A Study Protocol for a Randomized Controlled Trial Evaluating the Benefits from Bimodal Solution with Cochlear Implant and Hearing Aid vs. Bilateral Hearing Aids in Patients with Asymmetric Speech Identification Scores.

A Data Management Plan created using DMPonline

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Project abstract:

Abstract Introduction Cochlear implant (CI) and hearing aid (HA) combined in the bimodal solution (CI + HA) will be compared to bilateral hearing aids (HA +HA) in a randomized controlled trial to test if the bimodal solution leads to better speech intelligibility in quiet and in noise and self-reported quality of life. Methods and Analysis This prospective, randomized controlled trial (RCT) will be conducted in Odense University Hospital, Denmark. Sixty adult bilateral HA users referred for CI surgery will be enrolled if eligible and undergo: audiometry, speech perception in noise (HINT: Hearing in Noise Test), Speech Identification Scores (SIS) and video head impulse test (vHIT). All participants will receive new replacement HAs which will be used throughout the study. After one month they will be randomly assigned (1:1) to the intervention group (CI+HA) or to the delayed intervention control group(HA+HA). The intervention group (CI+HA) will receive a CI on the ear with a poorer speech recognition score and continue using the HA on the other ear. The control group (HA+HA) will receive a CI after a total of 4 months of bilateral HA use. There will be follow-up visits at three-, six- and twelve-months after CI activation. The primary outcome measures are Speech intelligibility measured objectively with HINT (sentences in noise) and DANTALE 1 (words) and subjectively with the Speech, Spatial and Qualities of Hearing scale questionnaire (SSQ-12). Secondary outcomes are patient reported Health-Related Quality of Life (HRQoL) scores assessed with the Nijmegen Cochlear Implant Questionnaire (NCIQ), the Tinnitus Handicap Inventory (THI) and Dizziness Handicap Inventory (DHI). Third outcome is listening effort assessed with pupil dilation during HINT and the benefits of an optimized bimodal fitting solution of CI by loudness balancing. In conclusion, the purpose of this randomized controlled trial is to improve clinical decision-making for CI candidacy and optimize bimodal solutions. Ethics and Dissemination This study protocol was approved by the Ethics Committee Southern Denmark project ID S-20200074G. All participants are given both oral and written information about the study and are required to sign an informed consent form. This study will be published upon completion in a peer-reviewed publications and scientific conferences. Trial Registration Number: NCT04919928 (ClinicalTrials.gov)

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Data Collection

Speech intelligibility scores measured objectively with HINT(Hearing in Noise Test) and DANTALE 1 and subjectively with Speech, Spatial and Qualities of Hearing scale (SSQ-12).

Patient reported outcomes with Health-Related Quality of Life (HRQoL) scores assessed with the Nijmegen Cochlear Implant Questionnaire (NCIQ), The Tinnitus Handicap Inventory (THI) and Dizziness Handicap Inventory (DHI).

Listening effort assessed with pupil dilation with HINT.

Study Population

This study will enrol 60 adult participants with bilateral hearing-loss and asymmetric speech identification scores referred for CI candidacy. They will be screened for eligibility in this study and invited to participate if willing, which is illustrated in flowchart (Figure 1).

These are patients that report limited benefits with appropriately fitted bilateral HAs in daily speech communication in quiet and noise. In addition, they will report difficulties understanding speech when communicating through a telephone on the side considered for CI.

All patients will receive new replacement HAs to provide optimal best-aided hearing prior to surgery. These HAs will be used throughout the study period. If the participants refuse to use the new HAs and use their old HAs instead, they will still be enrolled in the study as long as the HA can be fitted and used together with a CI in a bimodal solution and provide adequate gain.

All sixty participants will undergo the listed measurements and HRQoL questionnaires in the (Figure 2) after 1 month of new replacement HA+HA use.

Setup

A timeline of the study is shown in (Figure 2).

All enrolled participants will be tested with measurements as audiometry and vHIT to determine hearing thresholds and status of balance function at baseline. Patients will receive new replacement HA and fitted and if necessary refitted at every visit in the clinic throughout the study. The participants will be randomized to either the intervention group (CI+HA) or the control group (HA + HA). The baseline measurements will be conducted when both groups have used the new replacement HAs to ensure acclimatation. The measurements are SIS using Dantale I, the auditive and the audio-visual presentation mode will be the same test condition with speech level 65db in quiet and in noise, the noise level at 65dB as real life “babble” sound in free field. When testing with headphones, it will be with the individual most comfortable loudness (MCL) tested monoaurally.

Participants will answer all four questionnaires at baseline: SSQ12, NCIQ, THI and DHI.

Pupil dilation is measured as well: Peak Pupil Dilation (PPD) and peaktime using HINT (sentence and word) with pupillometry. PPD is calculated based on the number of pixels so PPD of 0.01 would mean 1% change in pupil dilation. The peaktime is the time it takes for the pupil to reach peak dilation.

The HINT sentence is presented at speech level 65dB and initial SNR at +10dB and then the adaptive SNR will be established. The noise is multi-talker babble noise and the hardware is the Oticon Medical Pupil Labs glasses.

The CI surgery will take place after randomization and baseline measurements. The CI will be fitted one month after surgery and audiometry and vHIT will be measured to determine post-operative status of hearing and balance in the CI+HA group.

The interventions group will be tested in following conditions: CI+HA, CI only and HA only. The purpose of the monoaural test is to demonstrate whether the bimodal solution results in better speech intelligibility compared to monoaural treatment with either CI or HA.

The control group (HA+HA) will be tested with the measurements (Figure 2) again after three months of additional use with new replacement HAs (a total of four months of use).

Then the control group will undergo same procedure as intervention group if they accept the CI surgery. If the participant decides to continue with bilateral HAs and decline to participate the project, it will be respected, and consent will be confirmed for saving his data for future analysis.

All the participants will be tested at 3, 6 and 12 months of follow-up after CI-fitting.

Control Group

Thirty patients, who will be age-matched, randomized and allocated to the control group HA+HA will continue the use of the new replacement HAs for another three months (total four months of new replacement HA+HA use), serving as the delayed intervention

control group.

After this period the participants will undergo measurements and answer questionnaires prior to the CI surgery exactly as the intervention group. From this point the control group will follow the same procedure as the intervention group with fitting, follow-up and loudness balancing.

Intervention Group

Thirty patients, who will be age-matched, randomized and allocated to the intervention group CI+HA will undergo surgery as soon as possible. The intervention group will receive CI of the same manufacturer as the HA to enhance the bimodal connectivity. One-month post-surgery, the CI will be activated according to the settings and stimulation strategy as suggested by the CI manufacturer. Then the CI will be fitted with the HA on the contralateral ear.

At 3- months follow-up the post-surgery complications will be evaluated and the levels in the CI will be adjusted if necessary.

In the loudness balancing procedure, the patient will have both the hearing aid and CI activated and at the 6-month visit, when the CI mapping levels are stable, patients will be randomized and assigned to one of three bimodal fitting groups:

Group A) will not complete any specific loudness balancing procedures, CI and HA will be fitted independently based on individual feedback from the patient. When the HA is fitted appropriately, the CI will be increased or decreased in gain merely for comfort.

Group B) will be fitted/finetuned using a bimodal loudness balancing task at a medium input level and adjusted based on the patient feedback. The audiologist will present a mid-level sound (approx. 55dB SPL (sound pressure level)) at the center speaker.

Group C) will be fitted/finetuned using a bimodal loudness balancing task as group B but the audiologist will play three levels and adjust the gain for three input levels (soft, medium, and loud) according to the patient feedback.

For both groups B and C, the audiologist will present a series of sounds via a single loudspeaker placed directly in front of the patient. The patient will be given a 'Bimodal Fusion' illustration (see Figure 3) and asked to provide feedback about the location of the sound by tracing over the line of the head. The HA gain will be adjusted using the bimodal adjustment option in the HA software which adjusts the overall gain of the HA, until the patient reports that the sounds are perceived at the top or center of the head. Additional fine tuning may be carried out based on patient feedback.(23)

Documentation and Metadata

This study is registered in ClinicalTrials.gov: NCT04919928

The protocol and the Statistical Analysis Plan is submitted to BMJ Open for the purpose of publication.

Ethics and Legal Compliance

Ethics approval for the conduct of this study was obtained from the Ethics Committee Southern Denmark, 21st August 2020 project ID S-20200074G.

All participants are treated according to current clinical standards regardless of the randomized study participation. The participants are volunteers and can at any moment withdraw their participation in the study without affecting their current or future treatment rights.

The Informed Consent form will be found online as an online supplementary file and it will be signed by all participants willing to participate the study and stored in their electronic journals in Department of Audiology, Odense University Hospital. All patients are given both oral and written information about the study.

The project is approved by the Danish Data Protection Agency (file no. 20/22868) in Region South Denmark.

Storage and Backup

The project is registered at OPEN, Odense Patient data Explorative Network, Odense University Hospital, Odense, Denmark

The project is approved by the Danish Data Protection Agency (file no. 20/22868) in Region South Denmark.

Selection and Preservation

All of the data.

Results will be presented at national and international congresses and published in the scientific literature for the attention of professional and scientific audiences on behalf of all study sites and collaborators. A lay summary report will be published for patients and members of the public.

Data Sharing

Publications

All the data will be anonymized.

Responsibilities and Resources

Data capture: Yeliz Jakobsen
Metadata production: Yeliz Jakobsen
Data quality: Yeliz Jakobsen
Storage and backup: OPEN, Odense Patient data Explorative Network, Odense University Hospital, Odense, Denmark
Data archiving:OPEN, Odense Patient data Explorative Network, Odense University Hospital, Odense, Denmark
Data sharing: Yeliz Jakobsen

No additional resources are needed aside from what we already have.