

Dual Task Walking Performance in Adults with
Bilateral Hearing Loss Compared to
Adults with Normal Hearing

NCT05540535

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PROTOCOL PILOT STUDY:

1. Sign COVID screening at the lobby
 2. SIGN CONSENT
 3. ETDRS- eyes check (screening)
 4. MONOFILAMENT TEST- put the shoes on (screening)
 5. Vestibular examination: (screening)- Dizziness Handicap Inventory (DHI) questionnaire (in REDCAP)
 6. Auditory screening for the control group (screening older controls for ARHL rather than a full audiogram to everyone).
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Exclusion due to one of the followings:

- ETDRS - visual impairment above 20/63
 - MONOFILAMENT - No protective sensation at the bottom of their feet.
 - DHI- Participants will be included with a score of 10 or below indicating no more than minimal dizziness.
 - Auditory screening – participants in the control group that will exhibit a PTA higher than 40 dB (0.5–4 kHz) in the better ear (moderate HL and above) will be excluded.
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7. TAKE OFF HEARING AID
8. Wearing the APDM on both feet and pelvic where the ISPS
9. Balance testing: Standing feet attached with E/O, Standing feet attached with E/C, foam with E/O, foam with E/C for 30 sec. (descriptive)
10. 20 min: computerized cognitive battery
11. Randomized Trial of TUG (without hearing aid):
 1. TUG - 2 repetitions
 2. TUG DT_sub3- 2 repetitions
12. HI- MOCA or MOCA
13. TMT A & B
14. Practice trial: Walking back and forth the corridor

15. Randomized Trial- each trial will be done 1 time (without hearing aid):

1. Single cognitive task sub1 - [Baseline] while sitting (serial subtraction of 1) + record with phone
2. Single cognitive task sub3 - [Baseline] while sitting (serial subtraction of 3) + record with phone
3. Single motor – [Baseline] Walking on the ground for 1 min a 10 m long corridor – recording with a stopwatch
4. Dual task cognitive sub1 (DT_sub1) - serial subtraction of 1 + #3 - recorded with stopwatch + record with phone
5. Dual task cognitive sub3 (DT_sub3) - serial subtraction of 3 + #3 - recorded with stopwatch + record with phone

Using REDCAP:

16. DEMOGRAPHIC questionnaire (descriptive)
17. ABC – In healthy young adults ask: “have you never had any concern regarding: balance?” – if yes- fill up the questionnaire. (descriptive)
18. SSQ12
19. Each participant will receive \$20 for participation and sign up a form that received the gift card

Instructions:

TUG:

Instructions: “On the word GO you will stand up, walk to the line on the floor, turn around and walk back to the chair and sit down. Walk at your regular pace.”

The time to complete the test will be recorded using a stopwatch.

DT SUB 1 TUG:

Instructions: “On the word GO you will stand up, walk to the line on the floor, turn around and walk back to the chair and sit down. Walk at your regular pace. While walking you need to subtract 1 from a number that I will tell you (between 20 -100)”

DT SUB 3 TUG:

Instructions: “On the word GO you will stand up, walk to the line on the floor, turn around and walk back to the chair and sit down. Walk at your regular pace. While walking you need to subtract 3 from a number that I will tell you (between 20 -100)”

In DT cognitive TUG individuals will be asked to complete the walk while performing a cognitive task (counting backward by threes from any number between 20 to 100). The cut off times using DT TUG to discriminate between fallers and non-fallers in elderly is >15 seconds with an overall correct prediction rate of 87%.

Gait:

“Walk straight ahead at your comfortable speed until you see the mark on the floor and then turn and walk straight ahead to the opposite direction. Keep walking until I will tell you to stop. The total time for walking is 1 min. If you lose your balance do whatever feels safe to stay steady. One of the researchers is going to walk next to you to prevent any fall”.

Gait Serial Subtraction 1

“Walk straight ahead at your comfortable speed while counting backwards out loud in jumps of 1 from a number that I will tell. Start from the next number. For example, if I say 557, you start: 556, 555 and so on. When you see the mark on the floor you turn and walk straight ahead to the opposite direction. Keep walking and counting until I will tell you to stop. The total time for walking is 1 min. If you lose your balance do whatever feels safe to stay steady. One of the researchers is going to walk next to you to prevent any fall”.

Gait Serial Subtraction 3

“Walk straight ahead at your comfortable speed while counting backwards out loud in jumps of 1 from a number that I will tell. Start from the next number. For example, if I say 557, you start: 554, 551 and so on. When you see the mark on the floor you turn and walk straight ahead to the

opposite direction. Keep walking and counting until I will tell you to stop. The total time for walking is 1 min. If you lose your balance do whatever feels safe to stay steady. One of the researchers is going to walk next to you to prevent any fall”.

Data analysis:

Each variable was inspected for extreme outliers (i.e., data points that fell more than 4 standard deviations [SD] away from the mean) using summary statistics and box plots. An extreme outlier was excluded from the final analysis. Normality of the variables was determined based on skewness and kurtosis. Number that is greater than +1 or lower than -1 indicate a substantially skewed distribution. For kurtosis, if the number is greater than +1, the distribution is too peaked and less than -1 indicates a distribution that is too flat. If the distribution was found to deviate from normality, non-parametric statistical analysis was conducted.

Descriptive statistics described the study sample for age, sex, height, weight, race, current medication, education level, exercise level, DHI, ABC, history of falls, MoCA and HI- MoCA. To determine if the groups are similar with respect to background measures and demographics a comparison of the three groups Normal hearing, Mild BHL and > Moderate BHL (moderate, moderately-severe, severe and profound) was done using one-way analysis of variance (ANOVA) or non-parametric Kruskal-Wallis Test for continuous measures and Chi-square analyses for categorical measures (e.g., gender).

For Aim #1: Compare single task (=ST) gait parameters between individuals age and education-matched with Mild BHL, > Moderate BHL and controls with Normal hearing and Aim #3: Compare the effect of a cognitive task on gait parameters (=DT) between age and education-matched people with Mild BHL, > Moderate BHL and control with Normal hearing: For the primary outcome measure, gait speed and its variability, and secondary outcome measures (stride length, stride time and their variability) during the 1-min walk, a mixed model repeated measures (RM)- ANOVA was conducted with 1 within-factor (task) of 2 levels (ST and DT [‘subtraction 3’]) and 1 between factor (group) of 3 levels (Normal hearing, Mild BHL, Moderate BHL). When the distributions were found to deviate from normality the Kruskal-Wallis’ test was conducted for a between-group comparison and the Wilcoxon signed-rank test for a within-group comparison. Since I had a significant difference with age, I adjusted for age the ANOVA comparison.

Partial Eta Square (PET) Effect Size was reported for each main effect and interaction (small effect, $PET \geq 0.08$; middle effect, $PET \geq 0.20$; and high effect, $PET \geq 0.32$). P-values with a value of $p < 0.05$ were considered statistically significant. Bonferroni corrections were applied to post hoc comparisons as applicable.

For Aim #2: Compare cognitive function (i.e., the Neurocognitive Index) between individuals age and education-matched with Mild BHL, > Moderate BHL and controls with Normal hearing. One way ANOVA (or non-parametric Kruskal-Wallis Test) was used to compare the Neurocognitive Index between the three groups. Moreover, one way ANOVA (or non-parametric Kruskal-Wallis Test) was used to compare the secondary outcome measures, i.e., Composite Memory, Verbal Memory, Visual Memory, EF, Cognitive Flexibility, Complex RT, Working Memory and Sustained Attention and the cognitive ST and DT performance. I used one-way ANOVA with the dependent variable, the cognitive domain (Neurocognitive Index or any of the secondary outcome measures), and group as independent variable. For the raw scores I used the ACNOVA to adjust for age since we had significant age difference and these results do not present an age-matched score. Cohen's d effect size was calculated per comparison and was defined 'small' effect size as $d = 0.2$, 'medium' effect size as $d = 0.5$ and a 'large' effect size as $d = 0.8$.

For Aim #4: Explore whether cognitive performance (i.e., the Neurocognitive Index) is correlated with DTC per group. One way ANOVA (or non-parametric Kruskal-Wallis Test) was used to compare the DTC between the three groups. Correlations between the cognitive domains and DTC were assessed using Pearson's correlation (or its non-parametric equivalent Spearman's, if the distributions are found to deviate from normality) for continuous variables. Pearson's correlation for each comparison was defined as 'little to none' for $r = 0-0.24$, 'fair' for $r = 0.25-0.49$, 'moderate to good' for $r = 0.50-0.74$ and 'good to excellent' for $r = 0.75-1.00$.¹¹² SPSS version 27 IBM (NY, US) was used for all statistical analysis.