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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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3 4	1	A Study Protocol for a Dandomicod Controllod Trial Evaluating
5 6	1 2	A Study Protocol for a Randomised Controlled Trial Evaluating the Benefits from Bimodal Solution with Cochlear Implant and
7	2 3	Hearing Aid vs. Bilateral Hearing Aids in Patients with
8 9	3 4	Asymmetric Speech Identification Scores.
10 11	4 5	Asymmetric speech identification scores.
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19 20	13	*Correspondence to Dr. Yeliz Jakobsen; <u>Yeliz.jakobsen@rsyd.dk</u>
21	14	Date: Sunday, 21 <sup>st</sup> August 2022
	15 16	Version: 3
24	17	
25 26	18	Abstract
27 28		
29	19	Introduction
30 31 32	20	Cochlear implant (CI) and hearing aid (HA) in a bimodal solution (CI + HA) is compared to
33 34	21	bilateral HAs (HA +HA) to test if the bimodal solution result in better speech intelligibility and
35 36	22	self-reported quality of life.
37	22	
38 39	23	
40 41 42	24	Methods and Analysis
43 44	25	This randomised controlled trial (RCT) is conducted in Odense University Hospital, Denmark.
45 46	26	Sixty adult bilateral HA users referred for CI surgery is enrolled if eligible and undergo:
47 48 49	27	audiometry, speech perception in noise (HINT: Hearing in Noise Test), Speech Identification
49 50 51	28	Scores (SIS) and video head impulse test (v-HIT). All participants will receive new
52 53	29	replacement HAs. After one month they will be randomly assigned (1:1) to the intervention
54 55	30	group (CI+HA) or to the delayed intervention control group (HA+HA). The intervention group
56 57 58 59 60	31	(CI+HA) will receive a CI on the ear with a poorer speech recognition score and continue

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4 5	32	using the HA on the other ear. The control group (HA+HA) will receive a CI after a total of 4
6 7	33	months of bilateral HA use.
8 9 10	34	The primary outcome measures are Speech intelligibility measured objectively with HINT
11 12	35	(sentences in noise) and DANTALE I (words) and subjectively with the Speech, Spatial and
13 14 15	36	Qualities of Hearing scale questionnaire (SSQ-12). Secondary outcomes are patient reported
	37	Health-Related Quality of Life (HRQoL) scores assessed with the Nijmegen Cochlear Implant
18 19	38	Questionnaire (NCIQ), the Tinnitus Handicap Inventory (THI) and Dizziness Handicap
20 21 22	39	Inventory (DHI). Third outcome is listening effort assessed with pupil dilation during HINT
	40	In conclusion, the purpose is to improve clinical decision-making for CI candidacy and
25 26	41	optimize bimodal solutions.
27 28 29	42	
30 31	43	Ethics and Dissemination
32 33 34	44	This study protocol was approved by the Ethics Committee Southern Denmark project ID S-
35 36	45	20200074G. All participants are required to sign an informed consent form.
37 38	46	This study will be published upon completion in a peer-reviewed publications and scientific
39 40 41	47	conferences.
42 43	48	
44 45 46	49	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

#### 5 Background

66 Cochlear implants (CIs) have been used to restore hearing in individuals with severe to 67 profound sensorineural hearing loss. Initially, most patients receiving a cochlear implant were 68 profoundly deaf in both ears. (1, 2) However, recently it has become more common to implant 69 patients with significant residual hearing in the affected ear, as well as in patients with 70 asymmetric hearing loss and single-sided deafness, with significant residual hearing or normal 71 hearing on the contralateral side.(3, 4) A CI in one ear and a HA in the other ear can provide 72 enhanced hearing performance in patients with asymmetrical hearing.(5, 6) The combination 73 of CI and HA is referred to as bimodal hearing or bimodal solution.(7)

#### 5 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  $\geq$  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  $\leq 60\%$  (8). The Danish CI candidacy criteria consists of SIS (without HAs, measured with headphones)  $\leq$ 45% and a SIS  $\leq$ 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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$^{4}_{5}$ 101	The question is if the bimodal benefits are bigger than the bilateral hearing aid condition
$_{7}^{6}$ 102	when they are well fitted?
8 9 103 10	This study will therefore support and strengthen the preoperative clinical decision to
$^{11}_{12}104$	recommend a bimodal solution with a CI and a HA versus the continuous use of bilateral HAs.
13 14105 15	This may offer the patient faster and more effective treatment because delaying the surgery
<sup>16</sup> 106 17	may not be beneficial.
<sup>18</sup> 19 <sup>107</sup>	
20 21100	Dationt Deported Outcome Measures
<sup>21</sup> 108 22 23	Patient-Reported Outcome Measures
24109 25	Benefits of the CI are measured subjectively with Patient-Reported Outcome Measures
<sup>26</sup> 110 27	(PROMs) as SSQ12, NCIQ, THI and DHI.(17-24)
28 29111	
30 31112	The validity and reproducibility of the Danish version of THI has been reported(24). SSQ12,
32	
<sup>33</sup> 113 34	DHI, NCIQ have all been translated into Danish and backward translated to English following a
35 36114 37	cultural adaption and pilot-testing to ensure correct understanding of the questionnaires.
38115 39	Test-retest reliability has been assessed as well.(18, 20, 22)
<sup>40</sup> 116	
41 42	Listonia - Effort
43117 44	Listening Effort
45 46118	Patients with CI often experience high levels of listening effort, they often report that
47 48119 49	understanding speech causes high levels of increased sustained effort which results in
<sup>49</sup> 50120 51	feelings of fatigue.(25) These feelings may lead patients to withdraw socially due to the
<sup>52</sup> 121 53 54	stresses involved in communication even though they may not specifically report difficulties
55122	with speech understanding.(19)
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4 123 5	Effort in listeners with NH can be reflected by the relationship between speech intelligibility
6 7 124 8	and pupil-dilation.(26) Listening effort has been defined as the "Deliberate allocation of
9 125 10	mental resources to overcome obstacles in goal pursuit when carrying out a task" and is the
$^{11}_{12}126$	basis for the Framework for Understanding Effortful Listening (FUEL) model.(27)
13 14127 15	Understanding speech in challenging hearing environments results in increased auditory and
16128 17	cognitive processing which can be observed objectively by measuring the pupil dilation
<sup>18</sup> 129	during speech perception in noise, in a task such as the HINT(28-30)
20 21130 22	
<sup>23</sup> 131 24	Rationale and Objectives
25 26132 27	This randomised controlled trial is designed to improve clinical decision-making for CI
<sup>28</sup> 133 29	candidacy for patients with asymmetric hearing. It is necessary to establish more evidence to
<sup>30</sup> 31134	support the effectiveness and the fitting optimization of bimodal CI+HA versus HAs in patients
32 33135 34	with asymmetric hearing.
<sup>35</sup> 136 36	The first objective of the study is to evaluate the subjective (SSQ12) and objective (Hearing In
37 38 137 39	Noise Test (HINT) which is word and sentence based and DANTALE I, which is monosyllabic
40138 41	word-based) benefits of a bimodal solution (CI+HA) compared to (HA+HA).
<sup>42</sup> 139 43	The second objective is to compare and evaluate patient self-reported outcomes with NCIQ,
44 45 46	THI and DHI in the intervention group (CI+HA) with the control group (HA+HA).
47141 48	The third objective is to evaluate if listening effort, hypothesized to cause fatigue, can be
<sup>49</sup> 142 50	measured objectively by HINT with pupillometry.
51 52143 53	To minimize listening effort and optimize the fitting of bimodal solution the CI fitting and
54144 55	loudness balancing on individual level will be evaluated.(2, 31, 32)
<sup>56</sup> 145 57	
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1 2	
3 4 5 147	Methods and Analysis
6 7 148 8	Study Design, Ethics and Registration
9 10149 11	This study is a prospective randomised controlled trial based on a single centre conducted in
<sup>12</sup> 150 13	Odense University Hospital, Denmark. The study started 01/02/2022 and is expected to end
14 15 15	30/07/2024. It was successfully registered at ClinicalTrials.gov with registration number:
16 17152 18	NCT04919928.
<sup>19</sup> 153 20	This study has been approved at Research Ethics Committee Southern Denmark (Projekt-ID:
21 22 154 23	S-20200074G) 21 <sup>st</sup> August 2020 to 31 <sup>st</sup> December 2024.
23 24155 25	
<sup>26</sup> <sub>27</sub> 156	Study Population
28 29157 30	Sixty participants with bilateral hearing-loss and asymmetric speech identification scores
<sup>31</sup> 158 32	referred for CI surgery will be included (Figure 1).
33 34159 35	
<sup>36</sup> 160 37	Inclusion Criteria
38 39161 40	• Adults >18 years old.
<sup>41</sup> 42162	• Fluent in Danish, including reading and writing
43 44163 45	Acquired post-lingual deafness
45 46 47	• Use of bilateral HAs for at least one year prior to evaluation for cochlear implantation
48 49165	candidacy. This to ensure, that both ears have received auditive stimulation
50 51166 52	• PTA > 40 dB HL in the ear considered for CI implantation and PTA $\geq$ 40 and $\leq$ 70dB HL in
<sup>53</sup> 54 <sup>167</sup>	the contralateral ear in best aided condition, in quiet and in noise and in free field.
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$\frac{4}{5}$ 168	• SIS <70% in best aided condition in the ear considered for CI implantation and SIS $\geq$ 30%
6 7 169	and $\leq$ 70% in best aided condition in the contralateral ear, in quiet and in noise and in
8 9 170 10	free field.
11 12171	Exclusion Criteria
13 14 15172	• Vestibular loss in the ear not considered for CI implantation
16 <sup>17</sup> 173 18	• Surgical issues interfering with the site of implantation or anatomical contraindications
18 <sup>170</sup> 19 20174	such as cochlear malformations, which will be determined using MRI or CT-scans.
2017 1 21 22175	<ul> <li>Auditory nerve lesions.</li> </ul>
23	
<sup>24</sup> 25 26	Central auditory pathway pathologies.
27177 28	• Otosclerosis.
<sup>29</sup> 178 30	Single sided deafness (SSD).
31 32179	
33 34	
35180 36	Setup
37 38181 39	A timeline of the study is shown in (Figure 2).
40182 41	All enrolled participants will be tested with audiometry and v-HIT to determine hearing
42 43 183	thresholds and status of balance function during the first visit. Patients will receive new
44 45184 46	replacement HAs. These HAs will be fitted during the second visit and if necessary refitted at
40 47185 48	every visit in the clinic throughout the study. The baseline measurements will be conducted
49 50 <sup>186</sup>	when both groups have used the new replacement HAs to ensure acclimatisation. The
51 52187 53	measurements are SIS in quiet and in noise with a signal-to-noise ratio (SNR) of 0dB using
<sup>54</sup> 188 55	DANTALE I speech material. The speech and masking white noise stimulus will be presented at
<sup>56</sup> 57189	65 dB SPL in the free field. Stimuli will be presented as auditory stimuli only as well as with
58 59190 60	visual cues, the latter to allow participants to use lipreading cues.

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4 191	Pupillometry variables are Peak Pupil Dilation (PPD), Mean Pupil Dilation (MPD), peak-time
6 7 192 8	and standard deviation using HINT (sentences and words).
9 193 10	The HINT sentences are presented at a speech level of 65dB and initially an adaptive SNR is
<sup>11</sup> 194	used to identify the SNR of 70% correct word recognition. The SNR at 70% correct word
13 14195 15	recognition is used as a fixed SNR during HINT test. The noise is multi-talker babble noise, in
16196 17	free field, tested in best aided condition. The pupillometry glasses is the Oticon Medical Pupil
<sup>18</sup> 197 20 21198 22	Labs glasses.
23 24199 25	Recruitment, Stratification, Randomisation and Allocation
<sup>26</sup> 200 27	All eligible participants will sign a written, informed consent (supplementary file 1) in clinic
28 29201 30	after receiving verbal and written study information in Danish. The Danish consent form is
31202 32	available online at the Odense University Hospital Research Unit website.(33)
<sup>33</sup> 203 <sub>34</sub> 35	To ensure acclimatisation, participants will receive new replacement HAs fitted with the
<sup>35</sup> 36204 37	National Acoustic Laboratories (NAL) -non-linear (NL)2 fitting algorithm one month before
38205 39	the experiment.
<sup>40</sup> 206 41 42	They will then undergo stratification, depending on the hearing thresholds. One group will
42 43207 44	consist of participants with PTA $\geq$ 70dB HL; and the other group will consist of subjects with
45208 46 47	PTA $\leq$ 70dB HL and $\geq$ 40 dB HL according to the inclusion criteria. The reason for this
<sup>47</sup> 209 48 49	stratification is because pre-operative hearing thresholds may affect the measured outcomes
50210	in the study. Stratification ensures that both the intervention group and the control group will
52211 53 54242	have an equal distribution of patients with profound hearing loss on the ear considered for
<sup>54</sup> 212 55 57213 58 59 60	implantation.

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$\frac{4}{5}$ 214	Then the participants will be randomly allocated into two groups: the intervention group
6 7 215	(CI+HA) and the control group (HA+HA) according to 1:1 ratio using a blocked randomisation
8 9 216 10	with randomly varying block size (4 or 6).
$^{11}_{12}217$	This randomisation will be accomplished using a computer-generated random sequence in
13 14218 15	Research Electronic Data Capture (REDCap), hosted by Odense Patient Explorative Network
16219 17	(OPEN) in the Region of Southern Denmark and developed by Vanderbilt University,
<sup>18</sup> 19220	Nashville, Tennessee, United States.(34)
20 21221 22	REDCap will also be used to send out the questionnaires to the participants' online mailbox
<sup>23</sup> 222 24	(called Eboks in Denmark) throughout the study (see timeline (Figure 2)) and automatically
<sup>25</sup> 26223 27	save the data.
27 28224 29	Participants will have the opportunity to return to their original HAs if they prefer to do so
<sup>30</sup> 225 31	after one-month of acclimatisation.
<sup>32</sup> 33226 34	
35 <u>22</u> 7 36	Control Group
37 38228	Thirty patients, who will be age-matched, randomised and allocated to the control group
39 <sup>40</sup> 229 41	HA+HA will continue the use of the new replacement HAs for another three months (total four
42 43230	months of new replacement HA+HA use), serving as the delayed intervention control group.
44 45231 46	
47 48232	Intervention Group
49 <sup>50</sup> 233 51	Thirty patients, who will be age-matched, randomised and allocated to the intervention group
<sup>52</sup> 53234	CI+HA will undergo surgery as soon as possible after the HA acclimatisation period.
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3 4 5 237	HA Fitting
6 7 238 8	The participant will receive either Phonak (Phonak Link M) or GN (ReSound LiNX Quattro or
9 10 <sup>239</sup>	Resound ENZO Q) based on their personal preference. Both these HA models can be fitted
11 12240	with a CI by Advanced Bionics and Cochlear, respectively.
13 14241	The HAs will be fitted according to NAL-NL2 procedures prescriptive fitting formula, which
15 16 17242	optimizes audibility in the bimodal solution(2) and will be verified with REM (Real Ear
18 19243	Measurement) to ensure that the HA is providing adequate gain and then further adjusted for
20 21244	comfort based on patient feedback.(35)
22 23 24 245	The new HAs will be prescribed to the patients free of charge and future service will also be
24 25 26246	free of charge.
27 28247	Participants can drop out of the study if they do not want CI surgery. Collected data will be
<sup>29</sup> <sup>30</sup> <sub>31</sub> 248	analysed if the patient still consents.
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<sup>35</sup> 250 <sub>36</sub> 37	CI fitting
38251 39	The CI will be selected depending on the participant's HA selection; that is, the CI that is
40 41 252	compatible with the HA will be selected in order to ensure the most optimal bimodal fitting.
42 43253 44	One-month post-surgery, the CI will be activated according to the settings and stimulation
45254 46	strategy based on patient's feedback. The CI will then be fitted with the HA according to the
47 48255	bimodal fitting formula allowing the HA to keep the NAL-NL2 fitting along with the wireless
49 50256	connection with the CI. (36, 37)
51 52257 53	Patients hearing thresholds will be tested on CI activation day. The residual hearing will not
<sup>54</sup> 258	be stimulated in this study.
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3 4 5 260	All participants are offered standard rehabilitation with a speech therapist, including three
6 7 261	visits a week up to 10 weeks following the initial fitting.
8 9 262 10	The training focuses on learning to identify different sounds from the environment and word
$^{11}_{12}263$	discrimination.
13 14264 15	The new CI will also be prescribed to the patients free of charge and future service will be free
16265 17	of charge as well.
<sup>18</sup> 266 19266 20	
21267 22	Loudness Balancing
<sup>23</sup> <sub>24</sub> 268	At 3- months follow-up the post-surgery complications will be evaluated and the levels in the
25 26269 27	CI will be adjusted if necessary.
<sup>28</sup> 270 29	In the loudness balancing procedure, the patient will have both the hearing aid and CI
<sup>30</sup> 31271 32	activated and at the 6-month follow-up, when the CI mapping levels are stable, patients will
32 33272 34	be randomised and assigned to one of three bimodal fitting groups:
<sup>35</sup> 273 36	Group A) will not complete any specific loudness balancing procedures, CI and HA will be
<sup>37</sup> 38274 39	fitted based on individual feedback from the patient.
40275 41	Group B) will be fitted/finetuned using a bimodal loudness balancing task at a medium input
<sup>42</sup> 276 43	level and adjusted based on the patient feedback. The audiologist will present a mid-level
44 45277 46	sound (approx. 55dB SPL (sound pressure level)) at the center-speaker.
47278 48	Group C) will be fitted/finetuned using a bimodal loudness balancing task as group B but the
<sup>49</sup> 279 50	audiologist will play three levels and adjust the gain for three input levels (soft, medium, and
<sup>51</sup> 52280 53	loud) according to the patient feedback.
54281 55	For both groups B and C, the patient will be given a 'Bimodal Fusion' illustration (see Figure 3)
56282 57 58 59 60	and asked to provide feedback about the location of the sound by tracing over the line of the

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4 5 283	head. The HA gain will be adjusted using the bimodal adjustment option until the patient
6 7 284	reports that the sounds are perceived at the center of the head.(24)
8 9 285 10	
11 12286	Primary Outcome
13 <sup>14</sup> 287 15	Primary outcomes are Speech intelligibility scores measured objectively with HINT
<sup>16</sup> 17 <sup>288</sup>	(sentences and words) and DANTALE I and subjectively with Speech, Spatial and Qualities of
18 19289 20	Hearing scale (SSQ-12). (9, 10, 22)
<sup>21</sup> 290 22	
23 24291 25	Secondary Outcome
<sup>26</sup> 292 27	Patient reported outcomes scores assessed with the Nijmegen Cochlear Implant
28 29293	Questionnaire (NCIQ), The Tinnitus Handicap Inventory (THI) and Dizziness Handicap
30 31294 32 <sup>33</sup> 295 34	Inventory (DHI). (18, 20, 24)
35 36296 37	Third Outcome
<sup>38</sup> 297 39 <sup>40</sup> 41298 42	Listening effort assessed with pupil dilation with HINT.(10)
43 44299	Statistics
45 46 47 48	Power calculation
<sup>49</sup> 50301	Power calculations with a power of 0.8 with a significance level of 0.05 have been made with
51 52302 53	STATA IC-15 using standard deviations for the HINT test and expected effect size (38) the
54303 55	NCIQ(18), and the SSQ (internal communication with BEAR (Better Hearing Rehabilitation)
<sup>56</sup> 304	study on hearing aid use in Denmark) (Table 1). An estimated within participant standard
<sup>58</sup> 59305 60	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%) ineach 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)

8 1. Attempt to follow-up on all randomised participants, even if they withdraw from

<sup>6</sup>319 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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7 8 326 9	Analysis specification
10 11327 12	A constrained linear mixed model is used to analyse the outcome.
<sup>12</sup> 13328 14	The model will include randomisation group (CI+HA / HA+HA) and time (baseline/follow-up)
15 16 <sup>329</sup>	and their interaction as fixed effects along with the threshold strata that were used in stratifying
17 18330 19	the randomisation. The model is constrained so that the mean at baseline agrees across the two
<sup>20</sup> 331 21	treatment groups adjusted for threshold stratum, which is reasonable due to the randomisation
22 23332 24	of implant fitting. Patient ID will be included as a random effect to account for the repeated
25333 26	measurements.
<sup>27</sup> 334 28 20	Secondary outcomes will be analysed analogously in a constrained linear mixed model
29 30335 31	adjusting for randomisation strata. Model validation checks will be undertaken as described
32336 33	above, switching to bootstrapping the standard errors when model assumptions are rejected.
<sup>34</sup> <sub>35</sub> 337 36 <sup>37</sup> <sub>38</sub> 338 39	Covariates such as age and gender will be included in all models.
40 41339 42	Sensitivity analysis
43 44340 45	Inclusion is performed conditional on Pure Tone Average (PTA) (from 0.5 to 4 kHz) PTA $> 40$
<sup>46</sup> 341 47	dB HL and SIS <50% in the ear considered for CI implantation and <70% in the best-aided
48 49342 50	condition which may lead to a truncation effect in the distribution of baseline measurements.
51343 52	To address this, an analysis of covariance (ANCOVA) model conditioning on the baseline will be
53344 54 55	used to obtain a sensitivity analysis estimate for the main outcome.(40)
56345 57	The statistical analysis plan is attached as "supplementary file" along with the Data Description
<sup>58</sup> 346 59 60	listed in Appendix A (supplementary file 3).

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6 7 348 8	Patient and Public Involvement
9 10349 11	A focus-group interview was established with six cochlear implant patients. The patients
<sup>12</sup> 350 13	commented on their decision to transition from HA to CI. Based on the feedback from the
14 15351	focus group, the research questions were developed.
16 17352 18	The patients also reported problems with adjustments of the CI, when meeting the audiologist
<sup>19</sup> 353 20	for CI adjustment controls.
<sup>21</sup> 22 <sup>354</sup>	
23 24 25 25	Ethics and Dissemination
26 27356 28	Ethics approval for the conduct of this study was obtained from the Ethics Committee
<sup>29</sup> 30 <sup>357</sup>	Southern Denmark, 21 <sup>st</sup> August 2020 project ID S-20200074G.
31 32358 33	The project is approved by the Danish Data Protection Agency (file no. 20/22868) in Region
34359 35	South Denmark.
<sup>36</sup> 37360	All participants are treated according to current clinical standards regardless of the
38 39361 40	randomised study participation. The participants are volunteers and can at any moment
<sup>41</sup> 362 42	withdraw their participation in the study without affecting their current or future treatment
43 44363 45	rights.
<sup>46</sup> 364 47	The Informed Consent form will be found online and it will be signed by all participants willing
48 49365 50	to participate the study and stored in their electronic journals in Department of Audiology,
51366 52	Odense University Hospital. All patients are given both oral and written information about the
<sup>53</sup> 367 54	study.
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6 7 371 8	Results
9 10 <sup>372</sup>	Results will be presented at national and international congresses and published in the
11 12373 13	scientific literature for the attention of professional and scientific audiences on behalf of all
14374 15	study sites and collaborators. A lay summary report will be published for patients and
<sup>16</sup> 17375	members of the public.
18 19376	
20 21	Feetretee
<sub>22</sub> 377 23	Footnotes
24378 25	Authors' Contributions:
26379	YJ and JHS are involved in the conception of the study. LCA and JHS wrote the grant application and the draft of the
<sup>27</sup> 28380	manuscrift. JHS and YJ designed and revised the draft methodological content. YJ reviewed the manuscript and JHS critiqued
<sup>29</sup> 381 30	it.
31382 32	Funding:
32 33383	This study is funded by William Demant grant no. 19-3470 and Interfond grant no. 33.188
<sup>34</sup> 35 <sup>384</sup>	Competing Interests:
<sup>36</sup> 385	None declared.
38386	Contributership Statement/Acknowledgements:
39 40387	We are very thankful of the academiz English editing of Ph.D. Kathleen Faulkner Scalzo and Assistant Professor Lindsey Van
41 42 <sup>388</sup>	Yper.
<sup>43</sup> 389	We are grateful for the contribution from the patient advisers.
<sup>45</sup> 390	Protocol and Registration:
46 47391	This study is registered in ClinicalTrials.gov: NCT04919928
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53394 54395	Reference List
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#### 3 4 Figure 1 5 6 7 Identification 8 Assessed for eligibility (n=) 9 10 Excluded (n=) Enrolment of sixty participants who 11 Not meeting inclusion criteria (n= ) will receive new replacement HAs 12 Declined to participate (n= ) one month before randomization Eligibility Other reasons (n= ) 13 14 Baseline (n=60)Baseline 15 16 17 18 Randomization 1:1 (n=60) 19 Allocation Control group (n=30) 20 Continuous HA+HA treatment (n=) Intervention group (n=30) Decline to proceed with new replacement HAs 21 Received CI surgery (n= ) (n=) Did not receive CI surgery (n=) 22 23 24 25 3 months follow-up 26 Surgery **CI SURGERY** (4 months of new replacement HAs use, 3 months 27 after randomization) 28 Lost to follow-up (n=) 29 èlien 30 31 32 **CI SURGERY CI+HA** fitting 33 34 35 36 **CI+HA** fitting 37 38 3 months after initial bimodal CI+HA fitting 39 Lost to follow-up (n= ) 40 Discontinued intervention (n= ) 41 3 months after initial bimodal CI+HA fitting 42 Lost to follow-up (n= ) 43 Discontinued intervention (n= ) 44 45 Follow-up 46 6 months after initial bimodal CI+HA fitting 47 Lost to follow-up (n= ) 48 49 Discontinued intervention (n= ) 6 months after initial bimodal CI+HA fitting 50 51 Lost to follow-up (n= ) 52 Discontinued intervention (n= ) 53 54 55 12 months after initial bimodal CI+HA fitting 56 57 Lost to follow-up (n= ) 58 Discontinued intervention (n= ) 59 12 months after initial bimodal CI+HA fitting 60 Lost to follow-up (n= ) Discontinued intervention (n= )

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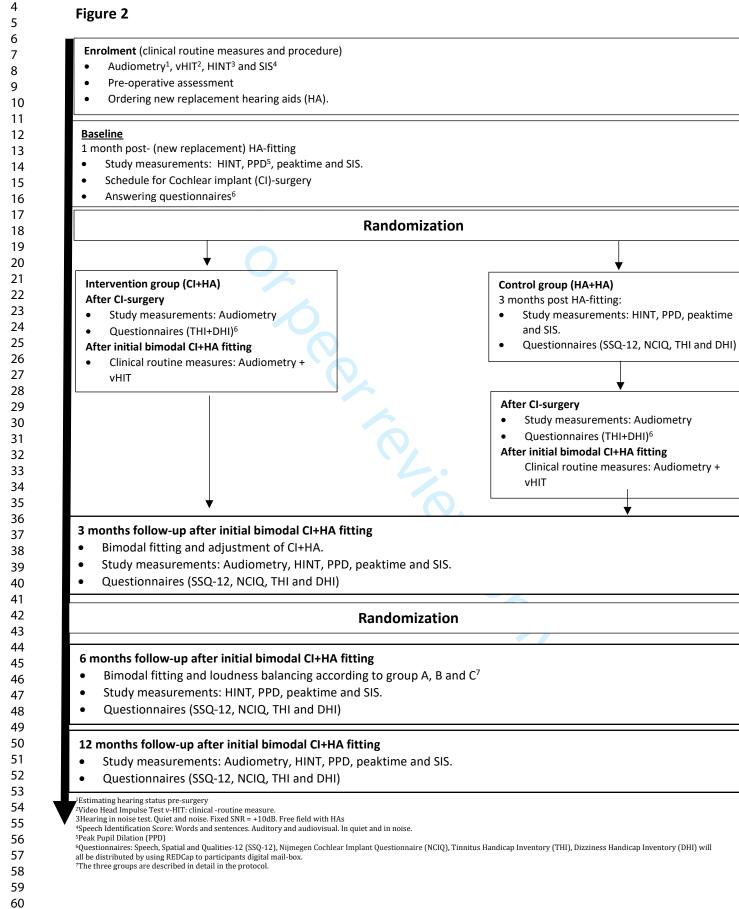
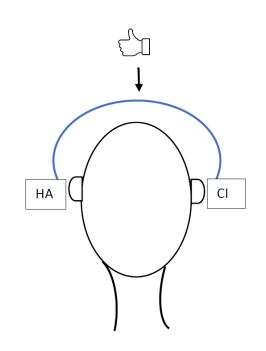


Figure 3



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)

## **Deltagerinformation**

-om deltagelse i et videnskabeligt forsøg

## Behandling af nedsat hørelse med cochlear implantat (CI) 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 

Øre-Næse-Halskirurgisk/Høreklinikken

**Odense Universitetshospital** 

#### 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.

> 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.

P. P. O.

#### 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 taleforstålighed. 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.

#### 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.

#### 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.

#### 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".

#### KONTAKTPERSONER

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

#### **PROJEKTKOORDINATOR:**

Læge Yeliz Jakobsen

Yeliz.jakobsen@rsyd.dk

Tlf: 65412536

#### FORSØGSANSVARLIG LÆGE:

Jesper Hvass Schmidt overlæge, ph.d. Øre-næse-hals/Høreklinikken afd. F Odense Universitetshospital Klinisk lektor, Klinisk Institut Syddansk Universitet Jesper.schmidt@rsyd.dk Tlf: 65412536

#### **BILAG:**

- "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt"
- Komitesystemets fortrykte samtykkeerklæringer.

#### 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

#### Den Videnskabsetiske Komité for Region Sjælland

Tlf.: +45 93 56 60 00 E-mail: RVKsjaelland@regionsjaelland.dk Hjemmeside: https://www.regionsjaelland. dk/sundhed/forskning/forfagf olk/videnskabsetiskkomite/Sider/default.aspx

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

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

#### National Videnskabsetisk Komité Tlf.: +45 72 21 68 55

E-mail: kontakt@nvk.dk Hjemmeside: www.nvk.dk

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#### 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 <u>frivilligt at deltage</u>, 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:		

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

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

 $Ja \_ (sæt x) \qquad Nej \_ (sæt x)$ 

#### 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



#### 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.



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).

## 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.



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. <u>https://doi.org/10.1136/bmj.d40</u>.

#### **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/followup) 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. (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. <u>https://doi.org/10.1002/sim.3639</u>.



For peer terier only

DATA DESCRIPTION APPENDIX A							
Variable name		Content		Datatype	9	Missing	Excepted range (numeric data)
Inc_date		Date of incl	usion	ddmmy	/	No missin	
Age		<b>C</b> Age at base	onfou	Inde		No missin	g 18-110
Sex				binary		No missin	0
Medicine		Pupil- constricting	/dilating	numeric		No missin	g
Variable name	Cor	Befo	ore Cl Dataty		<b>Sery</b> Miss		Excepted range
TRESHOLDS Day 0 Baseline	tested from 1 kHz. Tresho with h each e separa The m added air bon pureto	ttient can be at frequencies 25 Hz up to 8 olds is tested eadphones and , ar is tested tely, unaided. asker is only when there is a ne gap >10dB at ne audiometry	Numeric		Missing		(numeric data) 0 to 120 db HL
HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA right ear HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Numb words out of with 5 senten In free Speecl HL. Numb words out of with 5 senten In free	er of correct or sentences 20 sentences words pr ce. field. n level at 65dB er of correct or sentences 20 sentences words pr ce	Numeric			possible	0-100%

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HINT (word)	Number of correct	Numeric	Missing possible	0-100%
Day 0	words or sentences			
Baseline (One month with new	out of 20 sentences with 5 words pr			
replacement HA)	sentence			
Quiet	In free field.			
HA+HA	Speech level at 65dB			
	HL.			
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
Day 0 Baseline	sentences.			
(One month with new	(20 sentences in a HINT)			
replacement HA)	In free field.			
Quiet	Speech level at 65dB			
HA right ear	HL.			
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
Day 0 Baseline	sentences. (20 sentences in a			
(One month with new	HINT)			
replacement HA)	In free field.			
Quiet	Speech level at 65dB			
HA left ear HINT (sentence)	HL. Number of correct	Numeric	Missing possible	0-100%
Day 0	sentences.		61	
Baseline	(20 sentences in a			
(One month with new	HINT)			
replacement HA) Quiet	In free field. Speech level at 65dB			
HA+HA	HL.			
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
Day 0	words or sentences			
Baseline (One month with new	out of 20 sentences			
replacement HA)	with 5 words pr sentence			
Noise	In free field.			
HA right ear	Speech level at 65dB			
	HL.			
	SNR +10 and adapted. Multi-talker babble			
	noise.			
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
Day 0	words or sentences			
Baseline (One month with new	out of 20 sentences with 5 words pr			
replacement HA)	sentence			
Noise	In free field.			
HA left ear	Speech level at 65dB			
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HINT (word)	Number of correct	Numeric	Missing possible	0-100%
Day 0 Baseline	words or sentences out of 20 sentences			
(One month with new	with 5 words pr			
replacement HA)	sentence			
Noise	In free field.			
HA+HA	Speech level at 65dB HL.			
	SNR +10 and adapted.			
	Multi-talker babble noise.			
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
Day 0	sentences.			
Baseline (One month with new	(20 sentences in a HINT)			
replacement HA)	In free field.			
Noise	Speech level at 65dB			
HA right ear	HL.			
	SNR +10 and adapted.			

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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 is calculated	Numeric	Missing possible	0-1
(PPD)	based on the number	rumene	witssing possible	0-1
Day 0	of pixels. PPD of 0.01			
Baseline	would mean 1%			
(One month with new	change in pupil			
replacement HA)	dilation.			
Quiet	HINT sentence			
HA+HA	presented at +10dB SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Peak pupil dilation	PPD is calculated	Numeric	Missing possible	0-1
(PPD)	based on the number			
Day 0 Baseline	of pixels. PPD of 0.01 would mean 1%			
(One month with new	change in pupil			
replacement HA)	dilation.			
Noise	HINT sentence			
HA+HA	presented at +10dB			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Missing possible	0-10sec
Day 0	the pupil to reach			
Baseline	peak dilation.			
(One month with new	HINT sentence presented at +10dB			
replacement HA) Ouiet	SNR, multi-talker			
HA+HA	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			0.40
<b>Pupil Peaktime</b> Day 0	The time it takes for the pupil to reach	Numeric	Missing possible	0-10sec
Day 0 Baseline	peak dilation.			
(One month with new	HINT sentence			
replacement HA)	presented at +10dB			
Noise	SNR, multi-talker			
HA+HA	babble noise			
	Oticon Medical Pupil			
	Labs glasses Measurement &			
	analysis tools			
NCIQ	Questionnaire	numeric	Missing possible	0-100
Basic sound	-			
Day 0				
Baseline				
(One month with new				
replacement HA) NCIQ	Questionnaire	numeric	Missing possible	0-100
Advanced Sound	Questionnane	namene	missing possible	0-100
Day 0				
Baseline				
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(One month with new replacement HA)				

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NCIQ	Questionnaire	numeric	Missing possible	0-100
Speech production				
Day 0				
Baseline				
(One month with new				
replacement HA)				
NCIQ	Questionnaire	numeric	Missing possible	0-100
Activity limitation	-		<u> </u>	
Day 0				
Baseline				
(One month with new				
replacement HA)				
NCIQ	Questionnaire	numeric	Missing possible	0-100
Social interaction				
Day 0				
Baseline				
(One month with new				
replacement HA)				
NCIQ	Questionnaire	numeric	Missing possible	0-100
Total				
Day 0				
Baseline				
(One month with new				
replacement HA)				
SSQ	Questionnaire	numeric	Missing possible	0-100
Speech intelligibility				
Day 0				
Baseline				
(One month with new				
replacement HA)				
SSQ	Questionnaire	numeric	Missing possible	0-100
Spatial hearing				
Day 0				
Baseline				
(One month with new				
replacement HA)	Orrestia		Montan 11	0.100
SSQ	Questionnaire	numeric	Missing possible	0-100
Hearing quality				
Day 0 Baseline				
(One month with new				
(One month with new replacement HA)				
	Quastiannaina	numoric	Missing passil-1-	0-100
SSQ Total	Questionnaire	numeric	Missing possible	0-100
Total				
Day 0 Baseline				
(One month with new				
(One month with new replacement HA)				
THI	Questionneire	numorio	Missing possible	0-100
	Questionnaire	numeric	wissing possible	0-100
Day 0 Baseline				
(One month with new				
replacement HA)				
DHI	Questionnaire	numeric	Missing possible	0-100
Day 0	Quesuonnaire	numene	wissing possible	0-100
Baseline				
(One month with new				
replacement HA)				
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
3 months	words or sentences	Numenc	wissing possible	0-10070
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Quiet	sentence			
HA right ear				
m mgm cai	Number of correct	Numeric	Missing possible	0-100%
HINT (word)			missing possible	0 100/0
		1 (0110110	01	
HINT (word) 3 months Follow-up with new HA	words or sentences out of 20 sentences		01	

(Total of 4 months with new replacement HA)	with 5 words pr sentence			
Quiet HA left ear				
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
3 months	words or sentences	INUMERIC	wissing possible	0-10070
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Quiet	sentence			
HA+HA				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.		01	
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)	,			
Quiet				
HA right ear				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)				
Quiet				
HA left ear				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)				
Quiet				
HA+HA HINT (word)	Number of correct	Nouseuis	Missing associate	0.1000/
3 months	words or sentences	Numeric	Missing possible	0-100%
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Noise	sentence			
HA right ear				
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
3 months	words or sentences		withoung prossible	0 100/0
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Noise				
HA left ear				
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
3 months	words or sentences			
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Noise				
HA+HA				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)				
Noise				
HA right ear				0.4007
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)				
Noise				
HA left ear				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			

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Follow-up with new HA (Total of 4 months with	(20 sentences in a HINT)			
new replacement HA) Noise				
HA+HA				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is		01	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words.			
new replacement HA) Quiet	Speech level is 65dB.			
HA+HA				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is		01	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words.			
new replacement HA)	Speech level is 65dB.			
HA right ear				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is		61	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with new replacement HA)	words.			
Ouiet	Speech level is 65dB			
HA left ear				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA (Total of 4 months with	words out of 25 words.			
new replacement HA)	Speech level is 65dB			
Noise	and noise level is			
HA+HA	65dB. The noise	e.e		
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing a real life "babble"			
	noise.			
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with new replacement HA)	words. Speech level is 65dB			
Noise	and noise level is		3/	
HA right ear	65dB. The noise			
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing a real life "babble"			
	noise.			
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25 words.			
(Total of 4 months with new replacement HA)	words. Speech level is 65dB			
Noise	and noise level is			
HA left ear	65dB. The noise			
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing a real life "babble"			

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SIS Headphones	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is		• •	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Comfort			
new replacement HA)	speech level. Each ear			
Quiet	is tested unaided			
2	separately.			
	separatery.			
SIS Headphones	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is	1 (uniterio	nineeing persiene	0 100/0
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Comfort			
new replacement HA)	speech level. Each ear			
Noise	is tested unaided			
IVOISE	separately.			
	The noise signal is			
	amplitude modulated			
	and has a speech			
	shaped spectrum			
	representing a real life			
SIS free field	"babble" noise. Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is	indificite	missing possible	0-10070
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words out of 25 words. Speech level			
new replacement HA)	is 65dB .			
Quiet				
HA+HA			NC 1 11	0.1000/
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level			
new replacement HA)	is 65dB .			
Quiet				
HA right ear	~			0.1000/
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level			
new replacement HA)	is 65dB .			
Quiet				
HA left ear				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level is			
new replacement HA)	65db and noise level			
Noise	is 65dB. The noise			
HA+HA	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing			
	a real life "babble"			
	noise.			
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is		6 r - 551616	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level is			
new replacement HA)	65db and noise level			
Noise	is 65dB. The noise			
HA right ear	signal is amplitude			
TIA TIgin Cal	modulated and has a			
	speech shaped spectrum representing			

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	a real life "babble"			
SIS free field Audio-visual	noise. Speech identification score in Denmark is	Numeric	Missing possible	0-100%
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level is			
new replacement HA)	65db and noise level			
Noise	is 65dB. The noise			
HA left ear	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing			
	a real life "babble"			
<b>N</b> 1 111 /	noise.	NT :	NC : 11	0.1
Peak pupil dilation	PPD is calculated	Numeric	Missing possible	0-1
(PPD)	based on the number			
3 months Follow-up with new HA	of pixels. PPD of 0.01 would mean 1%			
(Total of 4 months with	change in pupil			
new replacement HA)	dilation.			
Quiet	HINT sentence			
HA+HA	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 is calculated	Numeric	Missing possible	0-1
(PPD)	based on the number	(evie		
3 months	of pixels. PPD of 0.01			
Follow-up with new HA	would mean 1%			
(Total of 4 months with	change in pupil dilation.			
new replacement HA) Noise	HINT sentence			
HA+HA	presented at speech			
	level 65dB and SNR			
	at +10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Missing possible	0-10sec
3 months	the pupil to reach			
Follow-up with new HA	peak dilation.			
(Total of 4 months with	HINT sentence			
new replacement HA)	presented speech level			
Quiet HA+HA	65dB and SNR at +10dB and adaptive			
HATIIA	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Missing possible	0-10sec
3 months	the pupil to reach		31	
Follow-up with new HA	peak dilation.			
(Total of 4 months with	HINT sentence			
new replacement HA)	presented speech level			
Noise	65dB and SNR at			
HA+HA	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil Labs glasses			

	Measurement & analysis tools			
NCIQ Basic sound 3 months Follow-up with new HA (Total of 4 months with	Questionnaire	numeric	Missing possible	0-100
new replacement HA)				
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	Questionnaire	numeric	Missing possible	0-100
new replacement HA)			NC 11	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
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
	Afte	er Cl surg	ery	
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
<b>PTA</b> 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
<b>TRESHOLDS</b> 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			
РТА	The patient can be	Numeric	Missing possible	0 to 120 db HL
6 months post bimodal	tested at frequencies			
CI+HA - fitting	from 125 Hz up to 8 kHz.			
	In free field.			
	In best aided			
	condition.			
	No stimuli.			
TRESHOLDS	The patient can be	Numeric	Missing possible	0 to 120 db HL
12 months post bimodal	tested at frequencies		•••	
CI+HA - fitting	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			
	purctone audiometry			
РТА	The patient can be	Numeric	Missing possible	0 to 120 db HL
12 months post bimodal	tested at frequencies		01	
CI+HA - fitting	from 125 Hz up to 8			
	kHz.			
	In free field.			
	In best aided condition.			
	No stimuli.			
HINT (word)	Number of correct	Numeric	Possible	0-100%
Post-surgery	words.			
3 months after fitting	(5 words per			
Quiet	sentences, 20			
CI alone	sentences in a HINT)			
	In free field.			
	Speech level at 65dB HL.			
HINT (word)	Number of correct	Numeric	Possible	0-100%
Post-surgery	words.			
6 months after fitting	(5 words per			
Quiet	sentences, 20			
CI alone	sentences in a HINT) In free field.			
	Speech level at 65dB			
	HL.			
HINT (word)	Number of correct	Numeric	Possible	0-100%
Post-surgery	words.			
12 months after fitting	(5 words per			
Quiet	sentences, 20			
CI alone	sentences in a HINT)			
	In free field.			
	Speech level at 65dB HL.			
HINT (sentence)	HL. Number of correct	Numeric	Possible	0-100%
Post-surgery	sentences.	1 (unione	1 0331010	0-100/0
3 months after fitting	(20 sentences in a			
Quiet	HINT)			
CI alone	In free field.			
	Speech level at 65dB			
	HL.			0.1000/
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HINT (sentence) Post-surgery	Number of correct sentences.	Numeric	Possible	0-100%

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6 months after fitting Quiet	(20 sentences in a HINT)			
CI alone	In free field. Speech level at 65dB HL.			
HINT (sentence) Post-surgery 12 month after fitting Quiet CI alone	HL.         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	HL. 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	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Quiet CI+HA	HL. 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.	Numerie	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	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Noise CI +HA	noise. 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	Speech identification score in Denmark is	Numeric	Possible	0-100%
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
CI only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Auditory	score in Denmark is			
Post-surgery	percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
HA only SIS free field	Speech level is 65dB Speech identification	Numeric	Possible	0-100%
Auditory	score in Denmark is	Numeric	Possible	0-100%
Post-surgery	percentage correct			
6 months after fitting	words out of 25			
Quiet	words.			
HA only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Auditory	score in Denmark is			
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
HA only	Speech level is 65dB	Normani	Decellal	0.1000/
SIS free field	Speech identification	Numeric	Possible	0-100%
Auditory Post-surgery	score in Denmark is percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
CI+HA	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Auditory	score in Denmark is			
Post-surgery	percentage correct			
6 months after fitting	words out of 25			
Quiet	words.			
CI+HA SIS free field	Speech level is 65dB	N	Possible	0.1000/
	Speech identification score in Denmark is	Numeric	Possible	0-100%
Auditory Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
CI+HA	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
CI+HA SIS free field	Speech level is 65dB	Numoria	Possible	0-100%
Audio-visual	Speech identification score in Denmark is	Numeric	rossible	0-10070
Post-surgery	percentage correct			
6 months after fitting	words out of 25			
Quiet	words.			
CI+HA	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
CI+HA SIS free field	Speech level is 65dB	Numoria	Possible	0-100%
Audio-visual	Speech identification score in Denmark is	Numeric	rossiole	0-10070
Post-surgery	percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
CI only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
6 months after fitting	words out of 25			
Quiet CI only	words.			
· · ·	Speech level is 65dB	1	1	1

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SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet CL only	words.			
CI only SIS free field	Speech level is 65dB Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is	municite	1 0551010	0-10070
Post-surgery	percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
HA only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
6 months after fitting	words out of 25 words.			
Quiet HA only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is	1 valiferite	1 0001010	5 100/0
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
HA only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
3 months after fitting Noise	words out of 25 words. Speech level is			
Noise CI+HA	65dB and noise level			
<i>C1</i> 11/1	is 65dB. The noise			
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing			
	a real life "babble"			
	noise.	N	D 11	0.1000/
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual Post-surgery	score in Denmark is percentage correct			
6 months after fitting	words out of 25			
Noise	words. Speech level is			
CI+HA	65dB and noise level			
	is 65dB. The noise			
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing a real life "babble"			
	a real life "babble" noise.			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is	1 (uniterie	1 0001010	0 10070
Post-surgery	score in Denmark is			
osi-surgery 2 months after fitting				
12 months after fitting	percentage correct words out of 25		4	
12 months after fitting Noise	percentage correct		1	
	percentage correct words out of 25 words. Speech level is 65dB and noise level		1	
Noise	percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise		1	
Noise	percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude		1	
Noise	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		1	
Noise	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		7	
Noise	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		4	
Noise	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"		7	
Noise	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%
Noise CI+HA	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"	Numeric	Possible	0-100%
Noise CI+HA SIS free field	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. Speech identification score in Denmark is percentage correct	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual	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. Speech identification score in Denmark is percentage correct words out of 25	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual Post-surgery 3 months after fitting Noise	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. Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual Post-surgery 3 months after fitting	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. Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual Post-surgery 3 months after fitting Noise	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. Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual Post-surgery 3 months after fitting Noise	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. Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level	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)	PPD is calculated based on the number	Numeric	Possible	0-1

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3 months after fitting	would mean 1%			
Ouiet	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Quiet	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
12 months after fitting	would mean 1%			
Quiet	change in pupil			
CI only	dilation.			
J	HINT sentence			
	presented at speech	revie		
	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
3 months after fitting	would mean 1%			
Quiet	change in pupil		2/	
HA only	dilation.			
<i></i>	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number		1 0001010	~ <b>1</b>
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Quiet	change in pupil			
HA only	dilation.			
TIA OIIIY	HINT sentence			
	presented at speech			
	level 65dB and SNR			
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	at +10dB and adaptive			

	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

Post-surgery	of pixels. PPD of 0.01			
3 months after fitting	would mean 1%			
Noise	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Noise	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
12 months after fitting	would mean 1%	(evie		
Noise	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number	-		
Post-surgery	of pixels. PPD of 0.01			
3 months after fitting	would mean 1%			
Noise	change in pupil		21	
HA only	dilation.			
5	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Noise	change in pupil			
HA only	dilation.			
1111 Olly	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
12 months after fitting	would mean 1%			
Noise	change in pupil			
HA only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
3 months after fitting	would mean 1%			
Noise	change in pupil			
CI+HA	dilation.			
ertik	HINT sentence			
	presented at speech			
	level 65dB and SNR			
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	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
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	Measurement &			
	analysis tools			
Peak pupil dilation	PPD is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Noise	change in pupil			
CI+HA	dilation.		7	
CITIA	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
	would mean 1%			
12 months after fitting	change in pupil			
12 months after fitting Noise		1		
Noise				
	dilation.			
Noise	dilation. HINT sentence			
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Noise	dilation. HINT sentence presented at speech level 65dB and SNR			
Noise	dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive			
Noise	dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker			
Noise	dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise			
Noise	dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil			
Noise	dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise			
Noise	dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil			

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Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
3 months after fitting	peak dilation.			
Quiet CI only	HINT sentence presented speech level			
Cromy	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
6 months after fitting	peak dilation.			
Quiet	HINT sentence			
CI only	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools		D 11	0.10
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
12 months after fitting Quiet	peak dilation. HINT sentence			
CI only	presented speech level			
Cronny	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	The time it takes for			
3 months after fitting	the pupil to reach			
Quiet	peak dilation.			
HA only	HINT sentence			
	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
Deve 11 Deve le 41	analysis tools	Normania	Dessible	0.10
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery 6 months after fitting	the pupil to reach peak dilation.			
	peak dilation. HINT sentence			
Quiet HA only	presented speech level			
11A Olly	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
1	analysis tools			
		NT ·	Possible	0-10sec
Pupil Peaktime	The time it takes for	Numeric		
Pupil Peaktime Post-surgery	The time it takes for the pupil to reach	Numeric	1 0351010	
Post-surgery	The time it takes for the pupil to reach peak dilation.	Numeric	1 0351010	
	the pupil to reach	Numeric		
Post-surgery 12 months after fitting	the pupil to reach peak dilation.	Numeric		
Post-surgery 12 months after fitting Quiet	the pupil to reach peak dilation. HINT sentence	Numeric		

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	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
3 months after fitting	peak dilation.			
Quiet	HINT sentence			
CI+HA	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
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Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
6 months after fitting	peak dilation.			
Quiet	HINT sentence			
CI+HA	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach	Ivuillerie	1 0331010	0-10300
12 months after fitting	peak dilation.			
Quiet	HINT sentence	CZIO		
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CI+HA	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise		2	
	Oticon Medical Pupil		-	
	Labs glasses			
	Measurement &	•		
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
3 months after fitting	peak dilation.			
Noise	HINT sentence		21	
CI only	presented speech level			
<i></i>	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses Measurement &			
D	analysis tools	Normani	Da ih 1	0.10
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
6 months after fitting	peak dilation.			
Noise	HINT sentence			
CI only	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
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Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			-
12 months after fitting	peak dilation.			
Noise	HINT sentence			
CI only	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach	INUITICITC	rossible	0-10800
3 months after fitting	peak dilation.			
Noise	HINT sentence			
HA only	presented speech level			
5	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
6 months after fitting	peak dilation.			
Noise	HINT sentence			
HA only	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach	Numeric	1 0551010	0-10500
12 months after fitting	peak dilation.			
Noise	HINT sentence			
HA only	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
3 months after fitting	peak dilation.			
Noise	HINT sentence			
CI+HA	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses Measurement &			
Dunil Doolstime	analysis tools	Numoric	Possible	0.10sac
Pupil Peaktime	The time it takes for	Numeric	POSSIBLE	0-10sec
Post-surgery 6 months after fitting	the pupil to reach peak dilation.			
Noise	HINT sentence			
CI+HA	presented speech level			
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CITIA	65dB and SNR at			
CI-IIA	65dB and SNR at +10dB and adaptive			

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	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement & analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach	Numerie	1 0551010	0-10500
12 months after fitting	peak dilation.			
Noise	HINT sentence			
CI+HA	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement & analysis tools			
NCIQ	Questionnaire	numeric	Possible	0-100
Basic sound	Questionnane	numene	rossible	0-100
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Advanced Sound				
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Speech production				
Post-surgery 3 months after fitting				
NCIO	Questionnaire	numeric	Possible	0-100
Self-esteem	Questionnane	indificite	1 0001010	0-100
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Activity limitation				
Post-surgery				
3 months after fitting			D 11	0.100
NCIQ Social interaction	Questionnaire	numeric	Possible	0-100
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Total				
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Basic sound				
Post-surgery				
6 months after fitting				0.100
NCIQ	Questionnaire	numeric	Possible	0-100
Advanced Sound Post-surgery				
6 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Speech production	Zuesusiniane	maniene	1 0001010	. 100
Post-surgery				
6 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Self-esteem				
Post-surgery				
6 months after fitting			D 11	0.100
NCIQ	Questionnaire	numeric	Possible	0-100
Activity limitation				
Post-surgery 6 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Social interaction	Questionnane	numerie	1 0001010	0 100
Post-surgery				
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NCIQ	Questionnaire	numeric	Possible	0-100
Total Post-surgery				
6 months after fitting				
NCIO	Questionnaire	numeric	Possible	0-100
Basic sound	Questionnane	numene	rossible	0-100
Post-surgery				
12 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Advanced Sound	Questionnune	numerie	1 0001010	0 100
Post-surgery				
12 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Speech production	Questionnin		1 0001010	0 100
Post-surgery				
12 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Self-esteem	Queenemine		1 0001010	0 100
Post-surgery				
12 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Activity limitation				
Post-surgery				
12 months after fitting				
NCIO	Questionnaire	numeric	Possible	0-100
Social interaction				· · · · ·
Post-surgery				
12 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Total	Questionnaire	numerie	1 0001010	0 100
Post-surgery				
12 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Speech intelligibility	Questionnane	numerie	1 0351010	0 100
Post-surgery				
3 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Spatial hearing	Questionnin		1 0001010	0 100
Post-surgery				
3 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Hearing quality	Questionnin		1 0001010	0 100
Post-surgery				
3 months after fitting				
SSQ	Questionnaire	numeric	Possible	0-100
Total	<b>C</b>			
Post-surgery				
3 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Speech intelligibility				
Post-surgery				
6 months after fitting				
SSQ	Questionnaire	numeric	Possible	0-100
Spatial hearing	Caronania			
Post-surgery				
6 months after fitting				
SSQ	Questionnaire	numeric	Possible	0-100
Hearing quality				
Post-surgery				
6 months after fitting				
SSQ	Questionnaire	numeric	Possible	0-100
Total				
Post-surgery				
6 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Speech intelligibility	2 uobioiniuno		1 3001010	\$ 100
Post-surgery				
12 months after fitting				
				0.100
	Questionnaire	numeric	Possible	0-100
SSQ Spatial hearing	Questionnaire	numeric	Possible	0-100

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



# BMJ Open CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	ltem No	Checklist item	Reported on page N
Title and abstract		9 De	
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance gee CONSORT for abstracts)	1
Introduction		2022.	
Background and	2a	Colortific bookground and exploration of rationals	3-6
objectives	2b	Specific objectives or hypotheses	5-6
Methods		Specific objectives or hypotheses	
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-10
5	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	How sample size was determined When applicable, explanation of any interim analyses and stopping guidelines Method used to generate the random allocation sequence Type of randomisation; details of any restriction (such as blocking and block size)	13-15
Randomisation:		202	
Sequence	8a	Method used to generate the random allocation sequence	9-10
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size) ਰੂ	9-10
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially mumbered containers),	9-10/14-15
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned b	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who a signed participants to interventions	
Blinding	11a	اf done, who was blinded after assignment to interventions (for example, participants, ﷺ providers, those	
CONSORT 2010 checklist		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	Pad

Page 73 of 79			BMJ Open	
			assessing outcomes) and how	
1		11b	If relevant, description of the similarity of interventions	14-15
2 3	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	14-15
4		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	14-15
5	Deculto			
6 7	<b>Results</b> Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	
8	diagram is strongly	154	were analysed for the primary outcome	
9	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	
10 11	Recruitment	14a	Dates defining the periods of recruitment and follow-up	
12	Reorditinent	14b	Why the trial ended or was stopped	
13	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
14	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	
15 16	Numbers analysed	10	by original assigned groups	
17	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	
18	estimation	n/a	precision (such as 95% confidence interval)	
19 20	oouniquon	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted adalyses, distinguishing	
22			pre-specified from exploratory	
23 24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for arms)	
25	Discussion			
26	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, mulgplicity of analyses	15
27 28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
20	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
30	•	~~		
31	Other information	00	Desistration number and name of trial registry	1 0 16 17
32 33	Registration	23	Registration number and name of trial registry	1, 2, 16, 17
34	Protocol	24 25	Where the full trial protocol can be accessed, if available	47
35	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17
36 37	<b>411</b> 7 / 1	1 1.		. 1
38	•••		g this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If rele extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and	
39	-		by the second se	pragmatic triais.
40 41	Additional extensions are		similing. for those and for up to date references relevant to this checknist, see <u>www.consort-statement.org</u> .	
42			wining. for those and for up to date references relevant to this eleckrist, see <u>www.consort-statement.org</u> .	
43	CONSORT 2010 checklist		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	Page 2
44 45				
45 46				

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

Section/item	ltem No	Description 2022	Addressed on
Administrative inf		Dow	page number
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 Date and version identifier Sources and types of financial, material, and other support	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	5a	Names, affiliations, and roles of protocol contributors	1,17
responsibilities	5b	Names, affiliations, and roles of protocol contributors	1,17
	5c	Role of study sponsor and funders, if any, in study design; collection, management, adalysis, 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 over seeing the trial, if applicable (see Item 21a for data monitoring committee)	17
		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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1 2	Introduction		022-07	
- 3 4 5	Background and rationale	6a	Description of research question and justification for undertaking the trial, including sugmmary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-6
6 7		6b	Explanation for choice of comparators	4-5
8 9	Objectives	7	Specific objectives or hypotheses	6
10 11 12 13	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factoria single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, explorator)	7
14 15	Methods: Participa	nts, inte	erventions, and outcomes	
16 17 18	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
19 20 21	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
22 23 24 25	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-13
26 27 28		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
29 30 31		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
32 33		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
34 35 36 37 38 39 40 41	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
42 43 44 45 46			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	2

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			BMJ Open	Page 76 c
1 2 3 4	Participant timeline	13		9,11-13 ppendix A, Figure and 2
5 6 7	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was $\frac{9}{6}$ etermined, including 14 clinical and statistical assumptions supporting any sample size calculations	1, Table 1
8 9	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10
10 11 12	Methods: Assignme	ent of i	nterventions (for controlled trials)	
13 14	Allocation:			
15 16 17 18 19	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any 9- 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	10
20 21 22 23 24 25 26 27 28 29 30	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, 9- opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to 9- interventions	10
	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome $9$ -assessors, data analysts), and how	10
31 32 33 34		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's 9- allocated intervention during the trial	10
35 36	Methods: Data colle	ection,	management, and analysis	
37 38 39 40 41 42 43 44 45	Data collection methods	18a	processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of pla study instruments (eg, questionnaires, laboratory tests) along with their reliability and galidity, if known.	3-15, statistical an(SAP), Data anagement an(DMP) 3

Page 77 of 79			BMJ Open 3. PP	
1 2 3 4 5 6 7 8 9 10		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		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
11 12		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13-15, SAP
13 14 15 16		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
17 18	Methods: Monitorin	g		
19 20 21 22 23 24	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
25 26 27		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
28 29 30	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously performed adverse events and other unintended effects of trial interventions or trial conduct	13-15, SAP
31 32 33	Auditing	23	from investigators and the sponsor	n/a
34 35 36	Ethics and dissemi	Lesst. Pr		
37 38 39 40 41	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2,7,16
42 43 44 45			ہج For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	4

			BMJ Open B	Pag
1 2 3 4	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility cheria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial regiseries, journals, regulators)	13-15, SAP
5 6 7	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
8 9 10		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
11 12 13	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
14 15 16 17	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
17 18 19 20	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
21 22 23	Ancillary and post- trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those whoes uffer harm from trial participation	Consent form
24 25 26 27	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
28 29		31b	Authorship eligibility guidelines and any intended use of professional writers	17
30 31 32 33		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	MAP
34	Appendices		gu es	
35 36 37	Informed consent materials	32	Model consent form and other related documentation given to participants and author is do surrogates	As online supplementary
	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for generatic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	file n/a
41 42 43 44 45			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license. 296 on 29

#### 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.

Journal:	BMJ Open
Manuscript ID	bmjopen-2022-070296.R1
Article Type:	Protocol
Date Submitted by the Author:	13-Dec-2022
Complete List of Authors:	Jakobsen, Yeliz; Odense University Hospital, Head & Neck Surgery and Audiology; Odense University Hospital Christensen Andersen, Lou-Ann; Vejle Hospital, Department of Ophthalmology Schmidt, Jesper; Odense University Hospital, Department of Audiology; Odense University Hospital, Department of Oto-Rhino-Laryngology
<b>Primary Subject Heading</b> :	Ear, nose and throat/otolaryngology
Secondary Subject Heading:	Evidence based practice, Surgery, Communication, Research methods
Keywords:	Audiology < OTOLARYNGOLOGY, Speech pathology < OTOLARYNGOLOGY, Adult otolaryngology < OTOLARYNGOLOGY



1 2		
3 4		A Study Dyste cal fage a Day downiaed Controlled Trial Evoluting
5 6	1	A Study Protocol for a Randomised Controlled Trial Evaluating the Penefits from Pimodal Solution with Cochlear Implant and
7	2	the Benefits from Bimodal Solution with Cochlear Implant and Hearing Aid vs. Bilatoral Hearing Aids in Patients with
8 9	3	Hearing Aid vs. Bilateral Hearing Aids in Patients with
10	4 5	Asymmetric Speech Identification Scores.
11 12	6	Yeliz Jakobsen <sup>1.2*</sup> , Lou-Ann Christensen Andersen <sup>3</sup> , Jesper Hvass Schmidt <sup>1.2</sup>
13	7	
14 15	8 9	Affiliation <sup>1</sup> Research Unit for ORL – Head & Neck Surgery and Audiology, Odense University Hospital, Odense,
16	10	Denmark; University of Southern Denmark, Odense, Denmark
17 18	11	<sup>2</sup> OPEN, Odense Patient data Explorative Network, Odense University Hospital, Odense, Denmark.
19 20	12 13	<sup>3</sup> Department of Ophthalmology, Lillebaelt Hospital, Vejle Hospital. *Correspondence to Dr. Yeliz Jakobsen; <u>Yeliz.jakobsen@rsyd.dk</u>
21	14	Date: Friday, 9 <sup>th</sup> December 2022
	15 16	Version: 4
24	10 17	
25 26	18	Abstract
27		
28 29	19	Introduction
30	20	Cochlear implant (CI) and hearing aid (HA) in a bimodal solution (CI + HA) is compared to
33 34	21	bilateral HAs (HA +HA) to test if the bimodal solution result in better speech intelligibility and
35 36 37	22	self-reported quality of life.
	23	
40 41 42	24	Methods and Analysis
43 44	25	This randomised controlled trial (RCT) is conducted in Odense University Hospital, Denmark.
45 46 47	26	Sixty adult bilateral HA users referred for CI surgery is enrolled if eligible and undergo:
47 48 49	27	audiometry, speech perception in noise (HINT: Hearing in Noise Test), Speech Identification
50 51	28	Scores (SIS) and video head impulse test (v-HIT). All participants will receive new
52 53 54	29	replacement HAs. After one month they will be randomly assigned (1:1) to the intervention
54 55 56	30	group (CI+HA) or to the delayed intervention control group (HA+HA). The intervention group
57 58 59 60	31	(CI+HA) will receive a CI on the ear with a poorer speech recognition score and continue

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2 3		
4 5	32	using the HA on the other ear. The control group (HA+HA) will receive a CI after a total of 4
6 7	33	months of bilateral HA use.
8 9 10	34	The primary outcome measures are Speech intelligibility measured objectively with HINT
11 12	35	(sentences in noise) and DANTALE I (words) and subjectively with the Speech, Spatial and
13 14 15	36	Qualities of Hearing scale questionnaire (SSQ-12). Secondary outcomes are patient reported
	37	Health-Related Quality of Life (HRQoL) scores assessed with the Nijmegen Cochlear Implant
18 19	38	Questionnaire (NCIQ), the Tinnitus Handicap Inventory (THI) and Dizziness Handicap
20 21 22	39	Inventory (DHI). Third outcome is listening effort assessed with pupil dilation during HINT
	40	In conclusion, the purpose is to improve clinical decision-making for CI candidacy and
25 26	41	optimize bimodal solutions.
27 28 29	42	
30 31	43	Ethics and Dissemination
32 33 34	44	This study protocol was approved by the Ethics Committee Southern Denmark project ID S-
35 36	45	20200074G. All participants are required to sign an informed consent form.
37 38	46	This study will be published upon completion in a peer-reviewed publications and scientific
39 40 41	47	conferences.
42 43	48	
44 45 46	49	Trial Registration Number: NCT04919928 (ClinicalTrials.gov)
47 48	50	
	51	
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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

#### 5 Background

66 Cochlear implants (CIs) have been used to restore hearing in individuals with severe to 67 profound sensorineural hearing loss. Initially, most patients receiving a cochlear implant were 68 profoundly deaf in both ears. (1, 2) However, recently it has become more common to implant 69 patients with significant residual hearing in the affected ear, as well as in patients with 70 asymmetric hearing loss and single-sided deafness, with significant residual hearing or normal 71 hearing on the contralateral side.(3, 4) A CI in one ear and a HA in the other ear can provide 72 enhanced hearing performance in patients with asymmetrical hearing.(5, 6) The combination 73 of CI and HA is referred to as bimodal hearing or bimodal solution.(7)

#### 5 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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28 29	88
30	89
31 32	90
33 34	90
35	91
36 37	
38 39	92
40	93
41 42	0.4
43	94
44 45	95
46 47	96
48	90
49 50	97
51 52	98
53	
54 55	99
56 <sub>1</sub>	100
57 <sup>-</sup> 58	
59 60	

to profound deafness who do not receive adequate benefit from acoustic hearing aids. Severe to profound deafness is defined as pure-tone audiometric threshold  $\geq$  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  $\leq 60\%$  (8). The Danish CI candidacy criteria consists of SIS (without HAs, measured with headphones)  $\leq$ 45% and a SIS  $\leq$ 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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2 3	
$^{4}_{5}$ 101	The question is if the bimodal benefits are bigger than the bilateral hearing aid condition
$_{7}^{6}$ 102	when they are well fitted?
8 9 103 10	This study will therefore support and strengthen the preoperative clinical decision to
$^{11}_{12}104$	recommend a bimodal solution with a CI and a HA versus the continuous use of bilateral HAs.
13 14105 15	This may offer the patient faster and more effective treatment because delaying the surgery
<sup>16</sup> 106 17	may not be beneficial.
<sup>18</sup> 19 <sup>107</sup>	
20 21100	Dationt Deported Outcome Measures
<sup>21</sup> 108 22 23	Patient-Reported Outcome Measures
24109 25	Benefits of the CI are measured subjectively with Patient-Reported Outcome Measures
<sup>26</sup> 110 27	(PROMs) as SSQ12, NCIQ, THI and DHI.(17-24)
28 29111	
30 31112	The validity and reproducibility of the Danish version of THI has been reported(24). SSQ12,
32	
<sup>33</sup> 113 34	DHI, NCIQ have all been translated into Danish and backward translated to English following a
35 36114 37	cultural adaption and pilot-testing to ensure correct understanding of the questionnaires.
38115 39	Test-retest reliability has been assessed as well.(18, 20, 22)
<sup>40</sup> 116	
41 42	Listonia - Effort
43117 44	Listening Effort
45 46118	Patients with CI often experience high levels of listening effort, they often report that
47 48119 49	understanding speech causes high levels of increased sustained effort which results in
<sup>49</sup> 50120 51	feelings of fatigue.(25) These feelings may lead patients to withdraw socially due to the
<sup>52</sup> 121 53 54	stresses involved in communication even though they may not specifically report difficulties
55122	with speech understanding.(19)
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4 123 5	Effort in listeners with NH can be reflected by the relationship between speech intelligibility
6 7 124 8	and pupil-dilation.(26) Listening effort has been defined as the "Deliberate allocation of
9 125 10	mental resources to overcome obstacles in goal pursuit when carrying out a task" and is the
$^{11}_{12}126$	basis for the Framework for Understanding Effortful Listening (FUEL) model.(27)
13 14127 15	Understanding speech in challenging hearing environments results in increased auditory and
<sup>16</sup> 128 17	cognitive processing which can be observed objectively by measuring the pupil dilation
<sup>18</sup> 129	during speech perception in noise, in a task such as the HINT(28-30)
20 21130 22	
<sup>23</sup> 131 24	Rationale and Objectives
25 26132 27	This randomised controlled trial is designed to improve clinical decision-making for CI
<sup>28</sup> 133 29	candidacy for patients with asymmetric hearing. It is necessary to establish more evidence to
<sup>30</sup> 31134	support the effectiveness and the fitting optimization of bimodal CI+HA versus HAs in patients
32 33135 34	with asymmetric hearing.
<sup>35</sup> 136 36	The first objective of the study is to evaluate the subjective (SSQ12) and objective (Hearing In
37 38 137 39	Noise Test (HINT) which is word and sentence based and DANTALE I, which is monosyllabic
40138 41	word-based) benefits of a bimodal solution (CI+HA) compared to (HA+HA).
<sup>42</sup> 139 43	The second objective is to compare and evaluate patient self-reported outcomes with NCIQ,
44 45 46	THI and DHI in the intervention group (CI+HA) with the control group (HA+HA).
47141 48	The third objective is to evaluate if listening effort, hypothesized to cause fatigue, can be
<sup>49</sup> 142 50	measured objectively by HINT with pupillometry.
51 52143 53	To minimize listening effort and optimize the fitting of bimodal solution the CI fitting and
54144 55	loudness balancing on individual level will be evaluated.(2, 31, 32)
<sup>56</sup> 145 57	
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1 2	
3 4 5 147	Methods and Analysis
6 7 148 8	Study Design, Ethics and Registration
9 10149 11	This study is a prospective randomised controlled trial based on a single centre conducted in
<sup>12</sup> 150 13	Odense University Hospital, Denmark. The study started 01/02/2022 and is expected to end
<sup>14</sup> 15 16	30/07/2024. It was successfully registered at ClinicalTrials.gov with registration number:
16 17152 18	NCT04919928.
<sup>19</sup> 153 20	This study has been approved at Research Ethics Committee Southern Denmark (Projekt-ID:
21 22154 23	S-20200074G) 21 <sup>st</sup> August 2020 to 31 <sup>st</sup> December 2024.
24155 25	
<sup>26</sup> 27156	Study Population
28 29157 30	Sixty participants with bilateral hearing-loss and asymmetric speech identification scores
<sup>31</sup> 158 32	referred for CI surgery will be included (Figure 1).
33 34159 35	
<sup>36</sup> 160 37	Inclusion Criteria
38 39161 40	• Adults >18 years old.
41 42162	Fluent in Danish, including reading and writing
43 44163 45	Acquired post-lingual deafness
46 47 47	• Use of bilateral HAs for at least one year prior to evaluation for cochlear implantation
48 49165	candidacy. This to ensure, that both ears have received auditive stimulation
50 51166 52	• PTA > 40 dB HL in the ear considered for CI implantation and PTA>40 and $\leq$ 70dB HL in
<sup>53</sup> 167 54	the contralateral ear in best aided condition, in quiet and in noise and in free field.
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$\frac{4}{5}$ 168	• SIS <70% in best aided condition in the ear considered for CI implantation and SIS $\geq$ 30%
6 7 169	and $\leq$ 70% in best aided condition in the contralateral ear, in quiet and in noise and in
8 9 170 10	free field.
11 12171	Exclusion Criteria
13 14 15172	• Vestibular loss in the ear not considered for CI implantation
16 <sup>17</sup> 173 18	• Surgical issues interfering with the site of implantation or anatomical contraindications
18 <sup>170</sup> 19 20174	such as cochlear malformations, which will be determined using MRI or CT-scans.
2017 1 21 22175	<ul> <li>Auditory nerve lesions.</li> </ul>
23	
<sup>24</sup> 25 26	Central auditory pathway pathologies.
27177 28	• Otosclerosis.
<sup>29</sup> 178 30	Single sided deafness (SSD).
31 32179	
33 34	
35180 36	Setup
37 38181 39	A timeline of the study is shown in (Figure 2).
40182 41	All enrolled participants will be tested with audiometry and v-HIT to determine hearing
42 43 183	thresholds and status of balance function during the first visit. Patients will receive new
44 45184 46	replacement HAs. These HAs will be fitted during the second visit and if necessary refitted at
47 47 48	every visit in the clinic throughout the study. The baseline measurements will be conducted
49 50 <sup>186</sup>	when both groups have used the new replacement HAs to ensure acclimatisation. The
51 52187 53	measurements are SIS in quiet and in noise with a signal-to-noise ratio (SNR) of 0dB using
<sup>54</sup> 188 55	DANTALE I speech material. The speech and masking white noise stimulus will be presented at
<sup>56</sup> 57189	65 dB SPL in the free field. Stimuli will be presented as auditory stimuli only as well as with
58 59190 60	visual cues, the latter to allow participants to use lipreading cues.

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4 191	Pupillometry variables are Peak Pupil Dilation (PPD), Mean Pupil Dilation (MPD), peak-time
6 7 192 8	and standard deviation using HINT (sentences and words).
9 193 10	The HINT sentences are presented at a speech level of 65dB and initially an adaptive SNR is
<sup>11</sup> 194	used to identify the SNR of 70% correct word recognition. The SNR at 70% correct word
13 14195 15	recognition is used as a fixed SNR during HINT test. The noise is multi-talker babble noise, in
16196 17	free field, tested in best aided condition. The pupillometry glasses is the Oticon Medical Pupil
<sup>18</sup> 197 20 21198 22	Labs glasses.
23 24199 25	Recruitment, Stratification, Randomisation and Allocation
<sup>26</sup> 200 27	All eligible participants will sign a written, informed consent (supplementary file 1) in clinic
28 29201 30	after receiving verbal and written study information in Danish. The Danish consent form is
31202 32	available online at the Odense University Hospital Research Unit website.(33)
<sup>33</sup> 203 <sub>34</sub> 35	To ensure acclimatisation, participants will receive new replacement HAs fitted with the
<sup>35</sup> 36204 37	National Acoustic Laboratories (NAL) -non-linear (NL)2 fitting algorithm one month before
38205 39	the experiment.
<sup>40</sup> 206 41 42	They will then undergo stratification, depending on the hearing thresholds. One group will
42 43207 44	consist of participants with PTA $\geq$ 70dB HL; and the other group will consist of subjects with
45208 46 47	PTA $\leq$ 70dB HL and $\geq$ 40 dB HL according to the inclusion criteria. The reason for this
<sup>47</sup> 209 48 49	stratification is because pre-operative hearing thresholds may affect the measured outcomes
50210	in the study. Stratification ensures that both the intervention group and the control group will
52211 53 54242	have an equal distribution of patients with profound hearing loss on the ear considered for
<sup>54</sup> 212 55 57213 58 59 60	implantation.

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$\frac{4}{5}$ 214	Then the participants will be randomly allocated into two groups: the intervention group
6 7 215	(CI+HA) and the control group (HA+HA) according to 1:1 ratio using a blocked randomisation
8 9 216 10	with randomly varying block size (4 or 6).
$^{11}_{12}217$	This randomisation will be accomplished using a computer-generated random sequence in
13 14218 15	Research Electronic Data Capture (REDCap), hosted by Odense Patient Explorative Network
16219 17	(OPEN) in the Region of Southern Denmark and developed by Vanderbilt University,
<sup>18</sup> 19220	Nashville, Tennessee, United States.(34)
20 21221 22	REDCap will also be used to send out the questionnaires to the participants' online mailbox
<sup>23</sup> 222 24	(called Eboks in Denmark) throughout the study (see timeline (Figure 2)) and automatically
<sup>25</sup> 26223 27	save the data.
27 28224 29	Participants will have the opportunity to return to their original HAs if they prefer to do so
<sup>30</sup> 225 31	after one-month of acclimatisation.
<sup>32</sup> 33226 34	
35 <u>22</u> 7 36	Control Group
37 38228	Thirty patients, who will be age-matched, randomised and allocated to the control group
39 <sup>40</sup> 229 41	HA+HA will continue the use of the new replacement HAs for another three months (total four
42 43230	months of new replacement HA+HA use), serving as the delayed intervention control group.
44 45231 46	
47 48232	Intervention Group
49 <sup>50</sup> 233 51	Thirty patients, who will be age-matched, randomised and allocated to the intervention group
<sup>52</sup> 53234	CI+HA will undergo surgery as soon as possible after the HA acclimatisation period.
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3 4 5 237	HA Fitting
6 7 238 8	The participant will receive either Phonak (Phonak Link M) or GN (ReSound LiNX Quattro or
9 10 <sup>239</sup>	Resound ENZO Q) based on their personal preference. Both these HA models can be fitted
11 12240	with a CI by Advanced Bionics and Cochlear, respectively.
13 14241	The HAs will be fitted according to NAL-NL2 procedures prescriptive fitting formula, which
15 16 17242	optimizes audibility in the bimodal solution(2) and will be verified with REM (Real Ear
18 19243	Measurement) to ensure that the HA is providing adequate gain and then further adjusted for
20 21244	comfort based on patient feedback.(35)
22 23 24 245	The new HAs will be prescribed to the patients free of charge and future service will also be
24 25 26246	free of charge.
27 28247	Participants can drop out of the study if they do not want CI surgery. Collected data will be
<sup>29</sup> <sup>30</sup> <sub>31</sub> 248	analysed if the patient still consents.
312 10 32 33249	
34	
<sup>35</sup> 250 <sub>36</sub> 37	CI fitting
38251 39	The CI will be selected depending on the participant's HA selection; that is, the CI that is
40 41 252	compatible with the HA will be selected in order to ensure the most optimal bimodal fitting.
42 43253 44	One-month post-surgery, the CI will be activated according to the settings and stimulation
45254 46	strategy based on patient's feedback. The CI will then be fitted with the HA according to the
47 48255	bimodal fitting formula allowing the HA to keep the NAL-NL2 fitting along with the wireless
49 50256	connection with the CI. (36, 37)
51 52257 53	Patients hearing thresholds will be tested on CI activation day. The residual hearing will not
<sup>54</sup> 258	be stimulated in this study.
56 57259	
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1 2	
3 4 5 260	All participants are offered standard rehabilitation with a speech therapist, including three
6 7 261	visits a week up to 10 weeks following the initial fitting.
8 9 262 10	The training focuses on learning to identify different sounds from the environment and word
$^{11}_{12}263$	discrimination.
13 14264 15	The new CI will also be prescribed to the patients free of charge and future service will be free
16265 17	of charge as well.
<sup>18</sup> 266 19266 20	
21267 22	Loudness Balancing
<sup>23</sup> <sub>24</sub> 268	At 3- months follow-up the post-surgery complications will be evaluated and the levels in the
25 26269 27	CI will be adjusted if necessary.
<sup>28</sup> 270 29	In the loudness balancing procedure, the patient will have both the hearing aid and CI
<sup>30</sup> 31271 32	activated and at the 6-month follow-up, when the CI mapping levels are stable, patients will
32 33272 34	be randomised and assigned to one of three bimodal fitting groups:
<sup>35</sup> 273 36	Group A) will not complete any specific loudness balancing procedures, CI and HA will be
<sup>37</sup> 38274 39	fitted based on individual feedback from the patient.
40275 41	Group B) will be fitted/finetuned using a bimodal loudness balancing task at a medium input
<sup>42</sup> 276 43	level and adjusted based on the patient feedback. The audiologist will present a mid-level
44 45277 46	sound (approx. 55dB SPL (sound pressure level)) at the center-speaker.
47278 48	Group C) will be fitted/finetuned using a bimodal loudness balancing task as group B but the
<sup>49</sup> 279 50	audiologist will play three levels and adjust the gain for three input levels (soft, medium, and
<sup>51</sup> 52280 53	loud) according to the patient feedback.
54281 55	For both groups B and C, the patient will be given a 'Bimodal Fusion' illustration (see Figure 3)
56282 57 58 59 60	and asked to provide feedback about the location of the sound by tracing over the line of the

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2 3	
4 5 283	head. The HA gain will be adjusted using the bimodal adjustment option until the patient
6 7 284	reports that the sounds are perceived at the center of the head.(24)
8 9 285 10	
11 12 12	Primary Outcome
13 <sup>14</sup> 287 15	Primary outcomes are Speech intelligibility scores measured objectively with HINT
<sup>16</sup> 17 <sup>288</sup>	(sentences and words) and DANTALE I and subjectively with Speech, Spatial and Qualities of
18 19289 20	Hearing scale (SSQ-12). (9, 10, 22)
<sup>21</sup> 290 22	
23 24291 25	Secondary Outcome
<sup>26</sup> 292 27	Patient reported outcomes scores assessed with the Nijmegen Cochlear Implant
28 29293	Questionnaire (NCIQ), The Tinnitus Handicap Inventory (THI) and Dizziness Handicap
30 31294 32 <sup>33</sup> 295 34	Inventory (DHI). (18, 20, 24)
35 36296 37	Third Outcome
<sup>38</sup> 297 39 40 41298 42	Listening effort assessed with pupil dilation with HINT.(10)
43 44299	Statistics
45 46 47 48	Power calculation
<sup>49</sup> 50301	Power calculations with a power of 0.8 with a significance level of 0.05 have been made with
51 52302 53	STATA IC-15 using standard deviations for the HINT test and expected effect size (38) the
54303 55	NCIQ(18), and the SSQ (internal communication with BEAR (Better Hearing Rehabilitation)
<sup>56</sup> 304	study on hearing aid use in Denmark) (Table 1). An estimated within participant standard
<sup>58</sup> 59305 60	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%) ineach 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)

8 1. Attempt to follow-up on all randomised participants, even if they withdraw from

<sup>6</sup>319 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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7 8 326 9	Analysis specification
10 11327 12	A constrained linear mixed model is used to analyse the outcome.
<sup>12</sup> 13328 14	The model will include randomisation group (CI+HA / HA+HA) and time (baseline/follow-up)
15 16 <sup>329</sup>	and their interaction as fixed effects along with the threshold strata that were used in stratifying
17 18330 19	the randomisation. The model is constrained so that the mean at baseline agrees across the two
<sup>20</sup> 331 21	treatment groups adjusted for threshold stratum, which is reasonable due to the randomisation
22 23332 24	of implant fitting. Patient ID will be included as a random effect to account for the repeated
25333 26	measurements.
<sup>27</sup> 334 28 20	Secondary outcomes will be analysed analogously in a constrained linear mixed model
29 30335 31	adjusting for randomisation strata. Model validation checks will be undertaken as described
32336 33	above, switching to bootstrapping the standard errors when model assumptions are rejected.
<sup>34</sup> <sub>35</sub> 337 36 <sup>37</sup> <sub>38</sub> 338 39	Covariates such as age and gender will be included in all models.
40 41339 42	Sensitivity analysis
43 44340 45	Inclusion is performed conditional on Pure Tone Average (PTA) (from 0.5 to 4 kHz) PTA $> 40$
<sup>46</sup> 341 47	dB HL and SIS <50% in the ear considered for CI implantation and <70% in the best-aided
48 49342 50	condition which may lead to a truncation effect in the distribution of baseline measurements.
51343 52	To address this, an analysis of covariance (ANCOVA) model conditioning on the baseline will be
53344 54 55	used to obtain a sensitivity analysis estimate for the main outcome.(40)
56345 57	The statistical analysis plan is attached as "supplementary file" along with the Data Description
<sup>58</sup> 346 59 60	listed in Appendix A (supplementary file 3).

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6 7 348 8	Patient and Public Involvement
9 10349 11	A focus-group interview was established with six cochlear implant patients. The patients
<sup>12</sup> 350 13	commented on their decision to transition from HA to CI. Based on the feedback from the
14 15351	focus group, the research questions were developed.
16 17352 18	The patients also reported problems with adjustments of the CI, when meeting the audiologist
<sup>19</sup> 353 20	for CI adjustment controls.
<sup>21</sup> 22354	
23 24 25 25	Ethics and Dissemination
26 27356 28	Ethics approval for the conduct of this study was obtained from the Ethics Committee
<sup>29</sup> 30 <sup>357</sup>	Southern Denmark, 21 <sup>st</sup> August 2020 project ID S-20200074G.
31 32358 33	The project is approved by the Danish Data Protection Agency (file no. 20/22868) in Region
34359 35	South Denmark.
<sup>36</sup> 37360	All participants are treated according to current clinical standards regardless of the
38 39361 40	randomised study participation. The participants are volunteers and can at any moment
<sup>41</sup> 362 42	withdraw their participation in the study without affecting their current or future treatment
43 44363 45	rights.
<sup>46</sup> 364 47	The Informed Consent form will be found online and it will be signed by all participants willing
48 49365 50	to participate the study and stored in their electronic journals in Department of Audiology,
51366 52	Odense University Hospital. All patients are given both oral and written information about the
<sup>53</sup> 367 54	study.
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6 7 371	Results
8 9 10 <sup>372</sup>	Results will be presented at national and international congresses and published in the
11 12373 13	scientific literature for the attention of professional and scientific audiences on behalf of all
<sup>14</sup> 374 15	study sites and collaborators. A lay summary report will be published for patients and
<sup>16</sup> 17375 18	members of the public.
19376 20	
21 22377	Footnotes
23 24378	Authors' Contributions:
25 26379	YJ and JHS are involved in the conception of the study. LCA and JHS wrote the grant application and the draft of the
<sup>27</sup> 28380	manuscript. JHS and YJ designed and revised the draft methodological content. YJ reviewed the manuscript and JHS critiqued
<sup>29</sup> 381 30	it.
31382 32	Funding:
33383	This study is funded by William Demant grant no. 19-3470 and Interfond grant no. 33.188
<sup>34</sup> 35 <sup>384</sup>	Competing Interests:
<sup>36</sup> 385 37	None declared.
<sup>38</sup> 386 39	Contributership Statement/Acknowledgements:
40387	We are very thankful of the academic English editing by Senior Researcher at Oticon Medical Kathleen Faulkner Scalzo and
41 42 <sup>388</sup>	Assistant Professor Lindsey Van Yper.
<sup>43</sup> 389	We are grateful for the contribution from the patient advisers.
<sup>45</sup> 390 46	Protocol and Registration:
47391 48 49392	This study is registered in ClinicalTrials.gov: NCT04919928
<sup>50</sup> 393	Figure 1: Flowchart
52394 53	Figure 2: Timeline
54395 55	Figure 3: Diagram for loudness balancing
56396 57397 58 59	Reference List
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#### 3 4 Figure 1 5 6 7 Identification 8 Assessed for eligibility (n=) 9 10 Excluded (n=) Enrolment of sixty participants who 11 Not meeting inclusion criteria (n= ) will receive new replacement HAs 12 Declined to participate (n= ) one month before randomization Eligibility Other reasons (n= ) 13 14 Baseline (n=60)Baseline 15 16 17 18 Randomization 1:1 (n=60) 19 Allocation Control group (n=30) 20 Continuous HA+HA treatment (n=) Intervention group (n=30) Decline to proceed with new replacement HAs 21 Received CI surgery (n= ) (n=) Did not receive CI surgery (n=) 22 23 24 25 3 months follow-up 26 Surgery **CI SURGERY** (4 months of new replacement HAs use, 3 months 27 after randomization) 28 Lost to follow-up (n=) 29 èlien 30 31 32 **CI SURGERY CI+HA** fitting 33 34 35 36 **CI+HA** fitting 37 38 3 months after initial bimodal CI+HA fitting 39 Lost to follow-up (n= ) 40 Discontinued intervention (n= ) 41 3 months after initial bimodal CI+HA fitting 42 Lost to follow-up (n= ) 43 Discontinued intervention (n= ) 44 45 Follow-up 46 6 months after initial bimodal CI+HA fitting 47 Lost to follow-up (n= ) 48 49 Discontinued intervention (n= ) 6 months after initial bimodal CI+HA fitting 50 51 Lost to follow-up (n= ) 52 Discontinued intervention (n= ) 53 54 55 12 months after initial bimodal CI+HA fitting 56 57 Lost to follow-up (n= ) 58 Discontinued intervention (n= ) 59 12 months after initial bimodal CI+HA fitting 60 Lost to follow-up (n= ) Discontinued intervention (n= )

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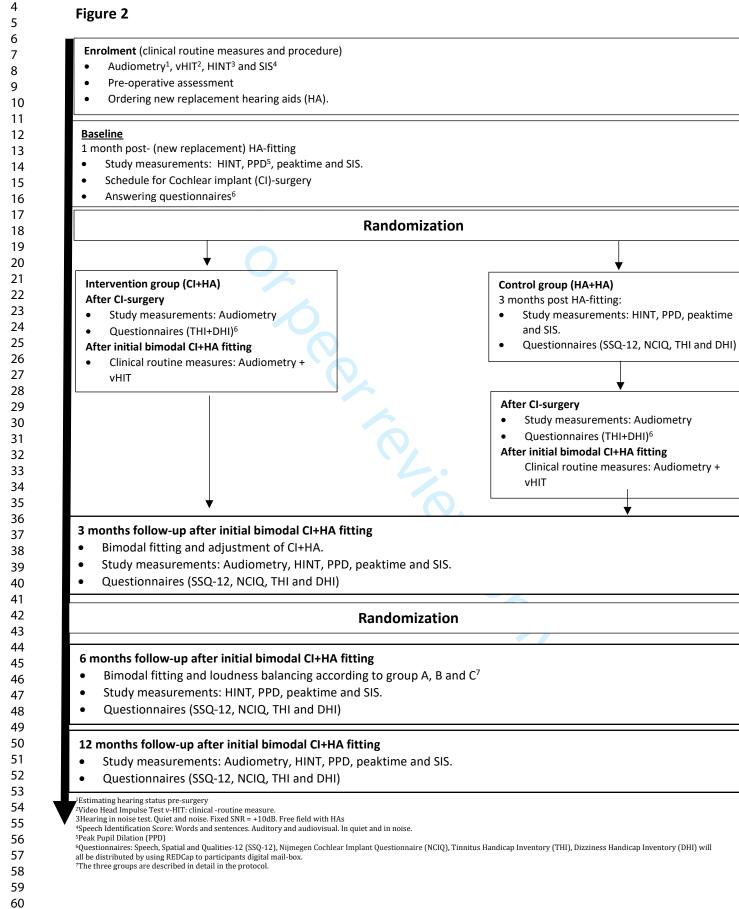
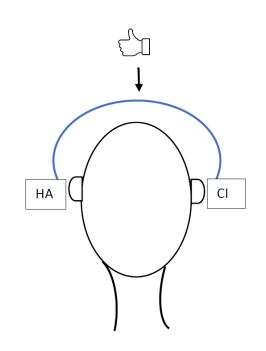


Figure 3



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)

# **Deltagerinformation**

-om deltagelse i et videnskabeligt forsøg

## Behandling af nedsat hørelse med cochlear implantat (CI) 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 

Øre-Næse-Halskirurgisk/Høreklinikken

**Odense Universitetshospital** 

#### 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.

> 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.

P. P. O.

# 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 taleforstålighed. 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.

### 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.

## 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.

#### 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".

#### KONTAKTPERSONER

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

#### **PROJEKTKOORDINATOR:**

Læge Yeliz Jakobsen

Yeliz.jakobsen@rsyd.dk

Tlf: 65412536

#### FORSØGSANSVARLIG LÆGE:

Jesper Hvass Schmidt overlæge, ph.d. Øre-næse-hals/Høreklinikken afd. F Odense Universitetshospital Klinisk lektor, Klinisk Institut Syddansk Universitet Jesper.schmidt@rsyd.dk Tlf: 65412536

#### **BILAG:**

- "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt"
- Komitesystemets fortrykte samtykkeerklæringer.

### 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

# Den Videnskabsetiske Komité for Region Sjælland

Tlf.: +45 93 56 60 00 E-mail: RVKsjaelland@regionsjaelland.dk Hjemmeside: https://www.regionsjaelland. dk/sundhed/forskning/forfagf olk/videnskabsetiskkomite/Sider/default.aspx

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

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

### National Videnskabsetisk Komité Tlf.: +45 72 21 68 55

E-mail: kontakt@nvk.dk Hjemmeside: www.nvk.dk

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#### 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 <u>frivilligt at deltage</u>, 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:		

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

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

 $Ja \_ (sæt x) \qquad Nej \_ (sæt x)$ 

#### 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



# 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.



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).

# 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.



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. <u>https://doi.org/10.1136/bmj.d40</u>.

#### **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/followup) 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. (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. <u>https://doi.org/10.1002/sim.3639</u>.



For peer terier only

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Variable name		Content		Datatype	9	Missing	Excepted range (numeric data)
Inc_date		Date of incl	usion	ddmmy	/	No missin	
Age		<b>C</b> Age at base	onfou	Inde		No missin	g 18-110
Sex				binary		No missin	5
Medicine		Pupil- constricting	/dilating	numeric		No missin	g
Variable name	Cor	Befo	ore Cl Dataty		<b>Sery</b> Miss		Excepted range
TRESHOLDS Day 0 Baseline	tested from 1 kHz. Tresho with h each e separa The m added air bon pureto	ttient can be at frequencies 25 Hz up to 8 olds is tested eadphones and , ar is tested tely, unaided. asker is only when there is a ne gap >10dB at ne audiometry	Numeric		Missing		(numeric data) 0 to 120 db HL
HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA right ear HINT (word) Day 0 Baseline (One month with new replacement HA) Quiet HA left ear	Numb words out of with 5 senten In free Speecl HL. Numb words out of with 5 senten In free	er of correct or sentences 20 sentences words pr ce. field. n level at 65dB er of correct or sentences 20 sentences words pr ce	Numeric			possible	0-100%

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HINT (word)	Number of correct	Numeric	Missing possible	0-100%
Day 0	words or sentences			
Baseline (One month with new	out of 20 sentences with 5 words pr			
replacement HA)	sentence			
Quiet	In free field.			
HA+HA	Speech level at 65dB			
	HL.			
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
Day 0 Baseline	sentences.			
(One month with new	(20 sentences in a HINT)			
replacement HA)	In free field.			
Quiet	Speech level at 65dB			
HA right ear	HL.			
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
Day 0 Baseline	sentences. (20 sentences in a			
(One month with new	HINT)			
replacement HA)	In free field.			
Quiet	Speech level at 65dB			
HA left ear HINT (sentence)	HL. Number of correct	Numeric	Missing possible	0-100%
Day 0	sentences.		61	
Baseline	(20 sentences in a			
(One month with new	HINT)			
replacement HA) Quiet	In free field. Speech level at 65dB			
HA+HA	HL.			
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
Day 0	words or sentences			
Baseline (One month with new	out of 20 sentences			
replacement HA)	with 5 words pr sentence			
Noise	In free field.			
HA right ear	Speech level at 65dB			
	HL.			
	SNR +10 and adapted. Multi-talker babble			
	noise.			
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
Day 0	words or sentences			
Baseline (One month with new	out of 20 sentences with 5 words pr			
replacement HA)	sentence			
Noise	In free field.			
HA left ear	Speech level at 65dB			
	HL.			
	SNR +10 and adapted. Multi-talker babble			
	noise.			
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
Day 0 Baseline	words or sentences out of 20 sentences			
(One month with new	with 5 words pr			
replacement HA)	sentence			
Noise	In free field.			
HA+HA	Speech level at 65dB HL.			
	SNR +10 and adapted.			
	Multi-talker babble noise.			
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
Day 0	sentences.			
Baseline (One month with new	(20 sentences in a HINT)			
replacement HA)	In free field.			
Noise	Speech level at 65dB			
HA right ear	HL.			
	SNR +10 and adapted.			

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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 is calculated	Numeric	Missing possible	0-1
(PPD)	based on the number	rumene	witssing possible	0-1
Day 0	of pixels. PPD of 0.01			
Baseline	would mean 1%			
(One month with new	change in pupil			
replacement HA)	dilation.			
Quiet	HINT sentence			
HA+HA	presented at +10dB SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Peak pupil dilation	PPD is calculated	Numeric	Missing possible	0-1
(PPD)	based on the number			
Day 0 Baseline	of pixels. PPD of 0.01 would mean 1%			
(One month with new	change in pupil			
replacement HA)	dilation.			
Noise	HINT sentence			
HA+HA	presented at +10dB			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Missing possible	0-10sec
Day 0	the pupil to reach			
Baseline	peak dilation.			
(One month with new	HINT sentence presented at +10dB			
replacement HA) Ouiet	SNR, multi-talker			
HA+HA	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			0.40
<b>Pupil Peaktime</b> Day 0	The time it takes for the pupil to reach	Numeric	Missing possible	0-10sec
Day 0 Baseline	peak dilation.			
(One month with new	HINT sentence			
replacement HA)	presented at +10dB			
Noise	SNR, multi-talker			
HA+HA	babble noise			
	Oticon Medical Pupil			
	Labs glasses Measurement &			
	analysis tools			
NCIQ	Questionnaire	numeric	Missing possible	0-100
Basic sound	-			
Day 0				
Baseline				
(One month with new				
replacement HA) NCIQ	Questionnaire	numeric	Missing possible	0-100
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Day 0				
Baseline				
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(One month with new replacement HA)				

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NCIQ	Questionnaire	numeric	Missing possible	0-100
Speech production				
Day 0				
Baseline				
(One month with new				
replacement HA)				
NCIQ	Questionnaire	numeric	Missing possible	0-100
Activity limitation	-		<u> </u>	
Day 0				
Baseline				
(One month with new				
replacement HA)				
NCIQ	Questionnaire	numeric	Missing possible	0-100
Social interaction				
Day 0				
Baseline				
(One month with new				
replacement HA)				
NCIQ	Questionnaire	numeric	Missing possible	0-100
Total				
Day 0				
Baseline				
(One month with new				
replacement HA)				
SSQ	Questionnaire	numeric	Missing possible	0-100
Speech intelligibility				
Day 0				
Baseline				
(One month with new				
replacement HA)				
SSQ	Questionnaire	numeric	Missing possible	0-100
Spatial hearing				
Day 0				
Baseline				
(One month with new				
replacement HA)	Orrestia		Montan 11	0.100
SSQ	Questionnaire	numeric	Missing possible	0-100
Hearing quality				
Day 0 Baseline				
(One month with new				
(One month with new replacement HA)				
	Quastignasing	numoric	Missing passil-1-	0-100
SSQ Total	Questionnaire	numeric	Missing possible	0-100
Total				
Day 0 Baseline				
(One month with new				
(One month with new replacement HA)				
THI	Questionneire	numorio	Missing possible	0-100
	Questionnaire	numeric	wissing possible	0-100
Day 0 Baseline				
(One month with new				
replacement HA)				
DHI	Questionnaire	numeric	Missing possible	0-100
Day 0	Quesuonnaire	numene	wissing possible	0-100
Baseline				
(One month with new				
replacement HA)				
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
3 months	words or sentences	Numenc	wissing possible	0-10070
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Quiet	sentence			
HA right ear				
m mgm cai	Number of correct	Numeric	Missing possible	0-100%
HINT (word)			missing possible	0 100/0
		1 (01110110	01	
HINT (word) 3 months Follow-up with new HA	words or sentences out of 20 sentences		01	

(Total of 4 months with new replacement HA)	with 5 words pr sentence			
Quiet HA left ear				
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
3 months	words or sentences	INUMERIC	wissing possible	0-10070
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Quiet	sentence			
HA+HA				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.		01	
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)	,			
Quiet				
HA right ear				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)				
Quiet				
HA left ear				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)				
Quiet				
HA+HA HINT (word)	Number of correct	Nouseuis	Missing associate	0.1000/
3 months	words or sentences	Numeric	Missing possible	0-100%
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Noise	sentence			
HA right ear				
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
3 months	words or sentences		withoung prossible	0 100/0
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Noise				
HA left ear				
HINT (word)	Number of correct	Numeric	Missing possible	0-100%
3 months	words or sentences			
Follow-up with new HA	out of 20 sentences			
(Total of 4 months with	with 5 words pr			
new replacement HA)	sentence			
Noise				
HA+HA				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)				
Noise				
HA right ear				0.4007
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			
Follow-up with new HA	(20 sentences in a			
(Total of 4 months with	HINT)			
new replacement HA)				
Noise				
HA left ear				
HINT (sentence)	Number of correct	Numeric	Missing possible	0-100%
3 months	sentences.			

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Follow-up with new HA (Total of 4 months with	(20 sentences in a HINT)			
new replacement HA) Noise				
HA+HA				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is		01	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words.			
new replacement HA) Quiet	Speech level is 65dB.			
HA+HA				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is		01	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words.			
new replacement HA)	Speech level is 65dB.			
HA right ear				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is		61	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with new replacement HA)	words.			
Ouiet	Speech level is 65dB			
HA left ear				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA (Total of 4 months with	words out of 25 words.			
new replacement HA)	Speech level is 65dB			
Noise	and noise level is			
HA+HA	65dB. The noise	e.e		
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing a real life "babble"			
	noise.			
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with new replacement HA)	words. Speech level is 65dB			
Noise	and noise level is		3/	
HA right ear	65dB. The noise			
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing a real life "babble"			
	noise.			
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25 words.			
(Total of 4 months with new replacement HA)	words. Speech level is 65dB			
Noise	and noise level is			
HA left ear	65dB. The noise			
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing a real life "babble"			

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SIS Headphones	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is		• •	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Comfort			
new replacement HA)	speech level. Each ear			
Quiet	is tested unaided			
2	separately.			
	separatery.			
SIS Headphones	Speech identification	Numeric	Missing possible	0-100%
Auditory	score in Denmark is	1 (uniterio	nineeing persiene	0 100/0
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Comfort			
new replacement HA)	speech level. Each ear			
Noise	is tested unaided			
IVOISE	separately.			
	The noise signal is			
	amplitude modulated			
	and has a speech			
	shaped spectrum			
	representing a real life			
SIS free field	"babble" noise. Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is	indificite	missing possible	0-10070
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words out of 25 words. Speech level			
new replacement HA)	is 65dB .			
Quiet				
HA+HA			NC 1 11	0.1000/
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level			
new replacement HA)	is 65dB .			
Quiet				
HA right ear	~			0.1000/
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level			
new replacement HA)	is 65dB .			
Quiet				
HA left ear				
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is			
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level is			
new replacement HA)	65db and noise level			
Noise	is 65dB. The noise			
HA+HA	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing			
	a real life "babble"			
	noise.			
SIS free field	Speech identification	Numeric	Missing possible	0-100%
Audio-visual	score in Denmark is		6 r - 551616	
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level is			
new replacement HA)	65db and noise level			
Noise	is 65dB. The noise			
HA right ear	signal is amplitude			
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	speech shaped spectrum representing			

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	a real life "babble"			
SIS free field Audio-visual	noise. Speech identification score in Denmark is	Numeric	Missing possible	0-100%
3 months	percentage correct			
Follow-up with new HA	words out of 25			
(Total of 4 months with	words. Speech level is			
new replacement HA)	65db and noise level			
Noise	is 65dB. The noise			
HA left ear	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing			
	a real life "babble"			
<b>N</b> 1 111 /	noise.	NT :	NC : 11	0.1
Peak pupil dilation	PPD is calculated	Numeric	Missing possible	0-1
(PPD)	based on the number			
3 months Follow-up with new HA	of pixels. PPD of 0.01 would mean 1%			
(Total of 4 months with	change in pupil			
new replacement HA)	dilation.			
Quiet	HINT sentence			
HA+HA	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 is calculated	Numeric	Missing possible	0-1
(PPD)	based on the number	(evie		
3 months	of pixels. PPD of 0.01			
Follow-up with new HA	would mean 1%			
(Total of 4 months with	change in pupil dilation.			
new replacement HA) Noise	HINT sentence			
HA+HA	presented at speech			
	level 65dB and SNR			
	at +10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Missing possible	0-10sec
3 months	the pupil to reach			
Follow-up with new HA	peak dilation.			
(Total of 4 months with	HINT sentence			
new replacement HA)	presented speech level			
Quiet HA+HA	65dB and SNR at +10dB and adaptive			
HATHA	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Missing possible	0-10sec
3 months	the pupil to reach		31	
Follow-up with new HA	peak dilation.			
(Total of 4 months with	HINT sentence			
new replacement HA)	presented speech level			
Noise	65dB and SNR at			
HA+HA	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil Labs glasses			

	Measurement & analysis tools			
NCIQ Basic sound 3 months Follow-up with new HA (Total of 4 months with	Questionnaire	numeric	Missing possible	0-100
new replacement HA)				
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	Questionnaire	numeric	Missing possible	0-100
new replacement HA)			NC 11	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
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
	Afte	er Cl surg	ery	
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
<b>PTA</b> 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
<b>TRESHOLDS</b> 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			
РТА	The patient can be	Numeric	Missing possible	0 to 120 db HL
6 months post bimodal	tested at frequencies			
CI+HA - fitting	from 125 Hz up to 8 kHz.			
	In free field.			
	In best aided			
	condition.			
	No stimuli.			
TRESHOLDS	The patient can be	Numeric	Missing possible	0 to 120 db HL
12 months post bimodal	tested at frequencies		•••	
CI+HA - fitting	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			
	purctone audiometry			
РТА	The patient can be	Numeric	Missing possible	0 to 120 db HL
12 months post bimodal	tested at frequencies		01	
CI+HA - fitting	from 125 Hz up to 8			
	kHz.			
	In free field.			
	In best aided condition.			
	No stimuli.			
HINT (word)	Number of correct	Numeric	Possible	0-100%
Post-surgery	words.			
3 months after fitting	(5 words per			
Quiet	sentences, 20			
CI alone	sentences in a HINT)			
	In free field.			
	Speech level at 65dB HL.			
HINT (word)	Number of correct	Numeric	Possible	0-100%
Post-surgery	words.			
6 months after fitting	(5 words per			
Quiet	sentences, 20			
CI alone	sentences in a HINT) In free field.			
	Speech level at 65dB			
	HL.			
HINT (word)	Number of correct	Numeric	Possible	0-100%
Post-surgery	words.			
12 months after fitting	(5 words per			
Quiet	sentences, 20			
CI alone	sentences in a HINT)			
	In free field.			
	Speech level at 65dB HL.			
HINT (sentence)	HL. Number of correct	Numeric	Possible	0-100%
Post-surgery	sentences.	1 (unione	1 0331010	0-100/0
3 months after fitting	(20 sentences in a			
Quiet	HINT)			
CI alone	In free field.			
	Speech level at 65dB			
	HL.			0.1000/
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HINT (sentence) Post-surgery	Number of correct sentences.	Numeric	Possible	0-100%

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6 months after fitting Quiet	(20 sentences in a HINT)			
CI alone	In free field. Speech level at 65dB HL.			
HINT (sentence) Post-surgery 12 month after fitting Quiet CI alone	HL.         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	HL. 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	Numeric	Possible	0-100%
HINT (sentence) Post-surgery 3 months after fitting Quiet CI+HA	HL. 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.	Numerie	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	Numeric	Possible	0-100%
HINT (word) Post-surgery 3 months after fitting Noise CI +HA	noise. 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	Speech identification score in Denmark is	Numeric	Possible	0-100%
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
CI only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Auditory	score in Denmark is			
Post-surgery	percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
HA only SIS free field	Speech level is 65dB Speech identification	Numeric	Possible	0-100%
Auditory	score in Denmark is	Numeric	Possible	0-100%
Post-surgery	percentage correct			
6 months after fitting	words out of 25			
Quiet	words.			
HA only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Auditory	score in Denmark is			
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
HA only	Speech level is 65dB	Normani	Decellal	0.1000/
SIS free field	Speech identification	Numeric	Possible	0-100%
Auditory Post-surgery	score in Denmark is percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
CI+HA	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Auditory	score in Denmark is			
Post-surgery	percentage correct			
6 months after fitting	words out of 25			
Quiet	words.			
CI+HA SIS free field	Speech level is 65dB	N	Possible	0.1000/
	Speech identification score in Denmark is	Numeric	Possible	0-100%
Auditory Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
CI+HA	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
CI+HA SIS free field	Speech level is 65dB	Numoria	Possible	0-100%
Audio-visual	Speech identification score in Denmark is	Numeric	rossible	0-10070
Post-surgery	percentage correct			
6 months after fitting	words out of 25			
Quiet	words.			<b></b>
CI+HA	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
CI+HA SIS free field	Speech level is 65dB	Numoria	Possible	0-100%
Audio-visual	Speech identification score in Denmark is	Numeric	rossiole	0-10070
Post-surgery	percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
CI only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
6 months after fitting	words out of 25			
Quiet CI only	words.			
· · ·	Speech level is 65dB	1	1	1

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SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet CL only	words.			
CI only SIS free field	Speech level is 65dB Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is	municite	1 0551010	0-10070
Post-surgery	percentage correct			
3 months after fitting	words out of 25			
Quiet	words.			
HA only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
6 months after fitting	words out of 25 words.			
Quiet HA only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is	1 valiferite	1 0001010	5 100/0
Post-surgery	percentage correct			
12 months after fitting	words out of 25			
Quiet	words.			
HA only	Speech level is 65dB			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is			
Post-surgery	percentage correct			
3 months after fitting Noise	words out of 25 words. Speech level is			
Noise CI+HA	65dB and noise level			
<i>C1</i> 11/1	is 65dB. The noise			
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing			
	a real life "babble"			
	noise.	N	D 11	0.1000/
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual Post-surgery	score in Denmark is percentage correct			
6 months after fitting	words out of 25			
Noise	words. Speech level is			
CI+HA	65dB and noise level			
	is 65dB. The noise			
	signal is amplitude			
	modulated and has a			
	speech shaped			
	spectrum representing a real life "babble"			
	a real life "babble" noise.			
SIS free field	Speech identification	Numeric	Possible	0-100%
Audio-visual	score in Denmark is	1 (uniferre	1 0001010	0 10070
Post-surgery	score in Denmark is			
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12 months after fitting	percentage correct words out of 25		4	
12 months after fitting Noise	percentage correct		1	
	percentage correct words out of 25 words. Speech level is 65dB and noise level		1	
Noise	percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise		1	
Noise	percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise signal is amplitude		1	
Noise	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		1	
Noise	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		1	
Noise	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		4	
Noise	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"		7	
Noise	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%
Noise CI+HA	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"	Numeric	Possible	0-100%
Noise CI+HA SIS free field	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. Speech identification score in Denmark is percentage correct	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual	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. Speech identification score in Denmark is percentage correct words out of 25	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual Post-surgery 3 months after fitting Noise	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. Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual Post-surgery 3 months after fitting	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. Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual Post-surgery 3 months after fitting Noise	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. Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level is 65dB. The noise	Numeric	Possible	0-100%
Noise CI+HA SIS free field Audio-visual Post-surgery 3 months after fitting Noise	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. Speech identification score in Denmark is percentage correct words out of 25 words. Speech level is 65dB and noise level	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)	PPD is calculated based on the number	Numeric	Possible	0-1

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3 months after fitting	would mean 1%			
Ouiet	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Quiet	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
12 months after fitting	would mean 1%			
Quiet	change in pupil			
CI only	dilation.			
J	HINT sentence			
	presented at speech	revie		
	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
3 months after fitting	would mean 1%			
Quiet	change in pupil		2/	
HA only	dilation.			
<i></i>	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number		1 0001010	~ <b>1</b>
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Quiet	change in pupil			
HA only	dilation.			
TIA OIIIY	HINT sentence			
	presented at speech			
	level 65dB and SNR			
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	at +10dB and adaptive			

	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

Post-surgery	of pixels. PPD of 0.01			
3 months after fitting	would mean 1%			
Noise	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Noise	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
12 months after fitting	would mean 1%	(evie		
Noise	change in pupil			
CI only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number	-		
Post-surgery	of pixels. PPD of 0.01			
3 months after fitting	would mean 1%			
Noise	change in pupil		21	
HA only	dilation.			
5	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Noise	change in pupil			
HA only	dilation.			
1111 Only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
12 months after fitting	would mean 1%			
Noise	change in pupil			
HA only	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
3 months after fitting	would mean 1%			
Noise	change in pupil			
CI+HA	dilation.			
ertik	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
6 months after fitting	would mean 1%			
Noise	change in pupil			
CI+HA	dilation.		7	
CITIA	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 is calculated	Numeric	Possible	0-1
(PPD)	based on the number			
Post-surgery	of pixels. PPD of 0.01			
	would mean 1%			
12 months after fitting	change in pupil			
12 months after fitting Noise		1		
Noise				
	dilation.			
Noise	dilation. HINT sentence			
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Noise	dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil			
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Noise	dilation. HINT sentence presented at speech level 65dB and SNR at +10dB and adaptive SNR, multi-talker babble noise Oticon Medical Pupil			

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

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Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
3 months after fitting	peak dilation.			
Quiet	HINT sentence			
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	65dB and SNR at			
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Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
6 months after fitting	peak dilation.			
Quiet	HINT sentence			
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Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach	Ivuillerie	1 0331010	0-10300
12 months after fitting	peak dilation.			
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	SNR, multi-talker			
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	Measurement &	•		
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
3 months after fitting	peak dilation.			
Noise	HINT sentence			
CI only	presented speech level			
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	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses Measurement &			
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Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
6 months after fitting	peak dilation.			
Noise	HINT sentence			
CI only	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
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Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			-
12 months after fitting	peak dilation.			
Noise	HINT sentence			
CI only	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach	INUITICITC	rossible	0-10800
3 months after fitting	peak dilation.			
Noise	HINT sentence			
HA only	presented speech level			
5	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
6 months after fitting	peak dilation.			
Noise	HINT sentence			
HA only	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach	Numeric	1 0551010	0-10500
12 months after fitting	peak dilation.			
Noise	HINT sentence			
HA only	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement &			
	analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach			
3 months after fitting	peak dilation.			
Noise	HINT sentence			
CI+HA	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
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Dunil Doolstime	analysis tools	Numoric	Possible	0.10sac
Pupil Peaktime	The time it takes for	Numeric	POSSIBLE	0-10sec
Post-surgery 6 months after fitting	the pupil to reach			
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	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement & analysis tools			
Pupil Peaktime	The time it takes for	Numeric	Possible	0-10sec
Post-surgery	the pupil to reach	Numerie	1 0351010	0-10300
12 months after fitting	peak dilation.			
Noise	HINT sentence			
CI+HA	presented speech level			
	65dB and SNR at			
	+10dB and adaptive			
	SNR, multi-talker			
	babble noise			
	Oticon Medical Pupil			
	Labs glasses			
	Measurement & analysis tools			
NCIO			Possible	0-100
NCIQ Basic sound	Questionnaire	numeric	Possible	0-100
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Advanced Sound				
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Speech production				
Post-surgery				
3 months after fitting NCIO	Quantiannation		Possible	0-100
NCIQ Self-esteem	Questionnaire	numeric	rossible	0-100
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Activity limitation	<b>C</b>			
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Social interaction				
Post-surgery				
3 months after fitting NCIQ	Questionnaire	numeric	Possible	0-100
Total	Quesuonnane	numerie	1 0551010	0-100
Post-surgery				
3 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Basic sound				
Post-surgery				
6 months after fitting				<u> </u>
NCIQ	Questionnaire	numeric	Possible	0-100
Advanced Sound				
Post-surgery				
6 months after fitting	Questionnaire	numorio	Possible	0-100
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NCIQ	Questionnaire	numeric	Possible	0-100
Self-esteem				
Post-surgery				
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NCIQ	Questionnaire	numeric	Possible	0-100
Activity limitation				
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NCIQ	Questionnaire	numeric	Possible	0-100
Social interaction Post-surgery				
6 months after fitting				
o monuis anoi mung				

NCIQ	Questionnaire	numeric	Possible	0-100
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6 months after fitting				
NCIO	Questionnaire	numeric	Possible	0-100
Basic sound	Questionnane	numene	rossible	0-100
Post-surgery				
12 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Advanced Sound	Questionnune	numerie	1 0001010	0 100
Post-surgery				
12 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
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NCIQ	Questionnaire	numeric	Possible	0-100
Self-esteem	Queronium e		1 0001010	0 100
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12 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Activity limitation				
Post-surgery				
12 months after fitting				
NCIO	Questionnaire	numeric	Possible	0-100
Social interaction				· · · · ·
Post-surgery				
12 months after fitting				
NCIQ	Questionnaire	numeric	Possible	0-100
Total	Questionnaire	numerie	1 0001010	0 100
Post-surgery				
12 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Speech intelligibility	Questionnane	numerie	1 0351010	0 100
Post-surgery				
3 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Spatial hearing	Questionnin		1 0001010	0 100
Post-surgery				
3 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Hearing quality	Questionnin		1 0001010	0 100
Post-surgery				
3 months after fitting				
SSQ	Questionnaire	numeric	Possible	0-100
Total	<b>C</b>			
Post-surgery				
3 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Speech intelligibility				
Post-surgery				
6 months after fitting				
SSQ	Questionnaire	numeric	Possible	0-100
Spatial hearing	Caronania			
Post-surgery				
6 months after fitting				
SSQ	Questionnaire	numeric	Possible	0-100
Hearing quality				
Post-surgery				
6 months after fitting				
SSQ	Questionnaire	numeric	Possible	0-100
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6 months after fitting				
SSO	Questionnaire	numeric	Possible	0-100
Speech intelligibility	2 uobioiniuno		1 3001010	\$ 100
Post-surgery				
12 months after fitting				
				0.100
	Questionnaire	numeric	Possible	0 - 100
SSQ Spatial hearing	Questionnaire	numeric	Possible	0-100

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



## BMJ Open CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	ltem No	Checklist item	Reported on page N
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 gee CONSORT for abstracts)	1
Introduction		2022.	
Background and	2a	Colortific bookground and exploration of rationals	3-6
objectives	2b	Specific objectives or hypotheses	5-6
Methods		Specific objectives or hypotheses	
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6-10
5	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	How sample size was determined When applicable, explanation of any interim analyses and stopping guidelines Method used to generate the random allocation sequence Type of randomisation; details of any restriction (such as blocking and block size)	13-15
Randomisation:		202	
Sequence	8a	Method used to generate the random allocation sequence	9-10
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size) ਰੂੰ	9-10
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially mumbered containers),	9-10/14-15
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned 구 한	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who as signed participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, 🖉	
CONSORT 2010 checklist		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	Pad

Page	: 73 of 79		BMJ Open	
			assessing outcomes) and how	
1		11b	If relevant, description of the similarity of interventions	14-15
2 3	Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	14-15
4		12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	14-15
5	Deculto			
6 7	<b>Results</b> Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	
8	diagram is strongly	154	were analysed for the primary outcome	
9	recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	
10 11	Recruitment	14a	Dates defining the periods of recruitment and follow-up	
12	Reorditinent	14b	Why the trial ended or was stopped	
13	Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
14	Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	
15 16	Numbers analysed	10	by original assigned groups	
17	Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	
18	estimation	170	precision (such as 95% confidence interval)	
19 20	ootimation	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
21	Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted adalyses, distinguishing	
22			pre-specified from exploratory	
23 24	Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for arms)	
25	Discussion			
26	Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, mulgplicity of analyses	15
27 28	Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
20	Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
30		~~		
31	Other information	22	Desistration number and name of trial registry	1 0 16 17
32 33	Registration	23	Registration number and name of trial registry	1, 2, 16, 17
34	Protocol	24 25	Where the full trial protocol can be accessed, if available	47
35	Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	17
36 37	Ψ <b>Τ</b> Τ / 1	1 1.		. 1
38	• •		g this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If rele extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and	
39	-		by the second se	pragmatic triais.
40 41	Additional extensions are		similing. for those and for up to date references relevant to this checknist, see <u>www.consort-statement.org</u> .	
42			wining. for those and for up to date references relevant to this eleckrist, see <u>www.consort-statement.org</u> .	
43	CONSORT 2010 checklist		For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	Page 2
44 45				
45 46				

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

Section/item	ltem No	Description 2022	Addressed on page number
Administrative inf		Dow	page number
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 Date and version identifier Sources and types of financial, material, and other support	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	5a	Names, affiliations, and roles of protocol contributors	1,17
responsibilities	5b	Names, affiliations, and roles of protocol contributors	1,17
	5c	Role of study sponsor and funders, if any, in study design; collection, management, a alysis, 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 over seeing the trial, if applicable (see Item 21a for data monitoring committee)	17
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1 2	Introduction		022-07	
- 3 4 5	Background and rationale	6a	Description of research question and justification for undertaking the trial, including sugmmary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-6
6 7		6b	Explanation for choice of comparators	4-5
8 9	Objectives	7	Specific objectives or hypotheses	6
10 11 12 13	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factoria single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, explorator)	7
14 15	Methods: Participa	nts, inte	erventions, and outcomes	
16 17 18	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
19 20 21	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
22 23 24 25	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-13
26 27 28		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
29 30 31		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	11-12
32 33		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	12
34 35 36 37 38 39 40 41	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
42 43 44 45 46			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	2

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			BMJ Open	Page 76 c
1 2 3 4	Participant timeline	13		9,11-13 ppendix A, Figure and 2
5 6 7	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was $\frac{9}{6}$ etermined, including 14 clinical and statistical assumptions supporting any sample size calculations	1, Table 1
8 9	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	10
10 11 12	Methods: Assignme	ent of i	nterventions (for controlled trials)	
13 14	Allocation:			
15 16 17 18 19	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any 9- 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	10
20 21 22 23 24	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, 9- opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
25 26 27	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to 9- interventions	10
28 29 30	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome $9$ -assessors, data analysts), and how	10
31 32 33 34		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's 9- allocated intervention during the trial	10
35 36	Methods: Data colle	ection,	management, and analysis	
37 38 39 40 41 42 43 44 45	Data collection methods	18a	processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of pla study instruments (eg, questionnaires, laboratory tests) along with their reliability and galidity, if known.	3-15, statistical an(SAP), Data anagement an(DMP) 3

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1 2 3 4 5 6 7 8 9 10		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		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
11 12		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13-15, SAP
13 14 15 16		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
17 18	Methods: Monitorin	g		
19 20 21 22 23 24	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
25 26 27		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
28 29 30 31 32 33	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously performed adverse events and other unintended effects of trial interventions or trial conduct	13-15, SAP
	Auditing	23	from investigators and the sponsor	n/a
34 35 36	Ethics and dissemi	nation	Pr	
37 38 39 40 41	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	2,7,16
42 43 44 45			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	4

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1 2 3 4	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility cheria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial regiseries, journals, regulators)	13-15, SAP
5 6 7	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
8 9 10		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
11 12 13	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
14 15 16 17	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	17
17 18 19 20	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
21 22 23	Ancillary and post- trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those whoesuffer harm from trial participation	Consent form
24 25 26 27	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
28 29		31b	Authorship eligibility guidelines and any intended use of professional writers	17
30 31 32 33		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	MAP
34	Appendices		gu es	
35 36 37	Informed consent materials	32	Model consent form and other related documentation given to participants and author is a surrogates	As online supplementary
	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for generatic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	file n/a
41 42 43 44 45			For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml	

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