the minimum of 30 and the sum of moca1 through moca 31
Degree of Hearing Loss – Pure Tone Average	PTA in better ear	Right ear: pta_right Left ear: pta_left Better ear: pta_better	We will use the pure tone average in the better ear. Take the average at frequencies 500, 1000, 2000, 4000 in both ears. The lower average is the better ear.
Hearing loss classification		hearing_loss_class	Binary <ul style="list-style-type: none"> • Mild: pta_better <= 40 • Moderate pta_better > 40
APHAB Change Score	Difference in aided APHAB scores at month 3 and unaided scores at baseline	aphab_change	Scale score – will need to calculate global communication scores at baseline (unaided) and 3 months (aided), subtract (3 months – baseline) A lower score on APHAB is better.

APHAB change score – binary, 3 months	Responders vs non-responders for primary APHAB outcome	<p>Decrease of 25 units: use <code>aphab_change_responder</code></p> <p>Decrease of 15 units: use <code>aphab_change_responder_15</code></p>	<p>Patients with a decrease of at least 25 units (or 15 units for the sensitivity analysis) on the APHAB scale at month 3 will be considered “responders.” Patients not returning or who do not have a score at 3 months will be considered “non-responders.”</p> <p>Binary (25 unit decrease):</p> <ul style="list-style-type: none"> • 1 if <code>aphab_change</code> ≤ -25 • 0 else <p>Binary (15 unit decrease);</p> <ul style="list-style-type: none"> • 1 if <code>aphab_change</code> ≤ -15 • 0 else
IOI-HA	This is measured only at 3 and 6 months	Total score: <code>ioiha_total_3m</code>	<p>Total score: sum responses to questions 1-7 (should be on a range between 1-5).</p> <p>Item 8 is self-perceived hearing difficulty used for normative purposes (currently not used as part of total score)</p> <p>This is initially coded as 0 to 4 in REDCap – changed to 1-5</p> <p>Currently, we’re treating IOI-HA total score as continuous, but this may need to be treated as ordinal.</p> <p>Higher scores are better</p>

SADL	<p>This is measured only at 3 and 6 months.</p> <p>Note: the “sister” questionnaire at baseline is ECHO</p>	<p>Global score: sadl_global_3m</p> <p>Positive effect subscale: sadl_positive_effect_3m</p> <p>Service cost subscale: sadl_service_cost_3m</p> <p>Negative features subscale: sadl_negative_features_3m</p> <p>Personal image subscale: sadl_personal_image_3m</p>	<p>Questions 1 – 15 are used. This is scored from 1-7 (or reversed for questions 2, 4, 7, 13).</p> <p>There are 4 subscales: Positive Effect, Service & Cost, Negative Features, Personal Image. For each subscale, the average score is calculated.</p> <p>For the global score, this is the mean of the scores for all items (excluding questions 11 and 14 if applicable).</p> <p>Higher scores are better (higher satisfaction).</p> <p>See PCORI Scoring file for more details</p>
SSQ	<p>This is measured at baseline, 3 months, and 6 months</p>	<p>Change score: ssq_change</p> <p><u>Baseline:</u> Overall score: ssq_overall_base</p> <p>Speech/hearing subscale: ssq_speech_hearing_base</p> <p>Spatial/hearing subscale: ssq_spatial_hearing_base</p> <p>Qualities of hearing subscale: ssq_qualities_of_hearing_base</p> <p><u>3-Months:</u> Overall score: ssq_overall_3m</p> <p>Speech/hearing subscale: ssq_speech_hearing_3m</p> <p>Spatial/hearing subscale: ssq_spatial_hearing_3m</p>	<p>3 subscales: Speech is questions 1 – 14 (corresponds to the “pt1” variables). Spatial is 17 questions (corresponds to the “pt2” variables). Qualities is 18 questions (correspond to the “pt3” variables).</p> <p>Overall score: mean of the items.</p> <p>For instances where people mark NA and a value, if the value is 50, set as NA. If a value other than 50, use that value.</p> <p>We will also create a change score as the difference in the</p>

		Qualities of hearing subscale: ssq_qualities_of_hearing_3m	overall score between 3 months and baseline (3 months – baseline) Higher scores are better
HHI-E	This is measured at baseline, 3 months, and 6 months	Change score: hhie_change <u>Baseline:</u> Total score: hhie_total_base Situational subscale: hhie_situational_base Emotional subscale: hhie_emotional_base <u>3-Months:</u> Total score: hhie_total_3m Situational subscale: hhie_situational_3m Emotional subscale: hhie_emotional_3m	Yes = 4 points, Sometimes = 2 points, and No = 0 points. Total scale score = sum of all 25 items Situational subscale: questions 1, 3, 6, 8, 10, 11 13, 15, 16, 19, 21, 23 Emotional subscale: questions 2, 4, 5, 7, 9, 12, 14, 17, 18, 20, 22, 24, 25 We will also create a change score as the difference in the total scale score between 3 months and baseline (3 months – baseline) Lower scores are better
Hours of Hearing Aid Use	Multiple time periods (every scheduled visit and unscheduled follow ups)	Right ear: r_avg_hrs_3m r_avg_hrs_3m_na (if right HA is NA) Left ear: l_avg_hrs_3m l_avg_hrs_3m_na	How many hours on average the right/left HA was worn. NA variables: value of 1 if that HA was NA
GHABP Unaided	GHABP is measured at baseline (unaided)	Question 2 average, 4 standard scenarios: ghabp_q2_4block_base Question 3 average, 4 standard scenarios: ghabp_q3_4block_base	For questions 2 and 3 (IF they answer yes to question 1), doing this separately by question: 1. Subtract 1, multiply by 25,

			<p>average answer to question across 4 standard scenarios</p> <p>There are 6 scenarios (4 standard, 2 user-nominated)</p> <p>Note that question 1 just asks if this scenario has happened – participants are only included in the averages if they answer “yes”</p> <p>Lower scores are better for both questions</p>
GHABP Aided	GHABP is measured at 3 months (aided)	<p>Question 2 average, 4 standard scenarios: ghabp_q2_4block_3m</p> <p>Question 3 average, 4 standard scenarios: ghabp_q3_4block_3m</p> <p>Question 4 average, 4 standard scenarios: ghabp_q4_4block_3m</p> <p>Question 5 average, 4 standard scenarios: ghabp_q5_4block_3m</p> <p>Question 6 average, 4 standard scenarios: ghabp_q6_4block_3m</p>	<p>For questions 3-6 (IF they answer yes to question 1), doing this separately by question:</p> <ol style="list-style-type: none"> 1. Subtract 1, multiply by 25, average answer to question across 4 standard scenarios <p>Note: ignore current question 2 for analyses as it is non-standard but report on this in a descriptive table</p> <p>There are 6 scenarios (4 standard, 2 user-nominated)</p> <p>Note that question 1 just asks if this scenario has happened – participants are only included in the</p>

			<p>averages if they answer “yes”</p> <p>Higher/lower scores are better depending on question</p>
Binaural loudness summation	<p>Baseline only</p> <p>CSL level right</p> <p>CSL level left</p> <p>CSL level both</p>	<p>binaural_r_base</p> <p>binaural_l_base</p> <p>binaural_both_base</p>	Continuous
Dichotic digit test	<p>Baseline only</p> <p>Right ear directed</p> <p>Left ear directed</p> <p>Free recall both ears</p> <p>Right ear free recall</p> <p>Left ear free recall</p>	<p>dichotic_r_base</p> <p>dichotic_l_base</p> <p>dichotic_free_both_base</p> <p>dichotic_free_r_base</p> <p>dichotic_free_l_base</p>	Continuous
Speech and Noise Test	<p>Baseline (unaided) and 3-months (aided)</p> <p>Speech and noise 0 degrees (collocated)</p> <p>Speech left, noise right</p> <p>Noise left, speech right</p>	<p>Baseline:</p> <p>sin_collocated_base</p> <p>sin_right_base</p> <p>sin_left_base</p> <p>3-Months:</p> <p>sin_collocated_3m</p> <p>sin_right_3m</p> <p>sin_left_3m</p> <p>Change:</p> <p>sin_collocated_change</p> <p>sin_r_change</p> <p>sin_l_change</p> <p>May also want change scores for speech to aided side and speech to unaided side</p>	<p>Continuous</p> <p>Change scores: 3m-baseline for each of collocated, speech left/noise right, noise left/speech right</p> <p>Positive values for unaided/aided variables indicate speech is louder than noise; negative indicate speech is under the noise</p> <p>For unilateral assigned, also have speech to aided side (advantage) and speech to unaided side (disadvantage).</p> <p>Speech to aided (advantage):</p> <ul style="list-style-type: none"> If assigned R, this is noise left, speech right

			<ul style="list-style-type: none"> If assigned L, this is speech left, noise right <p>Speech to unaided (disadvantage):</p> <ul style="list-style-type: none"> If assigned R, this is speech left, noise right If assigned L, this is noise left, speech right <p>Lower scores are better</p>
Auditory Working Memory	<p>Unaided and Aided (3 months)</p> <p>Recognition, judgement, recall</p>	<p>Change scores: warrm_recog_change warrm_recall_change</p> <p><u>Baseline:</u> warrm_recog_base warrm_recall_base warrm_judge_base</p> <p><u>3-Months:</u> warrm_recog_3m warrm_recall_3m warrm_judge_3m</p>	<p>Continuous</p> <p>Sum questions 2-6 for each tasks (recognition, judgement, recall) separately and get a % correct (out of 20)</p> <p>Construct change scores as difference between 3 months and baseline for recognition and recall.</p> <p>Judgement is more of a sanity check (<90% means they probably aren't engaged)</p> <p>Higher scores are better</p>
ECHO	<p>Baseline only</p> <p>Note: this is the "sister" questionnaire to SADL (aided)</p>	<p>Global score: echo_global_base</p> <p>Positive effect subscale: echo_positive_effect_base</p> <p>Service cost subscale: echo_service_cost_base</p> <p>Negative features subscale: echo_negative_features_base</p> <p>Personal image subscale: echo_personal_image_base</p>	<p>Questions 1 – 15 are used. This is scored from 1-7 (or reversed for questions 2, 4, 7, 13).</p> <p>There are 4 subscales: Positive Effect, Service & Cost, Negative Features, Personal Image. For each subscale, the average score is calculated.</p>

			<p>For the global score, this is the mean of the scores for all items (excluding question 11 if applicable).</p> <p>Higher scores are better (higher expectations).</p> <p>See PCORI Scoring file for more details</p>
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4 Statistical Analysis Plan

Analysis: To be completed by December 31, 2024.

4.1 Descriptive Table of Switched Configuration Status by Assigned Treatment

Analysis: This will be descriptive. As appropriate, we will present the frequency with percentage (see Table 1). Note that “switched configuration” will be defined as yes for those who switched configuration at 3 months and will be defined as no for those who did not switch configuration at 3 months.

Table 1: Switched HA Configuration and Choice vs. Assigned Treatment

	Assigned Unilateral Left (N=XXX)	Assigned Unilateral Right (N=XXX)	Assigned Bilateral (N=XXX)
Switched Configuration at 3 Months			
No	XXX (%)	XXX (%)	XXX (%)
Yes	XXX (%)	XXX (%)	XXX (%)
Missing	XXX (%)	XXX (%)	XXX (%)
Hearing Aid Configuration Choice at 3 Months			
Unilateral Left	XXX (%)	XXX (%)	XXX (%)
Unilateral Right	XXX (%)	XXX (%)	XXX (%)
Bilateral	XXX (%)	XXX (%)	XXX (%)
None	XXX (%)	XXX (%)	XXX (%)
Missing	XXX (%)	XXX (%)	XXX (%)

4.2 Investigate if assigned treatment influences switching at 3 months

Analysis: This will be done using assigned treatment for patients who have information on switching status at 3 months. This analysis will be performed using logistic regression where the outcome is switching status (the probability modelled is switching). The only covariate included in this model will be assigned treatment. A similar model will be fit for the binary outcome 6M HA configuration choice (unilateral vs bilateral).

$$\text{Hearing Aid Switching Status} = \beta_0 + \beta_1 * \text{treatment assignment}$$

Table 2 Logistic Regression OR Estimate for HA Assignment Probability Modelled: Switched HA Configuration			
Covariate	OR	95% C.I.	P-Value*
Hearing Aid Assignment (Reference: Bilateral)			
Unilateral	XXX	(XXX , XXX)	XXX
*Using XXX statistic			

4.3 Investigate what predicts switching at 3 months

Analysis: This will be done for all randomized patients who are not missing scores or other predictors of interest. This analysis will be performed using the LASSO for logistic regression where the outcome is switching status (the probability modelled is switching) or 6M HA configuration choice (modelled probability is unilateral). Covariates (denoted generally as L below) to include in these models are age at baseline, gender, pure tone average in the better ear, baseline global HHI-E, baseline APHAB Global, baseline APHAB AV, binaural loudness summation (both), REAfree (Dichotic Digits, free right minus free left), REAdirect (Dichotic Digits, direct right minus direct left), cognitive effect LE (Dichotic Digits, direct left minus free left), cognitive effect RE (Dichotic Digits, direct right minus free right), AWARRM recall, and education-adjusted MoCA total score. The selected variables, their odds ratios, and 95% confidence intervals constructed from post-selection inference methods (R package ‘selectiveInference’) will be reported.

$$\text{Hearing Aid Switching Status} = \beta_0 + \beta_L * L$$

Table 3: Logistic Regression OR Estimates Probability Modelled: Switched HA Configuration		
Covariate	OR	P-S 95% C.I.
Covariate 1 (Ref: category)		
Category x....	XXX	(XXX , XXX)
Covariate 2	XXX	(XXX , XXX)

4.4 Describe patient characteristics for those who switch their HA configuration vs. those who don’t

Analysis: The characteristics from “non-switchers” will be compared to “switchers” with the use of a “Table 1”. As appropriate, we will present the mean with standard deviation (SD), median with interquartile range (IQR), and ranges (min and max), or frequency with percentage. A similar table will be constructed with participants stratified by 6M HA configuration choice.

Table 4: Patient Characteristics for Non-Switchers and Switchers		
	Non-Switchers (N=XXX)	Switchers (N=XXX)
Clinical Site		
Duke	XXX (%)	XXX (%)
Vanderbilt	XXX (%)	XXX (%)
Gender		
Female	XXX (%)	XXX (%)
Male	XXX (%)	XXX (%)
Other	XXX (%)	XXX (%)
Age at Baseline Visit		
N	XXX	XXX

Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX
Race		
American Indian/Alaska Native	XXX (%)	XXX (%)
Asian	XXX (%)	XXX (%)
Black or African American	XXX (%)	XXX (%)
White	XXX (%)	XXX (%)
More than one race	XXX (%)	XXX (%)
Native Hawaiian/Pacific Islander	XXX (%)	XXX (%)
Declined	XXX (%)	XXX (%)
Ethnicity		
Hispanic or Latino	XXX (%)	XXX (%)
Not Hispanic or Latino	XXX (%)	XXX (%)
Declined	XXX (%)	XXX (%)
Personal Income Last Year		
\$0	XXX (%)	XXX (%)
\$1 to \$9999	XXX (%)	XXX (%)
\$10,000 to \$24,999	XXX (%)	XXX (%)
\$25,000 to \$49,999	XXX (%)	XXX (%)
\$50,000 to \$74,999	XXX (%)	XXX (%)
\$75,000 to \$99,999	XXX (%)	XXX (%)
\$100,000 to \$149,999	XXX (%)	XXX (%)
\$150,000 or greater	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)
Hearing Aid Health Insurance Benefits		
No	XXX (%)	XXX (%)
Yes	XXX (%)	XXX (%)
Not sure	XXX (%)	XXX (%)
Marital Status		
Married	XXX (%)	XXX (%)
Widowed	XXX (%)	XXX (%)
Divorced	XXX (%)	XXX (%)
Separated	XXX (%)	XXX (%)
Never married	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)
Living Arrangements		
Alone	XXX (%)	XXX (%)
With spouse	XXX (%)	XXX (%)
With spouse and others	XXX (%)	XXX (%)
Other	XXX (%)	XXX (%)
Prefer not to answer	XXX (%)	XXX (%)

Education		
Less than high school	XXX (%)	XXX (%)
High school	XXX (%)	XXX (%)
Some college	XXX (%)	XXX (%)
4-year degree	XXX (%)	XXX (%)
Graduate degree	XXX (%)	XXX (%)
Other	XXX (%)	XXX (%)
Quarter of Baseline Visit		
2021 Q2	XXX (%)	XXX (%)
2021 Q3	XXX (%)	XXX (%)
...	XXX (%)	XXX (%)
Total MoCA Score		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX
Pure Tone Average in Better Ear		
N	XXX	XXX
Missing	XXX	XXX
Mean (SD)	XXX (XXX)	XXX (XXX)
Median	XXX	XXX
Q1, Q3	XXX , XXX	XXX , XXX
Range	XXX - XXX	XXX - XXX
Hearing Loss Classification in Better Ear		
Mild	XXX (%)	XXX (%)
Moderate	XXX (%)	XXX (%)
(report generated on XXXXXXXX)		

4.5 Describe APHAB data over time

Analysis: This will be done graphically. We will plot the average APHAB subscale scores and global score over time (baseline, 3-months, 6-months). These plots will be grouped by hearing aid assignment/choice such as: individuals assigned 1 hearing aid and kept 1 hearing aid, individuals assigned 2 hearing aids and kept 2 hearing aids, and individuals who switched hearing aid configuration at 3 months. We may explore additional groups depending on the patterns we see.

We will use these plots to describe general trends (i.e., describe if score trajectories seem to differ by hearing aid configuration group).

5 Future Plans

There are additional items we may wish to explore in the future, at which point a new SAP will be developed, related to 6-month outcomes and/or switching at the 6-month time point.