Plan Overview

A Data Management Plan created using DeiC DMP

Title: A Study Protocol for a Randomised 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.

Creator:yeliz jakobsen

Principal Investigator: Yeliz Jakobsen, Jesper Hvass Schmidt

Data Manager: Yeliz Jakobsen

Affiliation: Syddansk Universitet / University of Southern Denmark

Template: DCC Template

ORCID iD: 0000-0001-8960-7412

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 randomised 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, randomised 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 (v-HIT). 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 randomised 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)

ID: 4239

Last modified: 30-06-2023

Grant number / **URL:** 19-3470

A Study Protocol for a Randomised 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.

Data Collection

What data will you collect or create?

Primary Outcome

Primary outcomes are Speech intelligibility scores measured objectively with HINT (sentences and words) and DANTALE I and subjectively with Speech, Spatial and Qualities of Hearing scale (SSQ-12).

Secondary Outcome

Patient reported outcomes scores assessed with the Nijmegen Cochlear Implant Questionnaire (NCIQ), The Tinnitus Handicap Inventory (THI) and Dizziness Handicap Inventory (DHI).

Third Outcome

Listening effort assessed with pupil dilation with HINT.

How will the data be collected or created?

Study Population

Sixty participants with bilateral hearing-loss and asymmetric speech identification scores referred for CI surgery will be included (Figure 1).

Setup

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

All enrolled participants will be tested with audiometry and v-HIT to determine hearing thresholds and status of balance function during the first visit. Patients will receive new replacement HAs. These HAs will be fitted during the second visit and if necessary refitted at every visit in the clinic throughout the study. The baseline measurements will be conducted when both groups have used the new replacement HAs to ensure acclimatisation. The measurements are SIS in quiet and in noise with a signal-to-noise ratio (SNR) of 0dB using DANTALE I speech material. The speech and masking white noise stimulus will be presented at 65 dB SPL in the free field. Stimuli will be presented as auditory stimuli only as well as with visual cues, the latter to allow participants to use lipreading cues.

Pupillometry variables are Peak Pupil Dilation (PPD), Mean Pupil Dilation (MPD), peak-time and standard deviation using HINT (sentences and words).

The HINT sentences are presented at a speech level of 65dB and initially an adaptive SNR is used to identify the SNR of 70% correct word recognition. The SNR at 70% correct word recognition is used as a fixed SNR during HINT test. The noise is multi-talker babble noise, in free field, tested in best aided condition. The pupillometry glasses is the Oticon Medical Pupil Labs glasses.

Recruitment, Stratification, Randomisation and Allocation

All eligible participants will sign a written, informed consent in clinic after receiving verbal and written study information in Danish. The Danish consent form is available online at the Odense University Hospital Research Unit website.(33)

To ensure acclimatisation, participants will receive new replacement HAs fitted with the National Acoustic Laboratories (NAL) -non-linear (NL)2 fitting algorithm one month before the experiment.

They will then undergo stratification, depending on the hearing thresholds. One group will consist of participants with PTA ≥ 70dB HL; and the other group will consist of subjects with PTA ≤ 70dB HL and ≥ 40 dB HL according to the inclusion criteria. The reason for this stratification is because pre-operative hearing thresholds may affect the measured outcomes in the study. Stratification ensures that both the intervention group and the control group will have an equal distribution of patients with profound hearing loss on the ear considered for implantation.

Then the participants will be randomly allocated into two groups: the intervention group (CI+HA) and the control group (HA+HA) according to 1:1 ratio using a blocked randomisation with randomly varying block size (4 or 6).

This randomisation will be accomplished using a computer-generated random sequence in Research Electronic Data Capture (REDCap), hosted by Odense Patient Explorative Network (OPEN) in the Region of Southern Denmark and developed by Vanderbilt University, Nashville, Tennessee, United States.(34)

REDCap will also be used to send out the questionnaires to the participants´ online mailbox (called Eboks in Denmark) throughout the study (see timeline (Figure 2)) and automatically save the data.

Participants will have the opportunity to return to their original HAs if they prefer to do so after one-month of acclimatisation.

Control Group

Thirty patients, who will be age-matched, randomised 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.

Intervention Group

Thirty patients, who will be age-matched, randomised and allocated to the intervention group CI+HA will undergo surgery as soon as possible after the HA acclimatisation period.

HA Fitting

The participant will receive either Phonak (Phonak Link M) or GN (ReSound LiNX Quattro or Resound ENZO Q) based on their personal preference. Both these HA models can be fitted with a CI by Advanced Bionics and Cochlear, respectively.

The HAs will be fitted according to NAL-NL2 procedures prescriptive fitting formula, which optimizes audibility in the bimodal solution(2) and will be verified with REM (Real Ear Measurement) to ensure that the HA is providing adequate gain and then further adjusted for comfort based on patient feedback.

The new HAs will be prescribed to the patients free of charge and future service will also be free of charge.

Participants can drop out of the study if they do not want CI surgery. Collected data will be analysed if the patient still consents.

CI fitting

The CI will be selected depending on the participant´s HA selection; that is, the CI that is compatible with the HA will be selected in order to ensure the most optimal bimodal fitting. One-month post-surgery, the CI will be activated according to the settings and stimulation strategy based on patient´s feedback. The CI will then be fitted with the HA according to the bimodal fitting formula allowing the HA to keep the NAL-NL2 fitting along with the wireless connection with the CI.

Patients hearing thresholds will be tested on CI activation day. The residual hearing will not be stimulated in this study.

All participants are offered standard rehabilitation with a speech therapist, including three visits a week up to 10 weeks following the initial fitting.

The training focuses on learning to identify different sounds from the environment and word discrimination.

The new CI will also be prescribed to the patients free of charge and future service will be free of charge as well.

Loudness Balancing

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 follow-up, when the CI mapping levels are stable, patients will be randomised 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 based on individual feedback from the patient.

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 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 until the patient reports that the sounds are perceived at the center of the head.

Documentation and Metadata

What documentation and metadata will accompany the data?

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

How will you manage any ethical issues?

Ethics and Dissemination
Ethics approval for the conduct of this study was obtained from the Ethics Committee Southern Denmark, 21st August 2020 project ID S-20200074G.
The project is approved by the Danish Data Protection Agency (file no. 20/22868) in Region South Denmark.
All participants are treated according to current clinical standards regardless of the randomised 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.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

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

Storage and Backup

How will the data be stored and backed up during the research?

The project is registered at OPEN, Odense Patient data Explorative Network, Odense University Hospital, Odense, Denmark.
Data will be storaged from 01.08.2020 to 01.07.25 in OPEN and Rigsarkivet (National Archives in Denmark).
Extracting data from OPEN is restricted to the investigators (Jesper Hvass Schmidt and Yeliz Jakobsen)
Data manager and staticians can be allowed access by the investigators.

How will you manage access and security?

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

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All of the data.

What is the long-term preservation plan for the dataset?

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

How will you share the data?

Flowdiagram
A flowdiagram for the project.
Metadata
Metadata/codebook from Redcap OPEN for the project.
All data files will be stored in OPEN (Odense Patient explorative network) analyze.
All identifiers will be removed before publication.
Flowdiagram is also attached to this DMP.

Data will be shared through publications as well.

Are any restrictions on data sharing required?

All the data will be anonymized.

Responsibilities and Resources

Who will be responsible for data management?

Data capture: Jesper Hvass Schmidt
Metadata production: Jesper Hvass Schmidt
Data quality: Jesper Hvass Svchmidt
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: Jesper Hvass Schmidt

We will strive to update DMP every three months.

All paper consent form will be disposed with seccure shredding after uploading in patient journal system.

What resources will you require to deliver your plan?

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