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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.

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Abstract

Introduction

Cochlear implant (CI) and hearing aid (HA) in a bimodal solution (CI + HA) is compared to bilateral HAs (HA +HA) to test if the bimodal solution result in better speech intelligibility and self-reported quality of life.

Methods and Analysis

This randomised controlled trial (RCT) is conducted in Odense University Hospital, Denmark. Sixty adult bilateral HA users referred for CI surgery is 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. 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

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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.

The primary outcome measures are Speech intelligibility measured objectively with HINT (sentences in noise) and DANTALE I (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

In conclusion, the purpose 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 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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Strengths and Limitations of This Study

- The study uses comprehensive measures of self-reported outcomes as well as objective tests of speech intelligibility.
- Listening effort controlled with pupillometry during objective tests of speech intelligibility.
- Open label RCT (blinding is not possible due to visibility of the CI).
- Possible large drop rates if new HAs improve speech intelligibility to an extent that CI treatment is rejected or postponed.

Introduction

Background

Cochlear implants (CIs) have been used to restore hearing in individuals with severe to profound sensorineural hearing loss. Initially, most patients receiving a cochlear implant were profoundly deaf in both ears. (1, 2) However, recently it has become more common to implant patients with significant residual hearing in the affected ear, as well as in patients with asymmetric hearing loss and single-sided deafness, with significant residual hearing or normal hearing on the contralateral side.(3, 4) A CI in one ear and a HA in the other ear can provide enhanced hearing performance in patients with asymmetrical hearing.(5, 6) The combination of CI and HA is referred to as bimodal hearing or bimodal solution.(7)

CI Candidacy

In the UK, The National Institute for Health and Care Excellence (NICE) have listed guidelines for cochlear implantation and recommends that unilateral CI is offered to patients with severe

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to profound deafness who do not receive adequate benefit from acoustic hearing aids. Severe to profound deafness is defined as pure-tone audiometric threshold ≥ 80 dB HL at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz). Another criteria is that SIS< 50% in the ear considered for implantation and in best aided condition SIS≤60%(8).

The Danish CI candidacy criteria consists of SIS (without HAs, measured with headphones) ≤45% and a SIS ≤65% (in best aided condition) in the ear considered for implantation using DANTALE I monosyllabic word-lists.(9) Additional testing to evaluate speech understanding is assessed by HINT.(10, 11)

The recommendation for a CI might be less clear for patients with asymmetric hearing because they may not fall into the traditional referral criteria but would likely benefit from a CI. It is therefore necessary to establish more evidence to support the effectiveness of bimodal CI+HA versus HAs in patients with asymmetric hearing.

Bimodal Solution vs. Bilateral HAs

Normal hearing listeners (NH) benefit from listening with two ears, which help them understand speech in noise and identify sound location.

Benefits from listening with two ears include: head shadow effect, binaural summation, binaural squelch, localization and spatial release from masking.(12-15)

Patients with hearing loss often do not have these benefits, and they are often not accessible to CI patients. (15)Many bimodal CI and HA users are missing these benefits because the devices are unsynchronized.(16)

Until now it is unknown when to introduce the bimodal solution and making sure that patients are well-fitted with hearing aids when they are given the candidacy assessment.

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The question is if the bimodal benefits are bigger than the bilateral hearing aid condition when they are well fitted?

This study will therefore support and strengthen the preoperative clinical decision to recommend a bimodal solution with a CI and a HA versus the continuous use of bilateral HAs. This may offer the patient faster and more effective treatment because delaying the surgery may not be beneficial.

Patient-Reported Outcome Measures

Benefits of the CI are measured subjectively with Patient-Reported Outcome Measures (PROMs) as SSQ12, NCIQ, THI and DHI.(17-24)

The validity and reproducibility of the Danish version of THI has been reported(24). SSQ12, DHI, NCIQ have all been translated into Danish and backward translated to English following a cultural adaption and pilot-testing to ensure correct understanding of the questionnaires. Test-retest reliability has been assessed as well.(18, 20, 22)

Listening Effort

Patients with CI often experience high levels of listening effort, they often report that understanding speech causes high levels of increased sustained effort which results in feelings of fatigue.(25) These feelings may lead patients to withdraw socially due to the stresses involved in communication even though they may not specifically report difficulties with speech understanding.(19)

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Effort in listeners with NH can be reflected by the relationship between speech intelligibility and pupil-dilation.(26) Listening effort has been defined as the "Deliberate allocation of mental resources to overcome obstacles in goal pursuit when carrying out a task" and is the basis for the Framework for Understanding Effortful Listening (FUEL) model.(27) Understanding speech in challenging hearing environments results in increased auditory and cognitive processing which can be observed objectively by measuring the pupil dilation during speech perception in noise, in a task such as the HINT(28-30)

Rationale and Objectives

This randomised controlled trial is designed to improve clinical decision-making for CI candidacy for patients with asymmetric hearing. It is necessary to establish more evidence to support the effectiveness and the fitting optimization of bimodal CI+HA versus HAs in patients with asymmetric hearing.

The first objective of the study is to evaluate the subjective (SSQ12) and objective (Hearing In Noise Test (HINT) which is word and sentence based and DANTALE I, which is monosyllabic word-based) benefits of a bimodal solution (CI+HA) compared to (HA+HA).

The second objective is to compare and evaluate patient self-reported outcomes with NCIQ, THI and DHI in the intervention group (CI+HA) with the control group (HA+HA).

The third objective is to evaluate if listening effort, hypothesized to cause fatigue, can be measured objectively by HINT with pupillometry.

To minimize listening effort and optimize the fitting of bimodal solution the CI fitting and loudness balancing on individual level will be evaluated.(2, 31, 32)

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Methods and Analysis

Study Design, Ethics and Registration

This study is a prospective randomised controlled trial based on a single centre conducted in Odense University Hospital, Denmark. The study started 01/02/2022 and is expected to end 30/07/2024. It was successfully registered at ClinicalTrials.gov with registration number: NCT04919928.

This study has been approved at Research Ethics Committee Southern Denmark (Projekt-ID: S-20200074G) 21st August 2020 to 31st December 2024.

Study Population

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

Inclusion Criteria

- Adults >18 years old.
- Fluent in Danish, including reading and writing
- Acquired post-lingual deafness
- Use of bilateral HAs for at least one year prior to evaluation for cochlear implantation candidacy. This to ensure, that both ears have received auditive stimulation
- PTA > 40 dB HL in the ear considered for CI implantation and PTA≥40 and ≤ 70dB HL in the contralateral ear in best aided condition, in quiet and in noise and in free field.

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- SIS <70% in best aided condition in the ear considered for CI implantation and SIS ≥30% and ≤70% in best aided condition in the contralateral ear, in quiet and in noise and in free field.

Exclusion Criteria

- Vestibular loss in the ear not considered for CI implantation
- Surgical issues interfering with the site of implantation or anatomical contraindications such as cochlear malformations, which will be determined using MRI or CT-scans.
- Auditory nerve lesions.
- Central auditory pathway pathologies.
- Otosclerosis.
- Single sided deafness (SSD).

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.

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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 (supplementary file 1) 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.

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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.

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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.(35)

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. (36, 37)

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

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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

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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.(24)

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). (9, 10, 22)

Secondary Outcome

Patient reported outcomes scores assessed with the Nijmegen Cochlear Implant Questionnaire (NCIQ), The Tinnitus Handicap Inventory (THI) and Dizziness Handicap Inventory (DHI). (18, 20, 24)

Third Outcome

Listening effort assessed with pupil dilation with HINT.(10)

Statistics

Power calculation

Power calculations with a power of 0.8 with a significance level of 0.05 have been made with STATA IC-15 using standard deviations for the HINT test and expected effect size (38) the NCIQ(18), and the SSQ (internal communication with BEAR (Better Hearing Rehabilitation) study on hearing aid use in Denmark) (Table 1). An estimated within participant standard deviation from the BEAR study of 1,9 in an HA population using the SSQ-12 is used to calculate

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the sample size. A difference of 1,4 will require 30 participants in each arm. The effect size is expected to be larger in the CI group which will lower the number of required subjects even further.

Based on this, 30 participants must be enrolled in each arm. Additional six patients (20%) in each arm will be enrolled in the study to account for dropouts.

Test	SD pre	SD post	Expected difference between the two treatment arms	Minimum required group size
1. HINT	6.3%	6.3%	5%	26
2. NCIQ – basic sound perception	14.4	23.5	53	4
2. NCIQ	13.4	19.6	34	6
2. NCIQ – speech perception	18.8	17.8	17	20
2.NCIQ Self-esteem	20.1	16.4	22	13
2.NCIQ Activity	23.0	15.9	27	10
2.NCIQ Social Interactions	19.8	14.5	25	9
3. SSQ Total	1.9	1.9	1.4	30

Table 1: Power calculations for the desired tests. Estimated within participant standard deviations (SD pre and SD post) with expected difference and the calculated required group size.

Detailed statistics is presented in the Statistical Analysis Plan (SAP) (supplementary file 2)

Definition of Analysis Sets

Strategy for intention to treat analysis with incomplete observations.(39)

1. Attempt to follow-up on all randomised participants, even if they withdraw from allocated treatment.
2. Perform a main analysis of all observed data that are valid under a plausible assumption about the missing data.
3. Perform sensitivity analyses to explore the effect of deviations from the assumption made in the main analysis.
4. Account for all randomised participants, at least in the sensitivity analyses.

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Analysis specification

A constrained linear mixed model is used to analyse the outcome.

The model will include randomisation group (CI+HA / HA+HA) and time (baseline/follow-up) and their interaction as fixed effects along with the threshold strata that were used in stratifying the randomisation. The model is constrained so that the mean at baseline agrees across the two treatment groups adjusted for threshold stratum, which is reasonable due to the randomisation of implant fitting. Patient ID will be included as a random effect to account for the repeated measurements.

Secondary outcomes will be analysed analogously in a constrained linear mixed model adjusting for randomisation strata. Model validation checks will be undertaken as described above, switching to bootstrapping the standard errors when model assumptions are rejected.

Covariates such as age and gender will be included in all models.

Sensitivity analysis

Inclusion is performed conditional on Pure Tone Average (PTA) (from 0.5 to 4 kHz) PTA > 40 dB HL and SIS <50% in the ear considered for CI implantation and <70% in the best-aided condition which may lead to a truncation effect in the distribution of baseline measurements. To address this, an analysis of covariance (ANCOVA) model conditioning on the baseline will be used to obtain a sensitivity analysis estimate for the main outcome.(40)

The statistical analysis plan is attached as “supplementary file” along with the Data Description listed in Appendix A (supplementary file 3).

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Patient and Public Involvement

A focus-group interview was established with six cochlear implant patients. The patients commented on their decision to transition from HA to CI. Based on the feedback from the focus group, the research questions were developed.

The patients also reported problems with adjustments of the CI, when meeting the audiologist for CI adjustment controls.

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 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.

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Results

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.

Footnotes

Authors´ Contributions:

YJ and JHS are involved in the conception of the study. LCA and JHS wrote the grant application and the draft of the manuscrift. JHS and YJ designed and revised the draft methodological content. YJ reviewed the manuscript and JHS critiqued it.

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Competing Interests:

None declared.

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We are grateful for the contribution from the patient advisers.

Protocol and Registration:

This study is registered in ClinicalTrials.gov: NCT04919928

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Figure 1

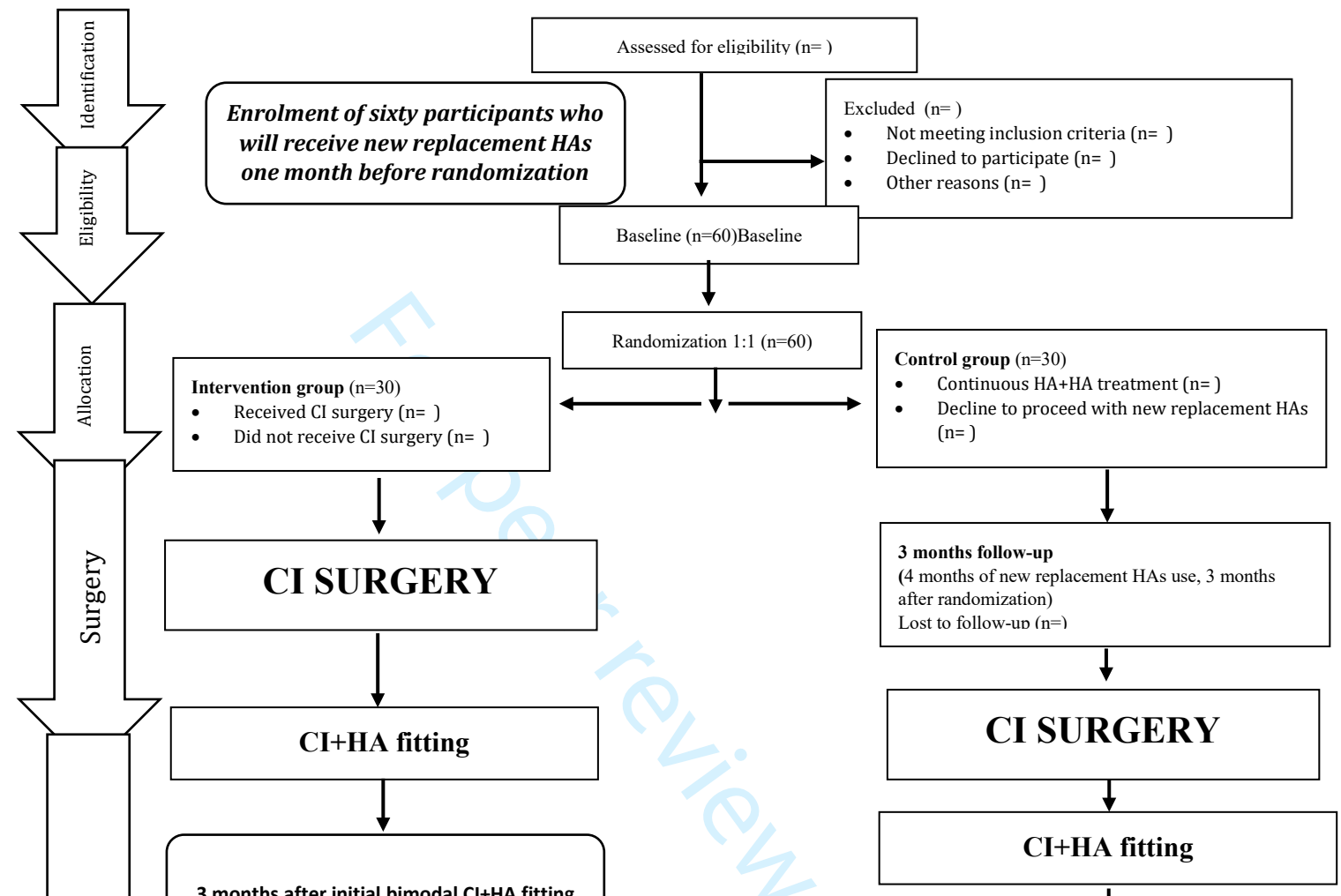

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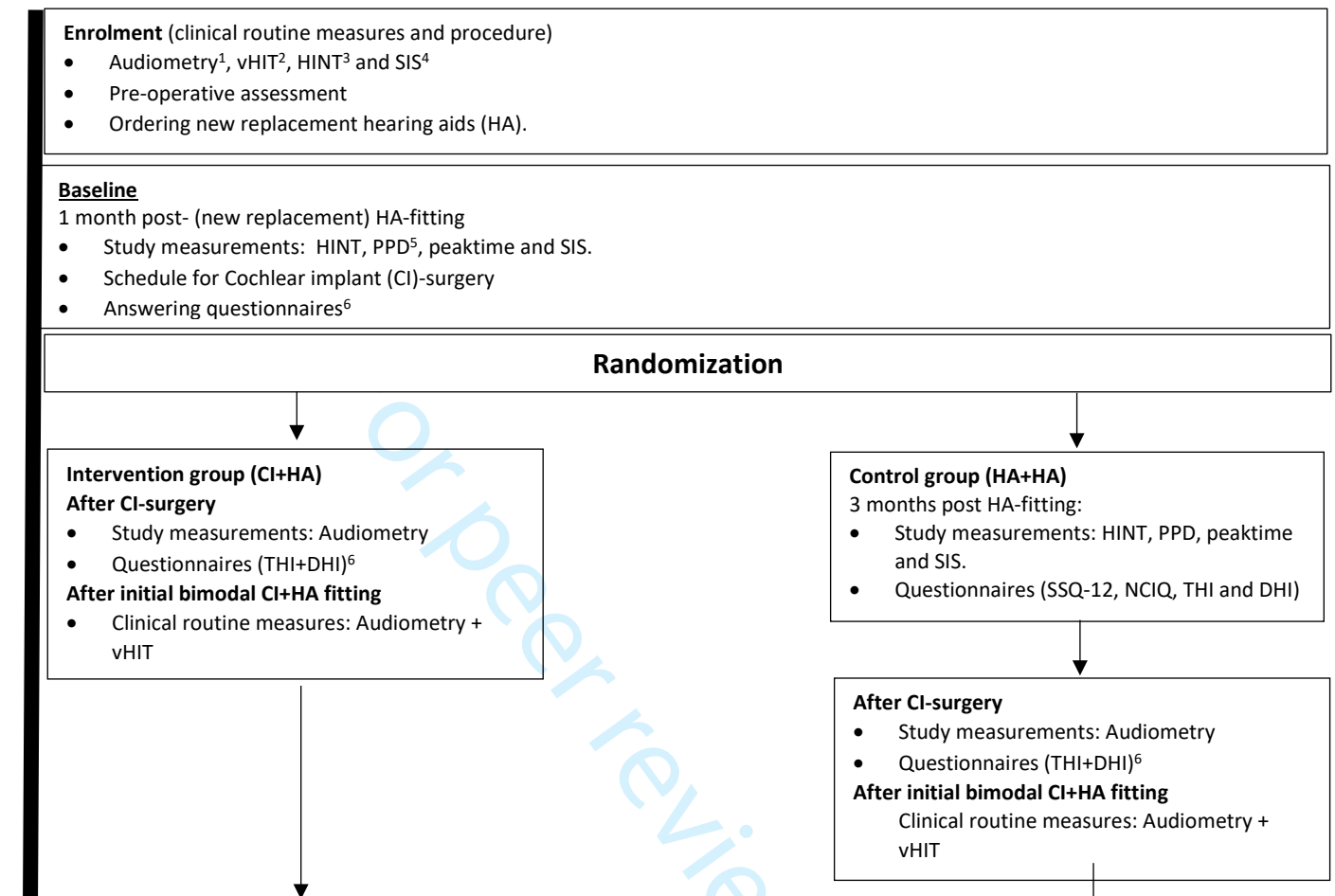
Figure 2



[1]Estimating hearing status pre-surgery
[2]Video Head Impulse Test v-HIT: clinical -routine measure.
3Hearing in noise test. Quiet and noise. Fixed SNR = +10dB. Free field with HAs
[4]Speech Identification Score: Words and sentences. Auditory and audiovisual. In quiet and in noise.
[5]Peak Pupil Dilation (PPD)
[6]Questionnaires: Speech, Spatial and Qualities-12 (SSQ-12), Nijmegen Cochlear Implant Questionnaire (NCIQ), Tinnitus Handicap Inventory (THI), Dizziness Handicap Inventory (DHI) will all be distributed by using REDCap to participants digital mail-box.
[7]The three groups are described in detail in the protocol.

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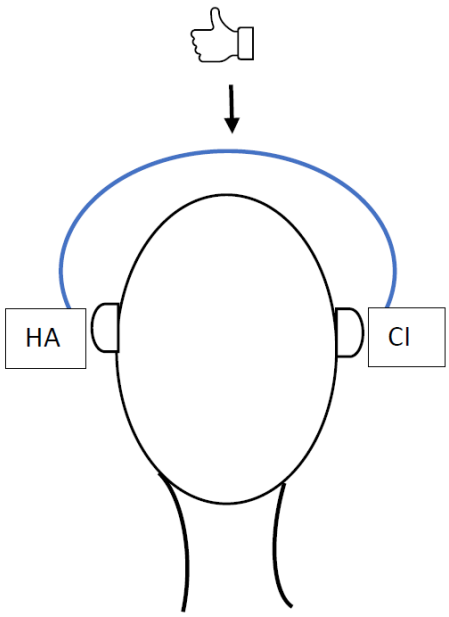
Figure 3



This diagram that will be placed in front of the patient to track that the sound is balanced by indicating where they hear it. A sound will be presented in front of the listener and hearing aid gain is adjusted until the patient hears the sounds 'fused' or that it is coming from the same location/sounds centered. The figure will be used for group B and C. (The diagram is created by YJ)

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Deltagerinformation

-om deltagelse i et videnskabeligt forsøg

Behandling af nedsat hørelse med cochlear implantat (CI) og høreapparat i kombination i forhold til høreapparater alene.

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Projektets originale titel:

Fordele ved bimodal tilpasning med cochlear implantat og høreapparat sammenlignet med dobbeltsidig høreapparat hos patienter med asymmetrisk taleforståelse: Et kontrolleret lodtrækningsforsøg

Øre-Næse-Halskirurgisk/Høreklinikken

Odense Universitetshospital

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Kære deltager

Kære Deltager

Vi vil spørge, om du vil deltage i et videnskabeligt forsøg.

Før du beslutter, om du vil deltage i forsøget, skal du fuldt ud forstå, hvad forsøget går ud på, og hvorfor vi gennemfører forsøget.

Vi vil derfor bede dig om at læse denne deltagerinformation grundigt.

Der er to QR koder i denne deltagerinformation, som beskriver projektet mere kortfattet.

Inden du kan indgå i forsøget, vil du ligeledes modtage mundtlig information af den forsøgsansvarlige læge.

Hvis du beslutter dig for at deltage i forsøget, vil vi bede dig om at underskrive en samtykkeerklæring. Denne samtykkeerklæring giver de forsøgsansvarlige mulighed for at få direkte adgang til relevante oplysninger i din journal for at kunne indsamle data, gennemføre, overvåge og kontrollere forsøget.

De oplysninger, der indsamles fra din journal vil være helbredsoplysninger, tidligere og aktuelle skanninger af forhold omkring øret, oplysninger om evt. øreoperationer og behandling med høreapparater samt resultater af de undersøgelser, vi udfører, og som du tidligere har fået udført omkring hørelse og balancefunktion.

Det vil kun være den forsøgsansvarlige læge og projektkoordinator, der har adgang til din journal i forbindelse med gennemførelse af forsøget. De relevante oplysninger fra din journal registreres i anonymiseret form i en database sammen med de data, der indsamles som en del af forsøget.

Samarbejdspartnere (producenter af måleapparater) har ikke adgang til din journal, men kan dog få adgang til en afgrænset del af data i anonymiseret form, når der opstår et specifikt behov herfor. Det kan f.eks. være relevant, hvis de forsøgsansvarlige får behov for teknisk hjælp i forbindelse med behandling af data. En sådan dataadgang vil kun blive givet, hvis der foreligger en godkendt databehandleraftale mellem virksomheden og Region Syddanmark, der er den dataansvarlige myndighed.

Husk, at du har ret til betænkningstid, før du beslutter, om du vil underskrive samtykkeerklæringen. Det er frivilligt at deltage i forsøget. Du kan når som helst trække dit samtykke tilbage. Det har stor gavn for forskningen at kende årsagen til, at du ikke ønsker at deltage, men du skal naturligvis ikke oplyse årsagen, hvis ikke du ønsker det.

Det vil ikke få konsekvenser for din behandling.

Hvis der er behov for ekstra besøg på Høreklinikken på Odense Universitetshospital i forbindelse med forsøget, vil der blive betalt transportgodtgørelse herfor.

Forsøget er et samarbejde mellem, Øre-næse-hals kirurgisk afdeling og Høreklinikken på Odense Universitetshospital, og Øre-Næse-halskirurgisk og Audiologisk afdeling på Rigshospitalet.

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På de følgende sider kan du læse, hvad det vil betyde for dig, hvis du vælger at deltage i forsøget.

Afslutningsvist kommer de sider, hvor både du og lægen, der informerer dig, skal skrive under.

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FORMÅL MED FORSØGET

Du er blevet spurgt, om du vil deltage i dette forsøg, fordi du har nedsat hørelse i svær grad og er derfor tilbudt operation med et høreimplantat = cochlear implantat også kaldet et CI, på det dårligst hørende øre.

Formålet med dette forsøg er at undersøge, hvilken behandling, der giver den bedste hørelse for dig som patient.

Alle patienter, der indgår i forsøget, får tilpasset to nye høreapparater, der kan tilpasses med et CI. Høreapparaterne skal man anvende og vænne sig til at bruge i ca. 1 måned.

Herefter trækkes der lod om du udvælges til at få en CI operation på det dårligst hørende øre og fortsætte med at anvende det nye høreapparat på det andet øre eller om du udvælges til at være i den anden gruppe som fortsætter yderligere 3 måneder med begge høreapparater for derefter at tilbydes CI operation.

Formålet er at undersøge om patienter hører bedre med et CI der kan arbejde sammen med et høreapparat sammenlignet med bedst tilpasset høreapparat behandling.

Vi vil undersøge mange aspekter af hørelsen herunder lydopfattelse med høreprøver og tests af taleforståelighed. Desuden vil vi som noget nyt måle på bevægelsen af dine øjne (pupiller), når du gennemfører disse tests. Dette har til formål at undersøge, hvor meget du anstrenger dig for at høre i de forskellige test situationer.

Hvis du bliver så glad for dine nye høreapparater at du ikke længere ønsker en operation med et CI, så får du selvfølgelig lov til at aflyse operationen.

Dette forsøg er vigtigt i forhold at forbedre retningslinjer med henblik på at give en mere præcis vurdering for den enkelte patient i forhold til at operere en patient med nedsat hørelse eller fortsætte behandling med høreapparater.

Alle høreapparater og høreimplantater, der anvendes til forsøget, er godkendte, og de er alle tilgængelige behandlingsmuligheder på klinikker i Danmark, hvor man udfører behandling med høre-implantater

Forsøget har brug for 60 deltagere i alt.

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NYTTE VED FORSØGET

CI er i rivende udvikling, men desværre er en behandling med disse ikke helt uden konsekvenser for dig som patient. En operation med et høreimplantat giver en risiko for at udvikle permanent svimmelhed, forstyrrelser af smagssansen, og påvirkning af ansigtsnerven samt infektion.

Det er ikke altid, at hørelsen forbedres så meget som ønsket ved en behandling med CI. Nogle patienter kan opleve øresusen (tinnitus) efter operationen, mens andre oplever at et CI har behandlet deres tinnitus.

I nogle situationer kan der være fordele ved høreapparatbehandling, frem for behandling med CI eks. hvis man lytter til musik eller når man taler i telefon. Derimod kan et CI give en bedre forståelse af tale i mindre forsamlinger end det opleves med et høreapparat.

Det forventes at alle disse fordele kan opleves med den bimodale løsning (et CI kombineret med et høreapparat).

Stærkt nedsat hørelse forringer livskvaliteten hos de fleste, det er derfor vigtigt, at du som patient kan tilbydes og hjælpes med den behandling, der er den helt rigtige for dig.

En behandling med et CI kan ikke laves om, så derfor er det meget vigtigt, at behandlingen tilbydes på det helt rigtige tidspunkt.

Fordelene ved behandlingen med et CI skal overstige de mulige ulemper for dig som patient.

Dette forsøg vil bidrage til, at sundhedspersonale, der arbejder med hørehæmmede, bliver bedre til at rådgive dig som patient, om det helt rigtige tidspunkt for at få foretaget en operation med et CI. Desuden indeholder forsøget en række andre og nye tests, der vil kunne anvendes til fremtidige patienter, hvis netop disse tests viser sig at kunne hjælpe dig som patient i samarbejde med sundhedspersonalet til at træffe den bedste beslutning for behandlingen af høretab.

Som patient vil man være meget sikker på, at man får et optimalt udbytte af behandlingen, og dette er også afgørende for det sundhedspersonale, der skal rådgive dig. Derfor vil et forsigtighedsprincip ofte gøre, at man i nogle situationer ikke ønsker eller ikke får tilbudt den behandling, der i virkeligheden var den, der kunne forbedre hørelsen og dermed livskvaliteten mest muligt.

Resultaterne af dette forsøg vil rykke ved de behandlingsgrænser, som vi i dag anvender, når vi skal behandle patenter med et svært høretab.

Dette projekt kan bane vej for, at hørehæmmede får bedre hørelse og taleforståelse samt højere livskvalitet.

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BIVIRKNINGER, RISICI, KOMPLIKATIONER OG ULEMPER

Du vil som deltager i dette studie få den sædvanlige information om bivirkninger og kendte komplikationer i relation til behandlingen med CI. Denne information findes i den patientfolder, som du har fået udleveret på Høreklinikken

I forbindelse med dette forsøg vil der ikke være bivirkninger, risici eller komplikationer udover dem, som du kan risikere i forbindelse med en behandling med et høreimplantat.

Ulemperne vil være, at halvdelen af deltagerne i dette studie skal vente yderligere 3 mdr. på operationen med CI, da effekten af de nye høreapparater skal afprøves og testes i denne gruppe.

PLAN FOR FORSØGET

Forsøget vil vare lidt over et år fra den dato, hvor du tilbydes behandling med høreimplantat. Du bliver undersøgt min. 4 gange efter operationen, hvilket er fastlagt 1,3,6 og 12 måneder efter operationen. Derudover er der opfølgninger som er standard procedure, når man får et CI.
Undersøgelserne udføres af en læge sammen med en audiolog eller audiologiassistent.
Undersøgelserne omfatter følgende:
Spørgeskemaer, der vil blive sendt til dig forud for undersøgelsestidspunktet.
Forskellige høreprøver af tone-opfattelse og tale forståelighed med og uden høreapparater.
Undersøgelse af din balancefunktion.
Observation af øjne (pupiller) i forbindelse med gennemførelse af test for tale forståelighed.

OPLYSNINGER OM ØKONOMISKE FORHOLD

Forsøget er støttet med en bevilling på 2.798.250 kr. fra William Demant Fonden, der indsættes på forskningskonto på Odense Universitetshospital. Bevillingen er givet som et totalt beløb for hele projektet, og det er ikke afhængt af, hvor mange patienter, der deltager i projektet. Herudover er der en bevilling på 180.000 kr. fra Interfond, der ligeledes indsættes på forskningskonto på Odense Universitetshospital. Forsøget er således støttet med 2.978.250 kr. I alt 2.165.000 kr. er afsat til aflønning af forskere og hjælpepersonale, der er ansat på Odense Universitetshospital i hele projektperioden, og som kan frikøbes helt eller delvist til gennemførelse af projektet. Der er ikke personer tilknyttet forskningsprojektet, som får særskilt honorering ud over den løn, der oppebæres ved ansættelse på Odense Universitetshospital, i forbindelse med gennemførelse af projektet.

Et evt. tilbageværende overskydende støttebeløb efter projektperioden vil blive forsøgt anvendt inden for projektets formål eks. til udgivelse af videre forskningsresultater på baggrund af undersøgelsen eller returneret som ubrugte midler til William Demant Fonden og Interfond.

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KOMPENSATION TIL FORSØGSPERSONER

Du kan som forsøgsperson ikke få betaling for deltagelse i forsøget, da forsøget udføres som en del af de normale besøg på høreklinikken, dog gives der transportgodtgørelse efter gældende regler og derudover, hvis der er såfremt der måtte opstå ekstra besøg mhp. flere undersøgelser.

ADGANG TIL FORSØGSRESULTATER

Du kan som forsøgsperson få oplysninger om forsøgets resultater ved at henvende dig til den forsøgsansvarlige. Resultater vil dog ikke være tilgængelige før tidligst 2 år efter, at du er inkluderet i forsøget. Du vil kunne få resultater at vide fra dine egne tests umiddelbart efter de er foretaget, men det samlede forsøgs hovedresultater vil først være tilgængelige, når alle deltagerne i forsøget har gennemført alle tests.

AFSLUTNING

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i forsøget, og at du føler dig rustet til at tage beslutningen om din eventuelle deltagelse.

Vi beder dig også om at læse det vedlagte materiale ”Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt”.

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KONTAKTPERSONER

Hvis du vil vide mere, er du meget velkommen til at os.

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Odense Universitetshospital

Klinisk lektor, Klinisk Institut

Syddansk Universitet

Jesper.schmidt@rsyd.dk

Tlf: 65412536

BILAG:

• "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt"

• Komitesystemets fortrykte samtykkeerklæringer.

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Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt
Som deltager i et sundhedsvidenskabeligt forskningsprojekt skal du vide, at:

- Din deltagelse i forskningsprojektet er helt frivillig og kun kan ske efter, at du har fået både skriftlig og mundtlig information om forskningsprojektet og underskrevet samtykkeerklæringen.
- Du til enhver tid mundtligt, skriftligt eller ved anden klar tilkendegivelse kan trække dit samtykke til deltagelse tilbage og udtræde af forskningsprojektet. Såfremt du trækker dit samtykke tilbage påvirker dette ikke din ret til nuværende eller fremtidig behandling eller andre rettigheder, som du måtte have.
- Du har ret til at tage et familiemedlem, en ven eller en bekendt med til informationssamtalen.
- Du har ret til betænkningstid, før du underskriver samtykkeerklæringen.
- Oplysninger om dine helbredsforhold, øvrige rent private forhold og andre fortrolige oplysninger om dig, som fremkommer i forbindelse med forskningsprojektet, er omfattet af tavshedspligt.
- Behandling af oplysninger om dig, herunder oplysninger i dine blodprøver og væv, sker efter reglerne i databeskyttelsesforordningen, databeskyttelsesloven samt sundhedsloven. Den dataansvarlige i forsøget skal orientere dig nærmere om dine rettigheder efter databeskyttelsesreglerne.
- Der er mulighed for at få aktindsigt i forsøgsprotokoller efter offentlighedslovens bestemmelser. Det vil sige, at du kan få adgang til at se alle papirer vedrørende forsøgets tilrettelæggelse, bortset fra de dele, som indeholder forretningshemmeligheder eller fortrolige oplysninger om andre.
- Der er mulighed for at klage og få erstatning efter reglerne i lov om klage- og erstatningsadgang inden for sundhedsvæsenet. Hvis der under forsøget skulle opstå en skade kan du henvende dig til Patienterstatningen, se nærmere på www.patienterstatningen.dk

De Videnskabsetiske Komiteer for Region Hovedstaden (6 komiteer)
Tlf.: +45 38 66 63 95
E-mail: vek@regionh.dk
Hjemmeside: www.regionh.dk/vek

De Videnskabsetiske Komiteer for Region Syddanmark (2 komiteer)
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De Videnskabsetiske Komiteer for Region Midtjylland (2 komiteer)
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(S1) Informeret samtykke til deltagelse i et sundhedsvidenskabeligt forskningsprojekt.

Forskningsprojektets titel:

Behandling af nedsat hørelse med cochlear implantat og høreapparat i kombination i forhold til høreapparater alene.

Projektets originale titel: Fordele ved bimodal tilpasning med cochlear implantat og høreapparat sammenlignet med dobbeltsidig høreapparat hos patienter med asymmetrisk taleforståelse: Et kontrolleret lodtrækningsforsøg.

Erklæring fra forsøgspersonen:

Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at miste mine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til, at deltage i forskningsprojektet, og har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Forsøgspersonens navn:_____

Dato: _____ Underskrift: _____

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser for dig?:

Ja _____ (sæt x) Nej _____ (sæt x)

Ønsker du at blive kontaktet ved fremtidige projekter på Høreklinikken/Øre-næse-hals afd.?:

Ja _____ (sæt x) Nej _____ (sæt x)

Erklæring fra den, der afgiver information:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet information: _____

Dato: _____ Underskrift: _____

Projektidentifikation: Sagsnummer 20202000-84

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OPEN
Open Patient data Explorative Network

Statistical analysis plan (SAP) for randomised clinical studies.

Project responsible Consultant Jesper Hvass Schmidt and Ph.D. student Yeliz Jakobsen
Title A Study Protocol for a Randomised Controlled Trial Evaluating the Benefits from Bimodal Solution with Cochlear Implant and Hearing Aids vs. Bilateral Hearing Aids in Patients with Asymmetric Speech Identification Scores.
Deadline 30.07.2024
Study design Randomised controlled trial
Samplesize 60 participants
Aim This randomised controlled trial is designed to improve clinical decision-making for CI candidacy for patients with asymmetric hearing. It is necessary to establish more evidence to support the effectiveness and the fitting optimization of bimodal CI+HA versus HAs in patients with asymmetric hearing.

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The first objective of the study is to evaluate the subjective (SSQ12) and objective (Hearing In Noise Test (HINT) which is word and sentence based and DANTALE I, which is monosyllabic word-based) benefits of a bimodal solution (CI+HA) compared to (HA+HA). The second objective is to compare and evaluate patient self-reported outcomes with NCIQ, THI and DHI in the intervention group (CI+HA) with the control group (HA+HA). The third objective is to evaluate if listening effort, hypothesized to cause fatigue, can be measured objectively by HINT with pupillometry. To minimize listening effort and optimize the fitting of bimodal solution the CI fitting and loudness balancing on individual level will be evaluated.
Hypothesis Patients treated with a CI on the poorer hearing ear and a HA to the better hearing ear (CI+HA) in a bimodal solution have increased objective and subjective measured speech intelligibility compared to patients treated with new bilateral replacement hearing aids (HA+HA).

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2) Data description

See Appendix A

3) The statistical analysis plan (SAP)

Definition of outcome 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.
Definition of treatment variables Treatments are HAs and CI-surgery assigned by randomisation. The primary comparison will be between the CI+HA and HA+HA groups.
Covariates used in analyses Stratified randomisation for thresholds of the ear to be implanted.
Definition of effect size/parameter of interest Primary effect size: Objective outcome: Mean difference in HINT in quiet and in noise between intervention group (HA+CI) and control group (HA+HA) at 3, 6 and 12 months follow-up post- bimodal CI+HA-fitting and 3 months post-HA-fitting respectively.

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Subjective outcome: Mean difference in SSQ-12-scores at 3, 6 and 12 months follow-up post- bimodal CI+HA-fitting and 3 months post-HA-fitting respectively

Definition of Analysis Sets

Strategy for intention to treat analysis with incomplete observations.1)

1. Attempt to follow-up on all randomised participants, even if they withdraw from allocated treatment.
2. Perform a main analysis of all observed data that are valid under a plausible assumption about the missing data.
3. Perform sensitivity analyses to explore the effect of deviations from the assumption made in the main analysis.
4. Account for all randomised participants, at least in the sensitivity analyses.

1)

White, Ian R., Nicholas J. Horton, James Carpenter, and Stuart J. Pocock. 2011. 'Strategy for Intention to Treat Analysis in Randomised Trials with Missing Outcome Data'. *BMJ* 342 (February): d40. https://doi.org/10.1136/bmj.d40.

Analysis specification

A constrained linear mixed model is used to analyse the outcome.

The model will include randomisation group (CI+HA / HA+HA) and time (baseline/follow-up) and their interaction as fixed effects along with the threshold strata that were used in stratifying the randomisation. The model is constrained so that the mean at baseline agrees

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across the two treatment groups adjusted for threshold stratum, which is reasonable due to the randomisation of implant fitting. Patient ID will be included as a random effect to account for the repeated measurements.

Secondary outcomes will be analysed analogously in a constrained linear mixed model adjusting for randomisation strata. Model validation checks will be undertaken as described above, switching to bootstrapping the standard errors when model assumptions are rejected. Covariates such as age and gender will be included in all models.

Sensitivity analysis

Inclusion is performed conditional on Pure Tone Average (PTA) (from 0.5 to 4 kHz) PTA > 40 dB HL and SIS <50% in the ear considered for CI implantation and <70% in the best-aided condition which may lead to a truncation effect in the distribution of baseline measurements. To address this, an analysis of covariance (ANCOVA) model conditioning on the baseline will be used to obtain a sensitivity analysis estimate for the main outcome. (2)

The statistical analysis plan is attached as "supplementary file" along with the Data Description listed in Appendix A.

2)

Liu, Guanghan F., Kaifeng Lu, Robin Mogg, Madhuja Mallick, and Devan V. Mehrotra. 'Should Baseline Be a Covariate or Dependent Variable in Analyses of Change from Baseline in Clinical Trials?: ANALYSES OF CHANGE FROM BASELINE IN CLINICAL TRIALS'. *Statistics in Medicine* 28, no. 20 (10 September 2009): 2509–30. https://doi.org/10.1002/sim.3639.

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DATA DESCRIPTION
APPENDIX A

Variable name	Content	Datatype	Missing	Excepted range (numeric data)
Inc_date	Date of inclusion	ddmmyy	No missing	

Confounders

Age	Age at baseline	numeric	No missing	18-110
Sex		binary	No missing	
Medicine	Pupil-constricting/dilating	numeric	No missing	

Before CI surgery

Variable name	Content	Datatype	Missing	Excepted range (numeric data)
TRESHOLDS Day 0 Baseline	The patient can be tested at frequencies from 125 Hz up to 8 kHz. Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry	Numeric	Missing possible	0 to 120 db HL
HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA right ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence. In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%

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HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Quiet HA right ear	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (word) Day 0 Baseline (One month with new replacement HA) Noise HA right ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
HINT (word) Day 0 Baseline (One month with new replacement HA) Noise HA left ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
HINT (word) Day 0 Baseline (One month with new replacement HA) Noise HA+HA	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Noise HA right ear	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted.	Numeric	Missing possible	0-100%

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	Multi-talker babble noise.			
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Noise HA left ear	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Noise HA+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA) Noise HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA) Noise HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA)	Speech identification score in Denmark is percentage correct words out of 25 words.	Numeric	Missing possible	0-100%

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Noise HA left ear	Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.			
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Quiet HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Noise HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Noise HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Noise HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped	Numeric	Missing possible	0-100%

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	spectrum representing a real life "babble" noise.			
Peak pupil dilation (PPD) Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at +10dB SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-1
Peak pupil dilation (PPD) Day 0 Baseline (One month with new replacement HA) Noise HA+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at +10dB SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-1
Pupil Peaktime Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented at +10dB SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-10sec
Pupil Peaktime Day 0 Baseline (One month with new replacement HA) Noise HA+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented at +10dB SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-10sec
NCIQ Basic sound Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Advanced Sound Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100

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NCIQ Speech production Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Activity limitation Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Social interaction Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Total Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Speech intelligibility Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Spatial hearing Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Hearing quality Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Total Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
THI Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
DHI Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA right ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (word) 3 months Follow-up with new HA	Number of correct words or sentences out of 20 sentences	Numeric	Missing possible	0-100%

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(Total of 4 months with new replacement HA) Quiet HA left ear	with 5 words pr sentence			
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA right ear	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA left ear	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA right ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA left ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA right ear	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA left ear	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (sentence) 3 months	Number of correct sentences.	Numeric	Missing possible	0-100%

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Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	(20 sentences in a HINT)			
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB.	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB.	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%

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SIS Headphones Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet	Speech identification score in Denmark is percentage correct words out of 25 words. Comfort speech level. Each ear is tested unaided separately.	Numeric	Missing possible	0-100%
SIS Headphones Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise	Speech identification score in Denmark is percentage correct words out of 25 words. Comfort speech level. Each ear is tested unaided separately. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB .	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB .	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB .	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65db and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65db and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing	Numeric	Missing possible	0-100%

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	a real life "babble" noise.			
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65db and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
Peak pupil dilation (PPD) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-1
Peak pupil dilation (PPD) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-1
Pupil Peaktime 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-10sec
Pupil Peaktime 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses	Numeric	Missing possible	0-10sec

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	Measurement & analysis tools			
NCIQ Basic sound 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Advanced Sound 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Speech production 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Self-esteem 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Activity limitation 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Social interaction 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Total 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Spatial hearing 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Hearing quality 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Total 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
THI 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100

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DHI 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	Numeric	Missing possible	0-100

After CI surgery

Variable name	Content	Datatype	Missing	Excepted range (numeric data)
TRESHOLDS CI activation day	The patient can be tested at frequencies from 125 Hz up to 8 kHz. Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry	Numeric	Missing possible	0 to 120 db HL
PTA CI activation day	The patient can be tested at frequencies from 125 Hz up to 8 kHz. In free field. In best aided condition. No stimuli.	Numeric	Missing possible	0 to 120 db HL
TRESHOLDS 3 months post bimodal CI+HA-fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry	Numeric	Missing possible	0 to 120 db HL
PTA 3 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. In free field. In best aided condition. No stimuli.	Numeric	Missing possible	0 to 120 db HL
TRESHOLDS 6 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz.	Numeric	Missing possible	0 to 120 db HL

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	Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry			
PTA 6 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. In free field. In best aided condition. No stimuli.	Numeric	Missing possible	0 to 120 db HL
TRESHOLDS 12 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry	Numeric	Missing possible	0 to 120 db HL
PTA 12 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. In free field. In best aided condition. No stimuli.	Numeric	Missing possible	0 to 120 db HL
HINT (word) Post-surgery 3 months after fitting Quiet CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Quiet CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Quiet CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Quiet CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery	Number of correct sentences.	Numeric	Possible	0-100%

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6 months after fitting Quiet CI alone	(20 sentences in a HINT) In free field. Speech level at 65dB HL.			
HINT (sentence) Post-surgery 12 month after fitting Quiet CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Quiet HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Quiet HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Quiet HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL..	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Quiet HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 6 months after fitting Quiet HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 12 months after fitting Quiet HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Quiet CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Quiet CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field.	Numeric	Possible	0-100%

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	Speech level at 65dB HL.			
HINT (word) Post-surgery 12 months after fitting Quiet CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Quiet CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 6 months after fitting Quiet CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 12 months after fitting Quiet CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Noise CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Noise CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Noise CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Noise CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted.	Numeric	Possible	0-100%

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	Multi-talker babble noise.			
HINT (sentence) Post-surgery 6 months after fitting Noise CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 12 months after fitting Noise CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Noise HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Noise HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Noise HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Noise HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 6 months after fitting Noise HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%

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	SNR +10 and adapted. Multi-talker babble noise.			
HINT (sentence) Post-surgery 12 months after fitting Noise HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Noise CI +HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Noise CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Noise CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Noise CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 6 months after fitting Noise CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 12 months after fitting Noise CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field.	Numeric	Possible	0-100%

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	Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.			
SIS free field Auditory Post-surgery 3 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 12 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing	Numeric	Possible	0-100%

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	a real life "babble" noise.			
SIS free field Auditory Post-surgery 12 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 12 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%

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SIS free field Auditory Post-surgery 12 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 12 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 12 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%

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SIS free field Audio-visual Post-surgery 12 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a	Numeric	Possible	0-100%

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	speech shaped spectrum representing a real life "babble" noise.			
SIS free field Audio-visual Post-surgery 6 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
Peak pupil dilation (PPD) Post-surgery	PPD is calculated based on the number of pixels. PPD of 0.01	Numeric	Possible	0-1

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3 months after fitting Quiet CI only	would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Quiet CI only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Quiet CI only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 3 months after fitting Quiet HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Quiet HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive	Numeric	Possible	0-1

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	SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Quiet HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 3 months after fitting Quiet CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Quiet CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Quiet CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD)	PPD is calculated based on the number	Numeric	Possible	0-1

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Post-surgery 3 months after fitting Noise CI only	of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Noise CI only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Noise CI only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 3 months after fitting Noise HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
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	SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Noise HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 3 months after fitting Noise CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Noise CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Noise CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1

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Pupil Peaktime Post-surgery 3 months after fitting Quiet CI only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 6 months after fitting Quiet CI only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 12 months after fitting Quiet CI only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 3 months after fitting Quiet HA only	The time it takes for The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 6 months after fitting Quiet HA only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 12 months after fitting Quiet HA only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at	Numeric	Possible	0-10sec

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	+10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Pupil Peaktime Post-surgery 3 months after fitting Quiet CI+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 6 months after fitting Quiet CI+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 12 months after fitting Quiet CI+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 3 months after fitting Noise CI only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 6 months after fitting Noise CI only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec

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Pupil Peaktime Post-surgery 12 months after fitting Noise CI only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 3 months after fitting Noise HA only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 6 months after fitting Noise HA only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 12 months after fitting Noise HA only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 3 months after fitting Noise CI+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 6 months after fitting Noise CI+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive	Numeric	Possible	0-10sec

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	SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Pupil Peaktime Post-surgery 12 months after fitting Noise CI+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
NCIQ Basic sound Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Advanced Sound Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Speech production Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Self-esteem Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Activity limitation Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Social interaction Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Total Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Basic sound Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Advanced Sound Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Speech production Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Self-esteem Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Activity limitation Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Social interaction Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100

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NCIQ Total Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Basic sound Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Advanced Sound Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Speech production Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Self-esteem Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Activity limitation Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Social interaction Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Total Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Speech intelligibility Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Spatial hearing Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Hearing quality Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Total Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Speech intelligibility Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Spatial hearing Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Hearing quality Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Total Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Speech intelligibility Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Spatial hearing Post-surgery	Questionnaire	numeric	Possible	0-100

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12 months after fitting				
SSQ Hearing quality Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Total Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
THI Post-surgery 2 weeks before fitting	Questionnaire	numeric	Possible	0-100
THI Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
THI Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
THI Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
DHI Post-surgery 2 weeks before fitting	Questionnaire	numeric	Possible	0-100
DHI Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
DHI Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
DHI Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-6
	2b	Specific objectives or hypotheses	5-6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-10
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	10-12
Participants	4a	Eligibility criteria for participants	10-12
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	12-13
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	13-15
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9-10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9-10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9-10/14-15
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	14-15
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	14-15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	14-15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	1, 2, 16, 17
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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SPIRIT 2013 Checklist for the ReTrain pilot RCT: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2,7,17
	2b	All items from the World Health Organization Trial Registration Data Set	Yes, clinicaltrials.org
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1,17
	5b	Name and contact information for the trial sponsor	1,17
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	17

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Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-6
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	1,7,9,10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	11
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10,13-15, Appendix A

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Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8-9,11-13 Appendix A, Figure 1 and 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14, Table 1
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7-10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9-10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9-10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9-10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9-10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	9-10
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-15, statistical plan(SAP), Data management plan(DMP)

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	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13-15, SAP, DMP,
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13-15, SAP, DMP, Appendix A
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-15, SAP
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13-15, SAP
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13-15, SAP
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13-15, SAP
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2,7,16

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Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13-15, SAP
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	2,9,11,16
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	2,9,11,16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17,MAP
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Consent form
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	17
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	MAP
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	As online supplementary file
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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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.

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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.

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Abstract

Introduction

Cochlear implant (CI) and hearing aid (HA) in a bimodal solution (CI + HA) is compared to bilateral HAs (HA +HA) to test if the bimodal solution result in better speech intelligibility and self-reported quality of life.

Methods and Analysis

This randomised controlled trial (RCT) is conducted in Odense University Hospital, Denmark. Sixty adult bilateral HA users referred for CI surgery is 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. 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

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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.

The primary outcome measures are Speech intelligibility measured objectively with HINT (sentences in noise) and DANTALE I (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

In conclusion, the purpose 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 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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Strengths and Limitations of This Study

- The study uses comprehensive measures of self-reported outcomes as well as objective tests of speech intelligibility.
- Listening effort controlled with pupillometry during objective tests of speech intelligibility.
- Open label RCT (blinding is not possible due to visibility of the CI).
- Possible large drop rates if new HAs improve speech intelligibility to an extent that CI treatment is rejected or postponed.

Introduction

Background

Cochlear implants (CIs) have been used to restore hearing in individuals with severe to profound sensorineural hearing loss. Initially, most patients receiving a cochlear implant were profoundly deaf in both ears. (1, 2) However, recently it has become more common to implant patients with significant residual hearing in the affected ear, as well as in patients with asymmetric hearing loss and single-sided deafness, with significant residual hearing or normal hearing on the contralateral side.(3, 4) A CI in one ear and a HA in the other ear can provide enhanced hearing performance in patients with asymmetrical hearing.(5, 6) The combination of CI and HA is referred to as bimodal hearing or bimodal solution.(7)

CI Candidacy

In the UK, The National Institute for Health and Care Excellence (NICE) have listed guidelines for cochlear implantation and recommends that unilateral CI is offered to patients with severe

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to profound deafness who do not receive adequate benefit from acoustic hearing aids. Severe to profound deafness is defined as pure-tone audiometric threshold ≥ 80 dB HL at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz). Another criteria is that SIS< 50% in the ear considered for implantation and in best aided condition SIS≤60%(8).

The Danish CI candidacy criteria consists of SIS (without HAs, measured with headphones) ≤45% and a SIS ≤65% (in best aided condition) in the ear considered for implantation using DANTALE I monosyllabic word-lists.(9) Additional testing to evaluate speech understanding is assessed by HINT.(10, 11)

The recommendation for a CI might be less clear for patients with asymmetric hearing because they may not fall into the traditional referral criteria but would likely benefit from a CI. It is therefore necessary to establish more evidence to support the effectiveness of bimodal CI+HA versus HAs in patients with asymmetric hearing.

Bimodal Solution vs. Bilateral HAs

Normal hearing listeners (NH) benefit from listening with two ears, which help them understand speech in noise and identify sound location.

Benefits from listening with two ears include: head shadow effect, binaural summation, binaural squelch, localization and spatial release from masking.(12-15)

Patients with hearing loss often do not have these benefits, and they are often not accessible to CI patients. (15)Many bimodal CI and HA users are missing these benefits because the devices are unsynchronized.(16)

Until now it is unknown when to introduce the bimodal solution and making sure that patients are well-fitted with hearing aids when they are given the candidacy assessment.

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The question is if the bimodal benefits are bigger than the bilateral hearing aid condition when they are well fitted?

This study will therefore support and strengthen the preoperative clinical decision to recommend a bimodal solution with a CI and a HA versus the continuous use of bilateral HAs. This may offer the patient faster and more effective treatment because delaying the surgery may not be beneficial.

Patient-Reported Outcome Measures

Benefits of the CI are measured subjectively with Patient-Reported Outcome Measures (PROMs) as SSQ12, NCIQ, THI and DHI.(17-24)

The validity and reproducibility of the Danish version of THI has been reported(24). SSQ12, DHI, NCIQ have all been translated into Danish and backward translated to English following a cultural adaption and pilot-testing to ensure correct understanding of the questionnaires. Test-retest reliability has been assessed as well.(18, 20, 22)

Listening Effort

Patients with CI often experience high levels of listening effort, they often report that understanding speech causes high levels of increased sustained effort which results in feelings of fatigue.(25) These feelings may lead patients to withdraw socially due to the stresses involved in communication even though they may not specifically report difficulties with speech understanding.(19)

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Effort in listeners with NH can be reflected by the relationship between speech intelligibility and pupil-dilation.(26) Listening effort has been defined as the "Deliberate allocation of mental resources to overcome obstacles in goal pursuit when carrying out a task" and is the basis for the Framework for Understanding Effortful Listening (FUEL) model.(27) Understanding speech in challenging hearing environments results in increased auditory and cognitive processing which can be observed objectively by measuring the pupil dilation during speech perception in noise, in a task such as the HINT(28-30)

Rationale and Objectives

This randomised controlled trial is designed to improve clinical decision-making for CI candidacy for patients with asymmetric hearing. It is necessary to establish more evidence to support the effectiveness and the fitting optimization of bimodal CI+HA versus HAs in patients with asymmetric hearing.

The first objective of the study is to evaluate the subjective (SSQ12) and objective (Hearing In Noise Test (HINT) which is word and sentence based and DANTALE I, which is monosyllabic word-based) benefits of a bimodal solution (CI+HA) compared to (HA+HA).

The second objective is to compare and evaluate patient self-reported outcomes with NCIQ, THI and DHI in the intervention group (CI+HA) with the control group (HA+HA).

The third objective is to evaluate if listening effort, hypothesized to cause fatigue, can be measured objectively by HINT with pupillometry.

To minimize listening effort and optimize the fitting of bimodal solution the CI fitting and loudness balancing on individual level will be evaluated.(2, 31, 32)

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Methods and Analysis

Study Design, Ethics and Registration

This study is a prospective randomised controlled trial based on a single centre conducted in Odense University Hospital, Denmark. The study started 01/02/2022 and is expected to end 30/07/2024. It was successfully registered at ClinicalTrials.gov with registration number: NCT04919928.

This study has been approved at Research Ethics Committee Southern Denmark (Projekt-ID: S-20200074G) 21st August 2020 to 31st December 2024.

Study Population

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

Inclusion Criteria

- Adults >18 years old.
- Fluent in Danish, including reading and writing
- Acquired post-lingual deafness
- Use of bilateral HAs for at least one year prior to evaluation for cochlear implantation candidacy. This to ensure, that both ears have received auditive stimulation
- PTA > 40 dB HL in the ear considered for CI implantation and PTA≥40 and ≤ 70dB HL in the contralateral ear in best aided condition, in quiet and in noise and in free field.

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- SIS <70% in best aided condition in the ear considered for CI implantation and SIS ≥30% and ≤70% in best aided condition in the contralateral ear, in quiet and in noise and in free field.

Exclusion Criteria

- Vestibular loss in the ear not considered for CI implantation
- Surgical issues interfering with the site of implantation or anatomical contraindications such as cochlear malformations, which will be determined using MRI or CT-scans.
- Auditory nerve lesions.
- Central auditory pathway pathologies.
- Otosclerosis.
- Single sided deafness (SSD).

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.

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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 (supplementary file 1) 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.

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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.

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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.(35)

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. (36, 37)

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

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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

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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.(24)

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). (9, 10, 22)

Secondary Outcome

Patient reported outcomes scores assessed with the Nijmegen Cochlear Implant Questionnaire (NCIQ), The Tinnitus Handicap Inventory (THI) and Dizziness Handicap Inventory (DHI). (18, 20, 24)

Third Outcome

Listening effort assessed with pupil dilation with HINT.(10)

Statistics

Power calculation

Power calculations with a power of 0.8 with a significance level of 0.05 have been made with STATA IC-15 using standard deviations for the HINT test and expected effect size (38) the NCIQ(18), and the SSQ (internal communication with BEAR (Better Hearing Rehabilitation) study on hearing aid use in Denmark) (Table 1). An estimated within participant standard deviation from the BEAR study of 1,9 in an HA population using the SSQ-12 is used to calculate

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the sample size. A difference of 1,4 will require 30 participants in each arm. The effect size is expected to be larger in the CI group which will lower the number of required subjects even further.

Based on this, 30 participants must be enrolled in each arm. Additional six patients (20%) in each arm will be enrolled in the study to account for dropouts.

Test	SD pre	SD post	Expected difference between the two treatment arms	Minimum required group size
1. HINT	6.3%	6.3%	5%	26
2. NCIQ – basic sound perception	14.4	23.5	53	4
2. NCIQ	13.4	19.6	34	6
2. NCIQ – speech perception	18.8	17.8	17	20
2.NCIQ Self-esteem	20.1	16.4	22	13
2.NCIQ Activity	23.0	15.9	27	10
2.NCIQ Social Interactions	19.8	14.5	25	9
3. SSQ Total	1.9	1.9	1.4	30

Table 1: Power calculations for the desired tests. Estimated within participant standard deviations (SD pre and SD post) with expected difference and the calculated required group size.

Detailed statistics is presented in the Statistical Analysis Plan (SAP) (supplementary file 2)

Definition of Analysis Sets

Strategy for intention to treat analysis with incomplete observations.(39)

1. Attempt to follow-up on all randomised participants, even if they withdraw from allocated treatment.
2. Perform a main analysis of all observed data that are valid under a plausible assumption about the missing data.
3. Perform sensitivity analyses to explore the effect of deviations from the assumption made in the main analysis.
4. Account for all randomised participants, at least in the sensitivity analyses.

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Analysis specification

A constrained linear mixed model is used to analyse the outcome.

The model will include randomisation group (CI+HA / HA+HA) and time (baseline/follow-up) and their interaction as fixed effects along with the threshold strata that were used in stratifying the randomisation. The model is constrained so that the mean at baseline agrees across the two treatment groups adjusted for threshold stratum, which is reasonable due to the randomisation of implant fitting. Patient ID will be included as a random effect to account for the repeated measurements.

Secondary outcomes will be analysed analogously in a constrained linear mixed model adjusting for randomisation strata. Model validation checks will be undertaken as described above, switching to bootstrapping the standard errors when model assumptions are rejected.

Covariates such as age and gender will be included in all models.

Sensitivity analysis

Inclusion is performed conditional on Pure Tone Average (PTA) (from 0.5 to 4 kHz) PTA > 40 dB HL and SIS <50% in the ear considered for CI implantation and <70% in the best-aided condition which may lead to a truncation effect in the distribution of baseline measurements. To address this, an analysis of covariance (ANCOVA) model conditioning on the baseline will be used to obtain a sensitivity analysis estimate for the main outcome.(40)

The statistical analysis plan is attached as “supplementary file” along with the Data Description listed in Appendix A (supplementary file 3).

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Patient and Public Involvement

A focus-group interview was established with six cochlear implant patients. The patients commented on their decision to transition from HA to CI. Based on the feedback from the focus group, the research questions were developed.

The patients also reported problems with adjustments of the CI, when meeting the audiologist for CI adjustment controls.

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 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.

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Results

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.

Footnotes

Authors´ Contributions:

YJ and JHS are involved in the conception of the study. LCA and JHS wrote the grant application and the draft of the manuscript. JHS and YJ designed and revised the draft methodological content. YJ reviewed the manuscript and JHS critiqued it.

Funding:

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Competing Interests:

None declared.

Contributership Statement/Acknowledgements:

We are very thankful of the academic English editing by Senior Researcher at Oticon Medical Kathleen Faulkner Scalzo and Assistant Professor Lindsey Van Yper.

We are grateful for the contribution from the patient advisers.

Protocol and Registration:

This study is registered in ClinicalTrials.gov: NCT04919928

Figure 1: Flowchart

Figure 2: Timeline

Figure 3: Diagram for loudness balancing

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Figure 1

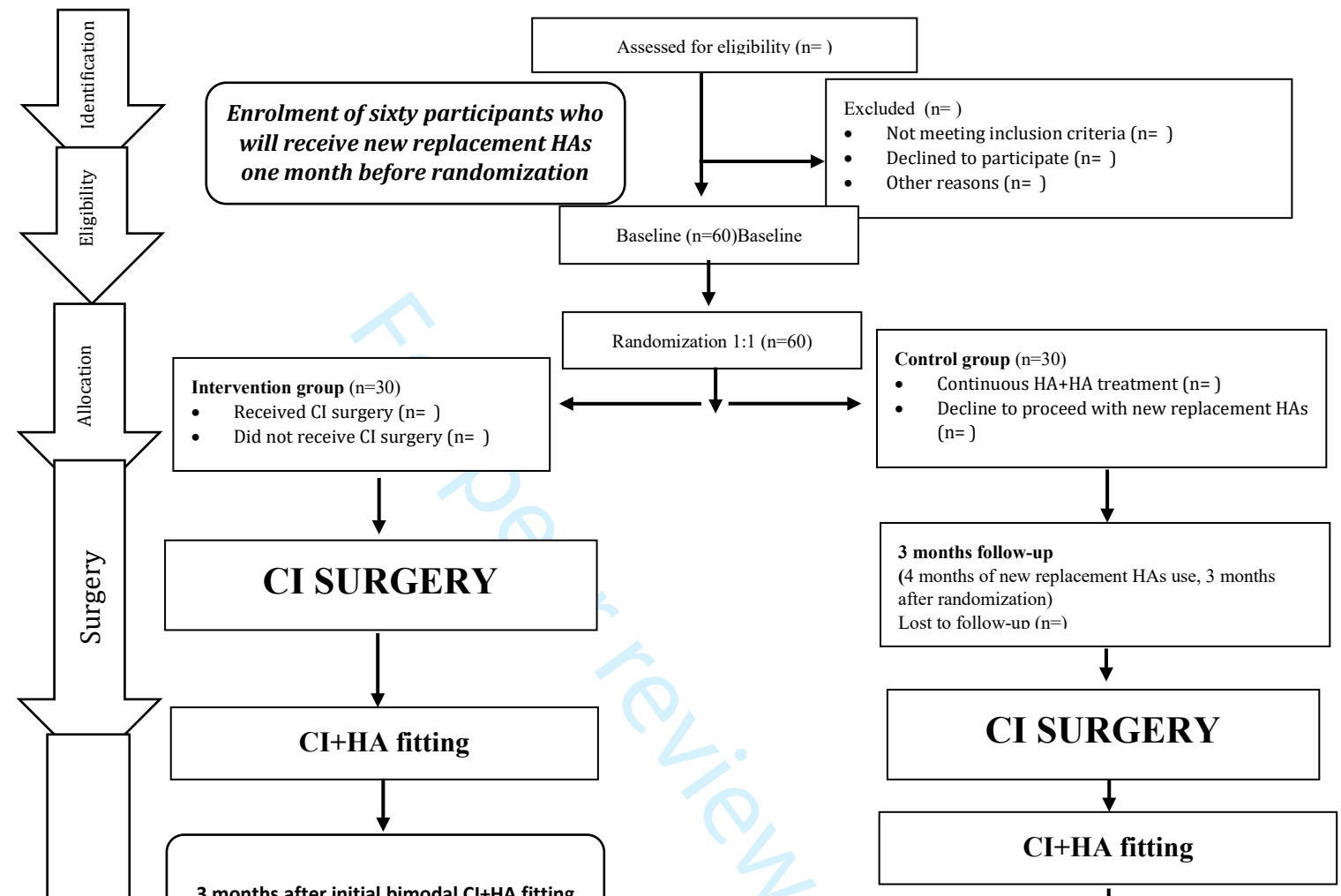

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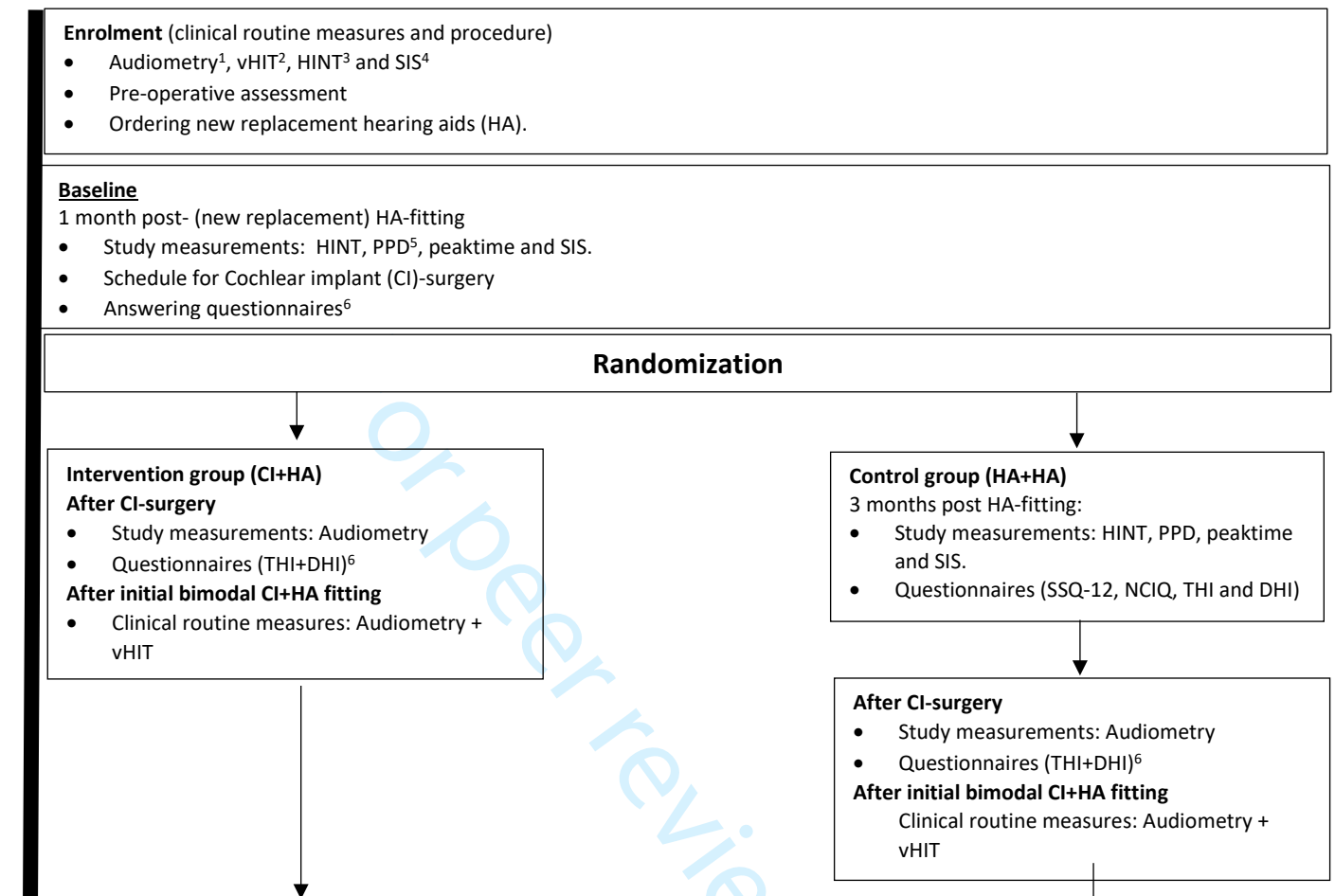
Figure 2



[1]Estimating hearing status pre-surgery
[2]Video Head Impulse Test v-HIT: clinical -routine measure.
3Hearing in noise test. Quiet and noise. Fixed SNR = +10dB. Free field with HAs
[4]Speech Identification Score: Words and sentences. Auditory and audiovisual. In quiet and in noise.
[5]Peak Pupil Dilation (PPD)
[6]Questionnaires: Speech, Spatial and Qualities-12 (SSQ-12), Nijmegen Cochlear Implant Questionnaire (NCIQ), Tinnitus Handicap Inventory (THI), Dizziness Handicap Inventory (DHI) will all be distributed by using REDCap to participants digital mail-box.
[7]The three groups are described in detail in the protocol.

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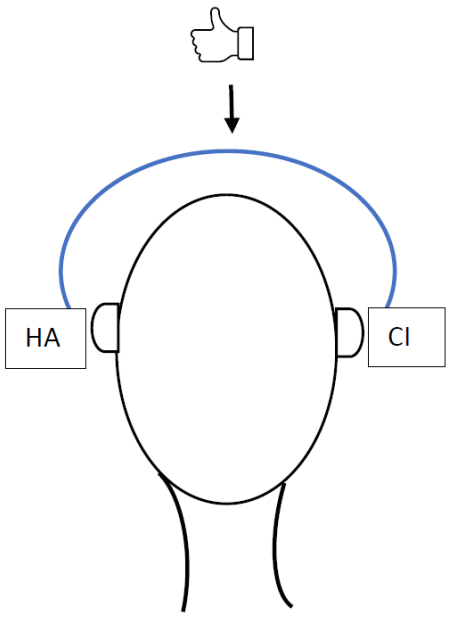
Figure 3



This diagram that will be placed in front of the patient to track that the sound is balanced by indicating where they hear it. A sound will be presented in front of the listener and hearing aid gain is adjusted until the patient hears the sounds 'fused' or that it is coming from the same location/sounds centered. The figure will be used for group B and C. (The diagram is created by YJ)

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Deltagerinformation

-om deltagelse i et videnskabeligt forsøg

Behandling af nedsat hørelse med cochlear implantat (CI) og høreapparat i kombination i forhold til høreapparater alene.

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Projektets originale titel:

Fordele ved bimodal tilpasning med cochlear implantat og høreapparat sammenlignet med dobbeltsidig høreapparat hos patienter med asymmetrisk taleforståelse: Et kontrolleret lodtrækningsforsøg

Øre-Næse-Halskirurgisk/Høreklinikken

Odense Universitetshospital

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Kære deltager

Kære Deltager

Vi vil spørge, om du vil deltage i et videnskabeligt forsøg.

Før du beslutter, om du vil deltage i forsøget, skal du fuldt ud forstå, hvad forsøget går ud på, og hvorfor vi gennemfører forsøget.

Vi vil derfor bede dig om at læse denne deltagerinformation grundigt.

Der er to QR koder i denne deltagerinformation, som beskriver projektet mere kortfattet.

Inden du kan indgå i forsøget, vil du ligeledes modtage mundtlig information af den forsøgsansvarlige læge.

Hvis du beslutter dig for at deltage i forsøget, vil vi bede dig om at underskrive en samtykkeerklæring. Denne samtykkeerklæring giver de forsøgsansvarlige mulighed for at få direkte adgang til relevante oplysninger i din journal for at kunne indsamle data, gennemføre, overvåge og kontrollere forsøget.

De oplysninger, der indsamles fra din journal vil være helbredsoplysninger, tidligere og aktuelle skanninger af forhold omkring øret, oplysninger om evt. øreoperationer og behandling med høreapparater samt resultater af de undersøgelser, vi udfører, og som du tidligere har fået udført omkring hørelse og balancefunktion.

Det vil kun være den forsøgsansvarlige læge og projektkoordinator, der har adgang til din journal i forbindelse med gennemførelse af forsøget. De relevante oplysninger fra din journal registreres i anonymiseret form i en database sammen med de data, der indsamles som en del af forsøget.

Samarbejdspartnere (producenter af måleapparater) har ikke adgang til din journal, men kan dog få adgang til en afgrænset del af data i anonymiseret form, når der opstår et specifikt behov herfor. Det kan f.eks. være relevant, hvis de forsøgsansvarlige får behov for teknisk hjælp i forbindelse med behandling af data. En sådan dataadgang vil kun blive givet, hvis der foreligger en godkendt databehandleraftale mellem virksomheden og Region Syddanmark, der er den dataansvarlige myndighed.

Husk, at du har ret til betænkningstid, før du beslutter, om du vil underskrive samtykkeerklæringen. Det er frivilligt at deltage i forsøget. Du kan når som helst trække dit samtykke tilbage. Det har stor gavn for forskningen at kende årsagen til, at du ikke ønsker at deltage, men du skal naturligvis ikke oplyse årsagen, hvis ikke du ønsker det.

Det vil ikke få konsekvenser for din behandling.

Hvis der er behov for ekstra besøg på Høreklinikken på Odense Universitetshospital i forbindelse med forsøget, vil der blive betalt transportgodtgørelse herfor.

Forsøget er et samarbejde mellem, Øre-næse-hals kirurgisk afdeling og Høreklinikken på Odense Universitetshospital, og Øre-Næse-halskirurgisk og Audiologisk afdeling på Rigshospitalet.

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På de følgende sider kan du læse, hvad det vil betyde for dig, hvis du vælger at deltage i forsøget.

Afslutningsvist kommer de sider, hvor både du og lægen, der informerer dig, skal skrive under.

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FORMÅL MED FORSØGET

Du er blevet spurgt, om du vil deltage i dette forsøg, fordi du har nedsat hørelse i svær grad og er derfor tilbudt operation med et høreimplantat = cochlear implantat også kaldet et CI, på det dårligst hørende øre.

Formålet med dette forsøg er at undersøge, hvilken behandling, der giver den bedste hørelse for dig som patient.

Alle patienter, der indgår i forsøget, får tilpasset to nye høreapparater, der kan tilpasses med et CI. Høreapparaterne skal man anvende og vænne sig til at bruge i ca. 1 måned.

Herefter trækkes der lod om du udvælges til at få en CI operation på det dårligst hørende øre og fortsætte med at anvende det nye høreapparat på det andet øre eller om du udvælges til at være i den anden gruppe som fortsætter yderligere 3 måneder med begge høreapparater for derefter at tilbydes CI operation.

Formålet er at undersøge om patienter hører bedre med et CI der kan arbejde sammen med et høreapparat sammenlignet med bedst tilpasset høreapparat behandling.

Vi vil undersøge mange aspekter af hørelsen herunder lydopfattelse med høreprøver og tests af taleforståelighed. Desuden vil vi som noget nyt måle på bevægelsen af dine øjne (pupiller), når du gennemfører disse tests. Dette har til formål at undersøge, hvor meget du anstrenger dig for at høre i de forskellige test situationer.

Hvis du bliver så glad for dine nye høreapparater at du ikke længere ønsker en operation med et CI, så får du selvfølgelig lov til at aflyse operationen.

Dette forsøg er vigtigt i forhold at forbedre retningslinjer med henblik på at give en mere præcis vurdering for den enkelte patient i forhold til at operere en patient med nedsat hørelse eller fortsætte behandling med høreapparater.

Alle høreapparater og høreimplantater, der anvendes til forsøget, er godkendte, og de er alle tilgængelige behandlingsmuligheder på klinikker i Danmark, hvor man udfører behandling med høre-implantater

Forsøget har brug for 60 deltagere i alt.

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NYTTE VED FORSØGET

CI er i rivende udvikling, men desværre er en behandling med disse ikke helt uden konsekvenser for dig som patient. En operation med et høreimplantat giver en risiko for at udvikle permanent svimmelhed, forstyrrelser af smagssansen, og påvirkning af ansigtsnerven samt infektion.

Det er ikke altid, at hørelsen forbedres så meget som ønsket ved en behandling med CI. Nogle patienter kan opleve øresusen (tinnitus) efter operationen, mens andre oplever at et CI har behandlet deres tinnitus.

I nogle situationer kan der være fordele ved høreapparatbehandling, frem for behandling med CI eks. hvis man lytter til musik eller når man taler i telefon. Derimod kan et CI give en bedre forståelse af tale i mindre forsamlinger end det opleves med et høreapparat.

Det forventes at alle disse fordele kan opleves med den bimodale løsning (et CI kombineret med et høreapparat).

Stærkt nedsat hørelse forringer livskvaliteten hos de fleste, det er derfor vigtigt, at du som patient kan tilbydes og hjælpes med den behandling, der er den helt rigtige for dig.

En behandling med et CI kan ikke laves om, så derfor er det meget vigtigt, at behandlingen tilbydes på det helt rigtige tidspunkt.

Fordelene ved behandlingen med et CI skal overstige de mulige ulemper for dig som patient.

Dette forsøg vil bidrage til, at sundhedspersonale, der arbejder med hørehæmmede, bliver bedre til at rådgive dig som patient, om det helt rigtige tidspunkt for at få foretaget en operation med et CI. Desuden indeholder forsøget en række andre og nye tests, der vil kunne anvendes til fremtidige patienter, hvis netop disse tests viser sig at kunne hjælpe dig som patient i samarbejde med sundhedspersonalet til at træffe den bedste beslutning for behandlingen af høretab.

Som patient vil man være meget sikker på, at man får et optimalt udbytte af behandlingen, og dette er også afgørende for det sundhedspersonale, der skal rådgive dig. Derfor vil et forsigtighedsprincip ofte gøre, at man i nogle situationer ikke ønsker eller ikke får tilbudt den behandling, der i virkeligheden var den, der kunne forbedre hørelsen og dermed livskvaliteten mest muligt.

Resultaterne af dette forsøg vil rykke ved de behandlingsgrænser, som vi i dag anvender, når vi skal behandle patenter med et svært høretab.

Dette projekt kan bane vej for, at hørehæmmede får bedre hørelse og taleforståelse samt højere livskvalitet.

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BIVIRKNINGER, RISICI, KOMPLIKATIONER OG ULEMPER

Du vil som deltager i dette studie få den sædvanlige information om bivirkninger og kendte komplikationer i relation til behandlingen med CI. Denne information findes i den patientfolder, som du har fået udleveret på Høreklinikken

I forbindelse med dette forsøg vil der ikke være bivirkninger, risici eller komplikationer udover dem, som du kan risikere i forbindelse med en behandling med et høreimplantat.

Ulemperne vil være, at halvdelen af deltagerne i dette studie skal vente yderligere 3 mdr. på operationen med CI, da effekten af de nye høreapparater skal afprøves og testes i denne gruppe.

PLAN FOR FORSØGET

Forsøget vil vare lidt over et år fra den dato, hvor du tilbydes behandling med høreimplantat. Du bliver undersøgt min. 4 gange efter operationen, hvilket er fastlagt 1,3,6 og 12 måneder efter operationen. Derudover er der opfølgninger som er standard procedure, når man får et CI.
Undersøgelserne udføres af en læge sammen med en audiolog eller audiologiassistent.
Undersøgelserne omfatter følgende:
Spørgeskemaer, der vil blive sendt til dig forud for undersøgelsestidspunktet.
Forskellige høreprøver af tone-opfattelse og tale forståelighed med og uden høreapparater.
Undersøgelse af din balancefunktion.
Observation af øjne (pupiller) i forbindelse med gennemførelse af test for tale forståelighed.

OPLYSNINGER OM ØKONOMISKE FORHOLD

Forsøget er støttet med en bevilling på 2.798.250 kr. fra William Demant Fonden, der indsættes på forskningskonto på Odense Universitetshospital. Bevillingen er givet som et totalt beløb for hele projektet, og det er ikke afhængt af, hvor mange patienter, der deltager i projektet. Herudover er der en bevilling på 180.000 kr. fra Interfond, der ligeledes indsættes på forskningskonto på Odense Universitetshospital. Forsøget er således støttet med 2.978.250 kr. I alt 2.165.000 kr. er afsat til aflønning af forskere og hjælpepersonale, der er ansat på Odense Universitetshospital i hele projektperioden, og som kan frikøbes helt eller delvist til gennemførelse af projektet. Der er ikke personer tilknyttet forskningsprojektet, som får særskilt honorering ud over den løn, der oppebæres ved ansættelse på Odense Universitetshospital, i forbindelse med gennemførelse af projektet.

Et evt. tilbageværende overskydende støttebeløb efter projektperioden vil blive forsøgt anvendt inden for projektets formål eks. til udgivelse af videre forskningsresultater på baggrund af undersøgelsen eller returneret som ubrugte midler til William Demant Fonden og Interfond.

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KOMPENSATION TIL FORSØGSPERSONER

Du kan som forsøgsperson ikke få betaling for deltagelse i forsøget, da forsøget udføres som en del af de normale besøg på høreklinikken, dog gives der transportgodtgørelse efter gældende regler og derudover, hvis der er såfremt der måtte opstå ekstra besøg mhp. flere undersøgelser.

ADGANG TIL FORSØGSRESULTATER

Du kan som forsøgsperson få oplysninger om forsøgets resultater ved at henvende dig til den forsøgsansvarlige. Resultater vil dog ikke være tilgængelige før tidligst 2 år efter, at du er inkluderet i forsøget. Du vil kunne få resultater at vide fra dine egne tests umiddelbart efter de er foretaget, men det samlede forsøgs hovedresultater vil først være tilgængelige, når alle deltagerne i forsøget har gennemført alle tests.

AFSLUTNING

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i forsøget, og at du føler dig rustet til at tage beslutningen om din eventuelle deltagelse.

Vi beder dig også om at læse det vedlagte materiale ”Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt”.

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KONTAKTPERSONER

Hvis du vil vide mere, er du meget velkommen til at os.

PROJEKTKOORDINATOR:

Læge Yeliz Jakobsen

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Tlf: 65412536

FORSØGSANSVARLIG LÆGE:

Jesper Hvass Schmidt overlæge, ph.d.

Øre-næse-hals/Høreklinikken afd. F

Odense Universitetshospital

Klinisk lektor, Klinisk Institut

Syddansk Universitet

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Tlf: 65412536

BILAG:

• "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt"

• Komitesystemets fortrykte samtykkeerklæringer.

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Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt
Som deltager i et sundhedsvidenskabeligt forskningsprojekt skal du vide, at:

- Din deltagelse i forskningsprojektet er helt frivillig og kun kan ske efter, at du har fået både skriftlig og mundtlig information om forskningsprojektet og underskrevet samtykkeerklæringen.
- Du til enhver tid mundtligt, skriftligt eller ved anden klar tilkendegivelse kan trække dit samtykke til deltagelse tilbage og udtræde af forskningsprojektet. Såfremt du trækker dit samtykke tilbage påvirker dette ikke din ret til nuværende eller fremtidig behandling eller andre rettigheder, som du måtte have.
- Du har ret til at tage et familiemedlem, en ven eller en bekendt med til informationssamtalen.
- Du har ret til betænkningstid, før du underskriver samtykkeerklæringen.
- Oplysninger om dine helbredsforhold, øvrige rent private forhold og andre fortrolige oplysninger om dig, som fremkommer i forbindelse med forskningsprojektet, er omfattet af tavshedspligt.
- Behandling af oplysninger om dig, herunder oplysninger i dine blodprøver og væv, sker efter reglerne i databeskyttelsesforordningen, databeskyttelsesloven samt sundhedsloven. Den dataansvarlige i forsøget skal orientere dig nærmere om dine rettigheder efter databeskyttelsesreglerne.
- Der er mulighed for at få aktindsigt i forsøgsprotokoller efter offentlighedslovens bestemmelser. Det vil sige, at du kan få adgang til at se alle papirer vedrørende forsøgets tilrettelæggelse, bortset fra de dele, som indeholder forretningshemmeligheder eller fortrolige oplysninger om andre.
- Der er mulighed for at klage og få erstatning efter reglerne i lov om klage- og erstatningsadgang inden for sundhedsvæsenet. Hvis der under forsøget skulle opstå en skade kan du henvende dig til Patienterstatningen, se nærmere på www.patienterstatningen.dk

De Videnskabsetiske Komiteer for Region Hovedstaden (6 komiteer)
Tlf.: +45 38 66 63 95
E-mail: vek@regionh.dk
Hjemmeside: www.regionh.dk/vek

De Videnskabsetiske Komiteer for Region Syddanmark (2 komiteer)
Tlf.: + 45 76 63 82 21
E-mail: komite@rsyd.dk
Hjemmeside: www.regionsyddanmark.dk/komite

Den Videnskabsetiske Komité for Region Nordjylland Tlf.: +45 97 64 84 40
E-mail: vek@rn.dk
Hjemmeside: www.rn.dk/vek

Den Videnskabsetiske Komité for Region Sjælland
Tlf.: +45 93 56 60 00
E-mail: RVK-sjaelland@regionsjaelland.dk
Hjemmeside: https://www.regionsjaelland.dk/sundhed/forskning/forfagfolk/videnskabsetisk-komite/Sider/default.aspx

De Videnskabsetiske Komiteer for Region Midtjylland (2 komiteer)
Tlf.: +45 78 41 01 83 / +45 78 41 01 82 / +45 78 41 01 81
E-mail: komite@rm.dk
Hjemmeside: www.komite.rm.dk

National Videnskabsetisk Komité
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Hjemmeside: www.nvk.dk

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(S1) Informeret samtykke til deltagelse i et sundhedsvidenskabeligt forskningsprojekt.

Forskningsprojektets titel:

Behandling af nedsat hørelse med cochlear implantat og høreapparat i kombination i forhold til høreapparater alene.

Projektets originale titel: Fordele ved bimodal tilpasning med cochlear implantat og høreapparat sammenlignet med dobbeltsidig høreapparat hos patienter med asymmetrisk taleforståelse: Et kontrolleret lodtrækningsforsøg.

Erklæring fra forsøgspersonen:

Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at miste mine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til, at deltage i forskningsprojektet, og har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Forsøgspersonens navn:_____

Dato: _____ Underskrift: _____

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser for dig?:

Ja _____ (sæt x) Nej _____ (sæt x)

Ønsker du at blive kontaktet ved fremtidige projekter på Høreklinikken/Øre-næse-hals afd.?:

Ja _____ (sæt x) Nej _____ (sæt x)

Erklæring fra den, der afgiver information:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet information: _____

Dato: _____ Underskrift: _____

Projektidentifikation: Sagsnummer 20202000-84

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Statistical analysis plan (SAP) for randomised clinical studies.

Project responsible Consultant Jesper Hvass Schmidt and Ph.D. student Yeliz Jakobsen
Title A Study Protocol for a Randomised Controlled Trial Evaluating the Benefits from Bimodal Solution with Cochlear Implant and Hearing Aids vs. Bilateral Hearing Aids in Patients with Asymmetric Speech Identification Scores.
Deadline 30.07.2024
Study design Randomised controlled trial
Samplesize 60 participants
Aim This randomised controlled trial is designed to improve clinical decision-making for CI candidacy for patients with asymmetric hearing. It is necessary to establish more evidence to support the effectiveness and the fitting optimization of bimodal CI+HA versus HAs in patients with asymmetric hearing.

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The first objective of the study is to evaluate the subjective (SSQ12) and objective (Hearing In Noise Test (HINT) which is word and sentence based and DANTALE I, which is monosyllabic word-based) benefits of a bimodal solution (CI+HA) compared to (HA+HA). The second objective is to compare and evaluate patient self-reported outcomes with NCIQ, THI and DHI in the intervention group (CI+HA) with the control group (HA+HA). The third objective is to evaluate if listening effort, hypothesized to cause fatigue, can be measured objectively by HINT with pupillometry. To minimize listening effort and optimize the fitting of bimodal solution the CI fitting and loudness balancing on individual level will be evaluated.
Hypothesis Patients treated with a CI on the poorer hearing ear and a HA to the better hearing ear (CI+HA) in a bimodal solution have increased objective and subjective measured speech intelligibility compared to patients treated with new bilateral replacement hearing aids (HA+HA).

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2) Data description

See Appendix A

3) The statistical analysis plan (SAP)

Definition of outcome 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.
Definition of treatment variables Treatments are HAs and CI-surgery assigned by randomisation. The primary comparison will be between the CI+HA and HA+HA groups.
Covariates used in analyses Stratified randomisation for thresholds of the ear to be implanted.
Definition of effect size/parameter of interest Primary effect size: Objective outcome: Mean difference in HINT in quiet and in noise between intervention group (HA+CI) and control group (HA+HA) at 3, 6 and 12 months follow-up post- bimodal CI+HA-fitting and 3 months post-HA-fitting respectively.

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Subjective outcome: Mean difference in SSQ-12-scores at 3, 6 and 12 months follow-up post- bimodal CI+HA-fitting and 3 months post-HA-fitting respectively

Definition of Analysis Sets

Strategy for intention to treat analysis with incomplete observations.1)

1. Attempt to follow-up on all randomised participants, even if they withdraw from allocated treatment.
2. Perform a main analysis of all observed data that are valid under a plausible assumption about the missing data.
3. Perform sensitivity analyses to explore the effect of deviations from the assumption made in the main analysis.
4. Account for all randomised participants, at least in the sensitivity analyses.

1)

White, Ian R., Nicholas J. Horton, James Carpenter, and Stuart J. Pocock. 2011. 'Strategy for Intention to Treat Analysis in Randomised Trials with Missing Outcome Data'. *BMJ* 342 (February): d40. https://doi.org/10.1136/bmj.d40.

Analysis specification

A constrained linear mixed model is used to analyse the outcome.

The model will include randomisation group (CI+HA / HA+HA) and time (baseline/follow-up) and their interaction as fixed effects along with the threshold strata that were used in stratifying the randomisation. The model is constrained so that the mean at baseline agrees

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across the two treatment groups adjusted for threshold stratum, which is reasonable due to the randomisation of implant fitting. Patient ID will be included as a random effect to account for the repeated measurements.

Secondary outcomes will be analysed analogously in a constrained linear mixed model adjusting for randomisation strata. Model validation checks will be undertaken as described above, switching to bootstrapping the standard errors when model assumptions are rejected. Covariates such as age and gender will be included in all models.

Sensitivity analysis

Inclusion is performed conditional on Pure Tone Average (PTA) (from 0.5 to 4 kHz) PTA > 40 dB HL and SIS <50% in the ear considered for CI implantation and <70% in the best-aided condition which may lead to a truncation effect in the distribution of baseline measurements. To address this, an analysis of covariance (ANCOVA) model conditioning on the baseline will be used to obtain a sensitivity analysis estimate for the main outcome. (2)

The statistical analysis plan is attached as "supplementary file" along with the Data Description listed in Appendix A.

2)

Liu, Guanghan F., Kaifeng Lu, Robin Mogg, Madhuja Mallick, and Devan V. Mehrotra. 'Should Baseline Be a Covariate or Dependent Variable in Analyses of Change from Baseline in Clinical Trials?: ANALYSES OF CHANGE FROM BASELINE IN CLINICAL TRIALS'. *Statistics in Medicine* 28, no. 20 (10 September 2009): 2509–30. https://doi.org/10.1002/sim.3639.

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DATA DESCRIPTION
APPENDIX A

Variable name	Content	Datatype	Missing	Excepted range (numeric data)
Inc_date	Date of inclusion	ddmmyy	No missing	

Confounders

Age	Age at baseline	numeric	No missing	18-110
Sex		binary	No missing	
Medicine	Pupil-constricting/dilating	numeric	No missing	

Before CI surgery

Variable name	Content	Datatype	Missing	Excepted range (numeric data)
TRESHOLDS Day 0 Baseline	The patient can be tested at frequencies from 125 Hz up to 8 kHz. Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry	Numeric	Missing possible	0 to 120 db HL
HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA right ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence. In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%

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HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Quiet HA right ear	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Missing possible	0-100%
HINT (word) Day 0 Baseline (One month with new replacement HA) Noise HA right ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
HINT (word) Day 0 Baseline (One month with new replacement HA) Noise HA left ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
HINT (word) Day 0 Baseline (One month with new replacement HA) Noise HA+HA	Number of correct words or sentences out of 20 sentences with 5 words pr sentence In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Noise HA right ear	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted.	Numeric	Missing possible	0-100%

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	Multi-talker babble noise.			
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Noise HA left ear	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
HINT (sentence) Day 0 Baseline (One month with new replacement HA) Noise HA+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA) Noise HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA) Noise HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Missing possible	0-100%
SIS free field Auditory Day 0 Baseline (One month with new replacement HA)	Speech identification score in Denmark is percentage correct words out of 25 words.	Numeric	Missing possible	0-100%

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Noise HA left ear	Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.			
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Quiet HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Noise HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Noise HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Audio-visual Day 0 Baseline (One month with new replacement HA) Noise HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped	Numeric	Missing possible	0-100%

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	spectrum representing a real life "babble" noise.			
Peak pupil dilation (PPD) Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at +10dB SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-1
Peak pupil dilation (PPD) Day 0 Baseline (One month with new replacement HA) Noise HA+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at +10dB SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-1
Pupil Peaktime Day 0 Baseline (One month with new replacement HA) Quiet HA+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented at +10dB SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-10sec
Pupil Peaktime Day 0 Baseline (One month with new replacement HA) Noise HA+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented at +10dB SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-10sec
NCIQ Basic sound Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Advanced Sound Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100

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NCIQ Speech production Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Activity limitation Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Social interaction Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Total Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Speech intelligibility Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Spatial hearing Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Hearing quality Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Total Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
THI Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
DHI Day 0 Baseline (One month with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA right ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (word) 3 months Follow-up with new HA	Number of correct words or sentences out of 20 sentences	Numeric	Missing possible	0-100%

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(Total of 4 months with new replacement HA) Quiet HA left ear	with 5 words pr sentence			
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA right ear	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA left ear	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA right ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA left ear	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (word) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	Number of correct words or sentences out of 20 sentences with 5 words pr sentence	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA right ear	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (sentence) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA left ear	Number of correct sentences. (20 sentences in a HINT)	Numeric	Missing possible	0-100%
HINT (sentence) 3 months	Number of correct sentences.	Numeric	Missing possible	0-100%

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Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	(20 sentences in a HINT)			
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB.	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB.	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%

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SIS Headphones Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet	Speech identification score in Denmark is percentage correct words out of 25 words. Comfort speech level. Each ear is tested unaided separately.	Numeric	Missing possible	0-100%
SIS Headphones Auditory 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise	Speech identification score in Denmark is percentage correct words out of 25 words. Comfort speech level. Each ear is tested unaided separately. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB .	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB .	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB .	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65db and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA right ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65db and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing	Numeric	Missing possible	0-100%

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	a real life "babble" noise.			
SIS free field Audio-visual 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA left ear	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65db and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Missing possible	0-100%
Peak pupil dilation (PPD) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-1
Peak pupil dilation (PPD) 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-1
Pupil Peaktime 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Quiet HA+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Missing possible	0-10sec
Pupil Peaktime 3 months Follow-up with new HA (Total of 4 months with new replacement HA) Noise HA+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses	Numeric	Missing possible	0-10sec

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	Measurement & analysis tools			
NCIQ Basic sound 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Advanced Sound 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Speech production 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Self-esteem 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Activity limitation 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Social interaction 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
NCIQ Total 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Spatial hearing 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Hearing quality 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
SSQ Total 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100
THI 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	numeric	Missing possible	0-100

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DHI 3 months Follow-up with new HA (Total of 4 months with new replacement HA)	Questionnaire	Numeric	Missing possible	0-100

After CI surgery

Variable name	Content	Datatype	Missing	Excepted range (numeric data)
TRESHOLDS CI activation day	The patient can be tested at frequencies from 125 Hz up to 8 kHz. Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry	Numeric	Missing possible	0 to 120 db HL
PTA CI activation day	The patient can be tested at frequencies from 125 Hz up to 8 kHz. In free field. In best aided condition. No stimuli.	Numeric	Missing possible	0 to 120 db HL
TRESHOLDS 3 months post bimodal CI+HA-fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry	Numeric	Missing possible	0 to 120 db HL
PTA 3 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. In free field. In best aided condition. No stimuli.	Numeric	Missing possible	0 to 120 db HL
TRESHOLDS 6 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz.	Numeric	Missing possible	0 to 120 db HL

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	Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry			
PTA 6 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. In free field. In best aided condition. No stimuli.	Numeric	Missing possible	0 to 120 db HL
TRESHOLDS 12 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. Tresholds is tested with headphones and , each ear is tested separately, unaided. The masker is only added when there is a air bone gap >10dB at puretone audiometry	Numeric	Missing possible	0 to 120 db HL
PTA 12 months post bimodal CI+HA - fitting	The patient can be tested at frequencies from 125 Hz up to 8 kHz. In free field. In best aided condition. No stimuli.	Numeric	Missing possible	0 to 120 db HL
HINT (word) Post-surgery 3 months after fitting Quiet CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Quiet CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Quiet CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Quiet CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery	Number of correct sentences.	Numeric	Possible	0-100%

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6 months after fitting Quiet CI alone	(20 sentences in a HINT) In free field. Speech level at 65dB HL.			
HINT (sentence) Post-surgery 12 month after fitting Quiet CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Quiet HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Quiet HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Quiet HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL..	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Quiet HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 6 months after fitting Quiet HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 12 months after fitting Quiet HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Quiet CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Quiet CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field.	Numeric	Possible	0-100%

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	Speech level at 65dB HL.			
HINT (word) Post-surgery 12 months after fitting Quiet CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Quiet CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 6 months after fitting Quiet CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 12 months after fitting Quiet CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Noise CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Noise CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Noise CI alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Noise CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted.	Numeric	Possible	0-100%

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	Multi-talker babble noise.			
HINT (sentence) Post-surgery 6 months after fitting Noise CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 12 months after fitting Noise CI alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Noise HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Noise HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Noise HA alone	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Noise HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 6 months after fitting Noise HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL.	Numeric	Possible	0-100%

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	SNR +10 and adapted. Multi-talker babble noise.			
HINT (sentence) Post-surgery 12 months after fitting Noise HA alone	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Noise CI +HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 6 months after fitting Noise CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (word) Post-surgery 12 months after fitting Noise CI+HA	Number of correct words. (5 words per sentences, 20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Noise CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 6 months after fitting Noise CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field. Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 12 months after fitting Noise CI+HA	Number of correct sentences. (20 sentences in a HINT) In free field.	Numeric	Possible	0-100%

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	Speech level at 65dB HL. SNR +10 and adapted. Multi-talker babble noise.			
SIS free field Auditory Post-surgery 3 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 12 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing	Numeric	Possible	0-100%

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	a real life "babble" noise.			
SIS free field Auditory Post-surgery 12 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 12 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%

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SIS free field Auditory Post-surgery 12 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 12 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 3 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 6 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Auditory Post-surgery 12 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Quiet CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%

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SIS free field Audio-visual Post-surgery 12 months after fitting Quiet CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Quiet HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Noise CI+HA	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life “babble” noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a	Numeric	Possible	0-100%

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	speech shaped spectrum representing a real life "babble" noise.			
SIS free field Audio-visual Post-surgery 6 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Noise CI only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 3 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 6 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
SIS free field Audio-visual Post-surgery 12 months after fitting Noise HA only	Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude modulated and has a speech shaped spectrum representing a real life "babble" noise.	Numeric	Possible	0-100%
Peak pupil dilation (PPD) Post-surgery	PPD is calculated based on the number of pixels. PPD of 0.01	Numeric	Possible	0-1

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3 months after fitting Quiet CI only	would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Quiet CI only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Quiet CI only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 3 months after fitting Quiet HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Quiet HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive	Numeric	Possible	0-1

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	SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Quiet HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 3 months after fitting Quiet CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Quiet CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Quiet CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD)	PPD is calculated based on the number	Numeric	Possible	0-1

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Post-surgery 3 months after fitting Noise CI only	of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Noise CI only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Noise CI only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 3 months after fitting Noise HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Noise HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive	Numeric	Possible	0-1

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	SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Noise HA only	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 3 months after fitting Noise CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 6 months after fitting Noise CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1
Peak pupil dilation (PPD) Post-surgery 12 months after fitting Noise CI+HA	PPD is calculated based on the number of pixels. PPD of 0.01 would mean 1% change in pupil dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-1

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Pupil Peaktime Post-surgery 3 months after fitting Quiet CI only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 6 months after fitting Quiet CI only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
Pupil Peaktime Post-surgery 12 months after fitting Quiet CI only	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
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	+10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
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	SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools			
Pupil Peaktime Post-surgery 12 months after fitting Noise CI+HA	The time it takes for the pupil to reach peak dilation. HINT sentence presented speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil Labs glasses Measurement & analysis tools	Numeric	Possible	0-10sec
NCIQ Basic sound Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Advanced Sound Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Speech production Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Self-esteem Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Activity limitation Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Social interaction Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Total Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Basic sound Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Advanced Sound Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Speech production Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Self-esteem Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Activity limitation Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Social interaction Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100

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NCIQ Total Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Basic sound Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Advanced Sound Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Speech production Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Self-esteem Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Activity limitation Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Social interaction Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
NCIQ Total Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Speech intelligibility Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Spatial hearing Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Hearing quality Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Total Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Speech intelligibility Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Spatial hearing Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Hearing quality Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Total Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Speech intelligibility Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Spatial hearing Post-surgery	Questionnaire	numeric	Possible	0-100

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12 months after fitting				
SSQ Hearing quality Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
SSQ Total Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
THI Post-surgery 2 weeks before fitting	Questionnaire	numeric	Possible	0-100
THI Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
THI Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
THI Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100
DHI Post-surgery 2 weeks before fitting	Questionnaire	numeric	Possible	0-100
DHI Post-surgery 3 months after fitting	Questionnaire	numeric	Possible	0-100
DHI Post-surgery 6 months after fitting	Questionnaire	numeric	Possible	0-100
DHI Post-surgery 12 months after fitting	Questionnaire	numeric	Possible	0-100

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-6
	2b	Specific objectives or hypotheses	5-6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-10
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	10-12
Participants	4a	Eligibility criteria for participants	10-12
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	12-13
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	13-15
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	9-10
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	9-10
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	9-10/14-15
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

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		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	14-15
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	14-15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	14-15
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	1, 2, 16, 17
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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SPIRIT 2013 Checklist for the ReTrain pilot RCT: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2,7,17
	2b	All items from the World Health Organization Trial Registration Data Set	Yes, clinicaltrials.org
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	17
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1,17
	5b	Name and contact information for the trial sponsor	1,17
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	17

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Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-6
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	1,7,9,10
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	11
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10,13-15, Appendix A

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Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	8-9,11-13 Appendix A, Figure 1 and 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14, Table 1
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7-10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	9-10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	9-10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	9-10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	9-10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	9-10
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	13-15, statistical plan(SAP), Data management plan(DMP)

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	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13-15, SAP, DMP,
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13-15, SAP, DMP, Appendix A
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-15, SAP
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13-15, SAP
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13-15, SAP
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	17
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	13-15, SAP
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2,7,16

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Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13-15, SAP
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	2,9,11,16
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	2,9,11,16
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17,MAP
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Consent form
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	17
	31b	Authorship eligibility guidelines and any intended use of professional writers	17
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	MAP
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	As online supplementary file
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

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