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Published in:
BMJ Open

DOI:
10.1136/bmjopen-2022-065777

Publication date:
2023

Document version:
Final published version

Document license:
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Citation for pulished version (APA):
Pedersen, C. C., Pedersen, E. R., Laugesen, S., Sanchez-Lopez, R., Nielsen, J., Sørensen, C. B., Sidiras, C., Pedersen, R. G., & Schmidt, J. H. (2023). Comparison of hearing aid fitting effectiveness with audiograms from either user-operated or traditional audiometry in a clinical setting: a study protocol for a blinded non-inferiority randomised controlled trial. *BMJ Open*, *13*(3), Article e065777. https://doi.org/10.1136/bmjopen-2022-065777

BMJ Open

Comparison of hearing aid fitting effectiveness with audiograms from either user-operated or traditional audiometry in a clinical setting: a study protocol for a blinded non-inferiority randomised controlled trial

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To cite: Pedersen CC, Pedersen ER, Laugesen S, *et al*. Comparison of hearing aid fitting effectiveness with audiograms from either user-operated or traditional audiometry in a clinical setting: a study protocol for a blinded non-inferiority randomised controlled trial. *BMJ Open* 2023;**13**:e065777. doi:10.1136/bmjopen-2022-065777

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-065777).

The Clinical Trial registration number of the study is NCT05043207. The findings of this project will be submitted to an international peer-reviewed journal and presented at national and international conferences.Any important protocol modifications will be highlighted in relevant publications.

Received 17 June 2022
Accepted 22 February 2023

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ABSTRACT

Introduction There is a worldwide need to enhance the capacity of audiometry testing. The objective of this study is to compare the User-operated Audiometry (UAud) system with traditional audiometry in a clinical setting, by investigating if hearing aid effectiveness based on UAud is non-inferior to hearing aid effectiveness based on traditional audiometry, and whether thresholds obtained with the user-operated version of the Audible Contrast Threshold (ACT) test correlates to traditional measures of speech intelligibility.

Methods and analysis The design will be a blinded non-inferiority randomised controlled trial. 250 adults referred for hearing aid treatment will be enrolled in the study. Study participants will be tested using both traditional audiometry as well as the UAud system and they will answer the questionnaire Speech, Spatial and Qualities of Hearing Scale (SSQ12) at baseline. Participants will be randomly divided to receive hearing aids fitted based on either UAud or traditional audiometry. Three months after participants have started using their hearing aids, they will undergo a hearing in noise test with hearing aids to measure their speech-in-noise performance and answer the following questionnaires: SSQ12, the Abbreviated Profile of Hearing Aid Benefit and the International Outcome Inventory for Hearing Aids. The primary outcome is a comparison of the change in SSQ12 scores from baseline to follow-up between the two groups. Participants will undergo the user-operated ACT test of spectro-temporal modulation sensitivity as part of the UAud system. The ACT results will be compared with measures of speech intelligibility from the traditional audiometry session and follow-up measurements.

Ethics and dissemination The project was evaluated by the Research Ethics Committee of Southern Denmark and judged not to need approval. The findings will be submitted to an international peer-reviewed journal and presented at national and international conferences.

Trial registration number NCT05043207.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study uses a randomised controlled trial to compare the outcomes of hearing aid fittings based on user-operated audiometry with those based on traditional audiometry.
⇒ This study uses comprehensive patient-reported outcomes measures and objective tests of speech intelligibility.
⇒ This study will compare how the language independent Audible Contrast Threshold test correlates with language dependent measures of speech intelligibility in noise.
⇒ There is a limited risk of selection bias due to how patients are referred to participate in the study, which can affect the generalisability of the results.

INTRODUCTION

There is a worldwide need to enhance the capacity of audiometry testing, so clinicians can detect and treat the growing number of people with hearing loss in the population. This is due to the fact that most countries have experienced a significant population ageing, which presumably will continue into the future.[1] Approximately 60% of people with hearing loss are older than 60 years of age,[2] and the average age of first-time hearing aid (HA) users is 67 years,[3] which means that the demand for hearing tests will increase.

Hearing loss can have a negative impact on a person's ability to work and function in their professional roles.[4] Furthermore, hearing loss is also a risk factor for cognitive decline and even dementia.[5] Therefore, it has great societal impact to diagnose and treat hearing

loss before these negative consequences of hearing loss appear.

Accurate examination of hearing for clinical decisions is the bottleneck in the current clinical system of hearing rehabilitation in many countries.[6] Today, examination is made using traditional manual audiometry, which requires a clinically trained person to conduct the procedure. It is necessary to examine a person's hearing with pure-tone audiometry at least one time, to be provided with HAs. Furthermore, it is recommended that people with substantial and chronic hearing loss are tested once a year, or at least once every 2 years.[6] Thus, there is a need for expanding the capacity or improving efficiency of the audiology services to reduce waiting time. A solution is user-operated audiometry[7] where patients test their own hearing without any involvement of an external operator of the audiometry equipment. This would allow for a more efficient examination of hearing loss compared with traditional audiometry. It has previously been estimated that user-operated audiometry can be used as a replacement for 80% of all current audiometry measurements.[6] In a global context, implementation of user-operated audiometry would also make it possible to provide examination of hearing to a larger share of the underserved population.[6]

User-operated audiometry

User-operated audiometry has been widely studied, but its clinical use and acceptance is still limited. One of the earliest versions of user-operated audiometry was the Bekesy audiometer.[8] Since then, different user-operated audiometry systems have been developed, both for clinical use[9 10] and for home testing through computer or smartphone and app-based platforms.[11–13]

In general, studies have found that user-operated audiometry is reliable and accurate, with most studies finding no significant difference between user-operated audiometry and traditional audiometry in measuring air-conduction pure-tone thresholds.[9 14 15] Additionally, a meta-analysis from 2013[16] found that the difference between user-operated automated audiometry and traditional audiometry was comparable with test–retest differences for traditional audiometry in measuring air-conduction pure-tone thresholds in adults. One of the most well-documented user-operated audiometry systems for clinical use is the Automated Method for Testing Auditory Sensitivity (AMTAS).[17] Several studies have investigated the accuracy and reliability of AMTAS, suggesting that the hearing thresholds obtained using AMTAS are comparable to the ones obtained using traditional audiometry.[18 19]

Supra-threshold audiometry test

Speech audiometry is an essential component of clinical audiology and hearing research, with the purpose of assessing the patient's speech intelligibility. Speech audiometry is used in diagnostics, and in the assessment of the hearing loss' effect on the individual listener's communication.[20]

Speech intelligibility is often tested using a standardised method and a validated speech material containing lists of monosyllabic or bisyllabic words phonetically balanced for each individual language. For example, NU-6 and PB-50 monosyllabic word lists are commonly used in English,[21 22] and the DANTALE[23] in Danish. The Hearing in Noise Test[24] (HINT), which uses everyday sentences, is also a widely used material and has been adapted to multiple languages,[25] including Danish.[26] These tests are all language dependent, which naturally limits their applicability when language borders are crossed.[20] This means that a person must master the specific language to perform the test, and tests must be developed and validated to be applicable in other languages. Furthermore, these tests are conducted by the patient repeating what he or she has heard, which then requires a skilled clinician to assess if the word or sentence was repeated correctly or not. This makes the test resource demanding, it relies on a subjective judgement from the clinician and might be complicated in cases where the patient is not tested in his/her mother tongue. Therefore, there is considerable potential for improvement towards a more effective, objective and language independent test of patients' speech intelligibility and supra-threshold hearing abilities.

The Audible Contrast Threshold (ACT) test is a new clinical test measuring spectro-temporal modulation sensitivity.[7] In the research literature, similar tests are often referred to as tests of Spectro-temporal Modulation Detection[27] (STMD). The patient's task is to discriminate between spectro-temporally modulated noise and non-modulated noise.[27] Results from ACT (or STMD) tests have in several studies shown good correlations with aided speech-in-noise performance,[27–29] in particular, when more 'ecologically valid' speech-in-noise test conditions were used with running speech maskers presented from separate loudspeakers in moderately reverberant conditions.[27] The advantages of using ACT as a proxy for an ecologically valid speech-in-noise test are simplicity in terms of equipment needed, short test time, and not least that ACT is truly language independent. As an alternative, multilingual speech-in-noise tests have been proposed in different forms.[30] These tests are easier to develop because of its limited speech material and showed promise as a universal screening hearing assessment tool.[31] However, matrix sentence tests or tests based on digit triplets might not be able to accurately capture essential hearing abilities in people with hearing loss.[32]

Thus, ACT is a potentially useful diagnostic tool in the assessment of the hearing loss' effect on the patient's communication abilities. Per the present study, the ACT test has been implemented in a user-operated version (UACT) suitable for a user-operated system.

Patient-reported outcome measures

Patient-reported outcome measures (PROMs) are validated self-reported questionnaires, which are completed

by patients to measure their perceptions of their own functional status and well-being.[33] PROMs are often used in clinical research and daily practice to assess the patients' perspective on their own disease, functional status, quality of life, satisfaction with treatment, etc,[34] and they are also fundamental in measuring the success of HA use.[3]

Some of the most used PROMs for evaluating the patients' perception of their own hearing difficulties and outcome of HA use are the Speech, Spatial and Qualities of Hearing Scale[35] (SSQ12), the Abbreviated Profile of Hearing Aid Benefit[36] (APHAB) and the International Outcome Inventory for HAs[37] (IOI-HA). All these questionnaires are often used to access the outcome of hearing interventions in clinical research.[3 38 39]

It is known that tinnitus has an impact on the patients' self-perceived hearing experience[3] and should, therefore, be considered when evaluating the benefit of HA use. An often-used PROM for quantifying the impact of tinnitus on daily living is the Tinnitus Handicap Inventory[40] (THI).

Objectives

Currently, the accuracy of user-operated audiometry is well documented, but the value for clinical use as a base for HA fitting is still unclear.

The objective of this study is to compare user-operated audiometry with traditional audiometry as a base for HA fitting, by using a blinded randomised control trial to investigate if HA fitting based on UAud is non-inferior compared with HA fitting based on traditional audiometry. The success of the HA fitting will be evaluated by comparing the changes in self-reported hearing difficulties, aided speech-in-noise performance and self-reported outcome of HA use between groups fitted with either UAud or traditional audiometry. Non-inferiority will be concluded if none of the comparisons show a statistically significant difference. Furthermore, the study will investigate if the UACT test can act as a proxy for measurement of speech intelligibility in a user-operated setting, by evaluating the correlations between UACT results, and measures of speech intelligibility, self-reported hearing difficulties and aided speech-in-noise performance. A desired outcome will be a strong significant correlation (above r=0.7) as observed in previous studies with less numerous samples.

METHODS AND ANALYSIS

This manuscript was written according to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines.[41]

Patient and public involvement

Prior to the design of the current study, we have investigated and interviewed adults with hearing loss and with experience in the traditional audiometry method as well as hearing care professionals (HCPs). Adults with hearing loss were in general positive about the implementation of a user-operated audiometry system, while the HCPs were, in general, more sceptical. The HCPs were especially worried about the validity of the test results, and thus worried about using them to fit HAs, therefore, the necessary steps to ensure the blindedness of the study have been taken with special caution.

Study participants

An expected group of 250 consecutively referred adults with a hearing impairment eligible for bilateral HAs, fulfilling the inclusion and escaping the exclusion criteria will be included in the study.

Inclusion criteria

- Sensorineural hearing loss with hearing thresholds exceeding 20 dB HL at two or more frequencies in the frequency range of 0.5–4 kHz.
- Symmetric hearing loss with a maximum pure-tone average (PTA) (mean of 0.5-1-2-4 kHz) difference between the ears of 15 dB HL.
- Danish native speaker.
- No previous experience with HAs.
- Capable of answering questionnaires through an online mailbox.

Exclusion criteria

- Air-conduction audiometry thresholds exceeding 80 dB HL at two or more frequencies.
- Treatment affected by conductive hearing loss (air-bone gap >10 dB on more than one frequency below 1 kHz).
- Conditions with fluctuating hearing loss, for example, Menière's, ongoing treatment with ototoxic drugs.
- Ear, nose or throat surgery in the past 12 months.
- Evidence that the participant has made minor use of the HAs during the study (eg, <2 hours per day).
- Visual or motor impairment that might affect the use of the UAud system.

The participants will be recruited to the study by referral from their local otolaryngologist, who will make an initial screening based on the inclusion and exclusion criteria. Written informed consent will be obtained at the first visit.

Study design

The study design will be a blinded non-inferiority randomised controlled trial. The study will take place from September 2022 to May 2023 at a public clinic for hearing assessments and hearing rehabilitation at Odense University Hospital (OUH), Denmark.

At the first visit, participants will either undergo a traditional audiometry session followed by a UAud session or vice versa. If a participant turns out not to fulfil all the inclusion and escape all exclusion criteria based on the results from one of these measurements the participant will be excluded from the study at this point and will not count as one of the expected 250 participants. Participants will answer the SSQ12 and a THI questionnaire (in

case of patient-reported tinnitus) at baseline. Participants can either fill in the PROMs online between the first and second visit or print them out and bring them to their second visit.

After the first visit, participants will be randomly assigned into one of the two groups: UAud group and control group. The UAud group will receive HAs fitted based on the audiogram obtained in the UAud session and the control group will receive HAs fitted based on the audiogram obtained in the traditional audiometry session. The HA fitting will take place at the second visit at OUH, approximately 10 weeks after the first visit.

Follow-up measurements will be conducted twelve weeks after the HA fitting. Participants will answer the SSQ12, APHAB and IOI-HA online or print out and bring them to their third visit. At the third visit, participants will undergo a battery of aided speech-in-noise performance tests using the HINT material.

Participants, who fail to show up at their appointments, will be contacted in order to reschedule. Participants who fail to show up for two consecutive appointments will be excluded from the study.

A flow diagram for the suggested study and possible time plan for each participant is represented in figure 1.

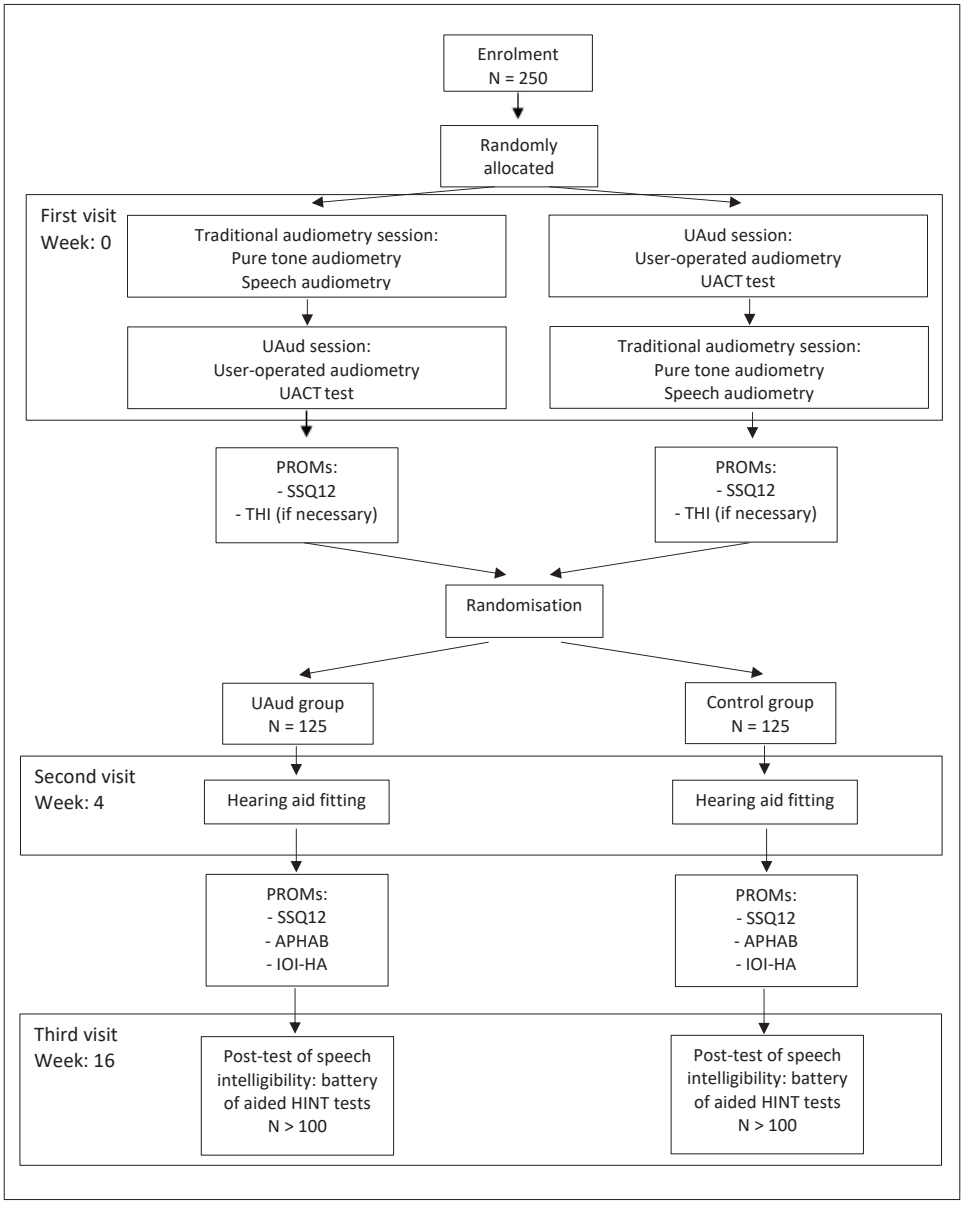

Figure 1 Flow diagram for the suggested study. APHAB, Abbreviated Profile of Hearing Aid Benefit; HINT, Hearing in Noise Test; IOI-HA, International Outcome Inventory for Hearing Aids; PROMs, patient-reported outcome measures; SSQ12, Speech, Spatial and Qualities of Hearing Scale 12; THI, Tinnitus Handicap Inventory.

Measurements and procedures

Randomisation and blinding

The participants will be randomly divided at two time points during the study. Before the first visit, the participants will be randomly allocated (alternately allocated on inclusion) to either start with the traditional audiometry session, followed by the UAud session or vice versa. Before the second visit, the participants will be randomised to either the UAud or the control group. This randomisation will be stratified according to over/under PTA=45 dB HL. The randomisation will be executed using a randomisation tool in Research Electronic Data Capture[42] (REDCap).

The HA fitting procedure will be blinded, so neither the participant, the audiologist, nor the follow-up test examiner knows which group the participant belongs to.

Traditional audiometry session

Traditional audiometry will be conducted in a soundproof booth by a trained audiologist. All participants will be examined bilaterally with otoscopy and tympanometry prior to testing to ensure normal middle ear functions. The tympanometry measurement will be carried out using the Madsen Zodiac Tympanometer (Natus, Taastrup, Denmark). Pure-tone air-conducted thresholds at octave (250–8000 Hz) and interoctave (3000 and 6000 Hz) frequencies will be examined as well as bone-conducted pure-tone thresholds at octave frequencies (250–4000 Hz) in both ears. During the examination, the audiologist will use pure-tone or alternatively warble tones in case of interfering tinnitus if it is deemed necessary for adequate threshold determination. The traditional audiometry session will also include a measure of speech intelligibility by measuring the word discrimination scores (DS) using the DANTALE I word lists. DS is the percentage of correctly repeated words. DANTALE consists of 8 word lists each containing 25 monosyllabic words.[23] Each participant will be presented with one list per ear at the most comfortable level (PTA+40 dB). The traditional audiometry will be carried out using a Madsen Astera^2 audiometer (Natus, Taastrup, Denmark) connected with the DD65 v2 headphones (RADIOEAR, Minnesota, USA) and in accordance with ISO 8253-1[43] international standard for audiometric procedures.

UAud session

The user-operated automated audiometry system which will be tested in this study is called UAud and is based on the AMTAS system. AMTAS is based on a single-interval psychophysical method using a yes-no paradigm.[17] Tone stimuli are presented in a temporal observation interval that is visually marked for the participant. Catch trials, an observation interval where no signal is presented, occur randomly throughout the test. The tone stimuli are changed with an adaptive method to find the threshold of audibility, and masking noise is always presented to the non-test ear.[17] While the original AMTAS is in English, the UAud version is in Danish.

The UAud session will be conducted in a quiet but non-soundproof room (with a mean ambient broadband noise level below 50 dB SPL) where the participants will be instructed to follow the instructions given on the screen. The participant is expected to begin the test by themselves, placing the headphones in the advised position and starting the test. The same eight air-conduction frequencies as in the traditional audiometry will be tested. The UAud session will also feature the UACT test, which will be performed immediately after the threshold testing, using the just established thresholds as input parameters for the UACT. The setup will be a combination of an external Affinity Compact audiometer (Interacoustics, Middelfart, Denmark), delivering the sound output, connected to a touch-screen computer via USB-connection. The sound stimuli will be delivered through a pair of DD65 v2 headphones connected to the audiometer.

HA fitting

The UAud group will receive fitted HAs based on audiometry obtained in the UAud session and the control group will receive fitted HAs based on the audiometry obtained in the traditional audiometry. All participants will receive Oticon *More* HAs (Oticon, Smørum, Denmark). The acoustic parameters of the HA's speaker and earpiece will be based on the recommendation from the Genie 2 HA fitting software from Oticon. HAs will be fitted with the NAL-NL2 rationale (National Acoustics Laboratories, Macquarie, Australia) and all participants will have real-ear measurements (REM) made to adjust the insertion gain of the HAs. REM will be carried out using the REM function of the Affinity Compact audiometer. Following standard procedures, a fitting within ±5 dB of target will be considered a successful result. The initial HA fitting will only include a standard programme fitted to the NAL-NL2 target and the volume control will be disabled. Likewise, the participants will be instructed not to use the HA app or mobile connection until after visit 3. The data log function of the HA will be used for monitoring the participants' HA use.

Outcome measures

The primary outcome will be before-and-after changes in subjectively assessed own hearing measured with the change in SSQ12 overall score from baseline to follow-up. SSQ12 is a questionnaire with 12 items covering the 10 subscales: speech in quiet, speech in noise, speech in speech contexts, multiple speech stream listening, localisation, distance and movement, segregation, identification of sound, quality and naturalness, and listening effort. Each item is scored on a scale from 0 to 10, with 0 as the worst and 10 as the best perception. The overall score is a mean score of the 12 items.[35]

The secondary outcomes include aided speech-in-noise performance measured by speech reception thresholds (SRT) in noise at the follow-up measurements, as well as change in the SSQ12 subscales scores from baseline to follow-up. The Danish version of HINT[26] will be used for

testing the patients' SRT in a speech-on-speech condition with spatially separated single-talker maskers in a sound field condition with moderate reverberation.[29] The HINT will be performed with a fixed target level of 65 dB SPL and an adaptive signal-to-noise-ratio to capture the threshold for 50% correct sentence reception in noise. The HINT target speech material consists of 10 test lists and 3 practice lists each containing 20 everyday sentences of 5 words.[26] Each participant will be tested using two concatenated test lists (40 sentences) following two training runs with 20 and 40 sentences, respectively.

The outcome of HA use measured with IOI-HA and APHAB at follow-up will be elaborative outcomes as well as tests targeting possible over or under amplifying HAs. The IOI-HA consists of seven items each representing one of the seven subscales: daily use, benefit, residual activity limitations, satisfaction, residual participation restrictions, impact on others and quality of life. The items are scored on a scale from 1 to 5, with a higher score reflecting a better outcome. The IOI-HA total score will be calculated as the sum of the seven items[44] and also by using the item specific category weights suggested by Leijon *et al*[45] to score the IOI-HA. The APHAB consists of 24 items, which are divided into four subscales. Three subscales reflect speech communication in various environments (ease of communication, background noise and reverberation) and one subscale reflects the perception of environmental sounds (aversiveness).[36] The items are scored on a scale from 1 to 7, with higher scores reflecting a higher occurrence of problems. APHAB also contains a global score, which is the average of the scores from the subscales reflecting speech communication in various environments. We will use variations of the HINT to test for possible under amplification (HINT-L) or over amplification (HINT-U). To test for underamplification, we will measure an aided SRT with target speech presented at low levels without background noise to capture the threshold for 50% correct sentence reception in quiet. Thus, the target level will be adapted. By comparing the distributions of these SRTs between the UAud and the control groups, an eventual tendency towards underamplification in the UAud group will be revealed. We will test for overamplification by using the HINT framework in an adaptive loudness scaling test. The aim is to estimate the target speech level in dB SPL for a loudness rating of 'too loud'[46] by varying the speech level with a fixed background noise level at 65 dB SPL and while wearing HAs. Again, by comparing the distributions of these 'too-loud' SPLs between the UAud and the control groups, an eventual tendency towards over-amplification in the UAud group will be revealed.

Statistics

All the statistical analyses will be conducted using STATA V.17 IC-15 (StataCorp).

The study is powered to be able to show a minimal clinically important difference in SSQ12 of 0.81, equal to an effect size of Cohen's d=0.5.[47] Power calculations with a power of 0.8 with a significance level of 0.05 have been made with STATA IC-17 using SD of 1.62 from the SSQ12 total score retrieved from the Better hEAring Rehabilitation (BEAR) project through personal communication. This leads to a sample size of 51 in each study group. Due to the likely impact of these results on the clinical practice, and because single-centre studies do not have the same scientific validity as multicentre studies,[48] we decided to raise the sample size to 100 in each group. This is equal to a power of 0.97. With an estimated drop-out rate of 25 %, the sample size requirements are 125 in each group.

The difference between the SSQ12 scores at baseline and follow-up will be compared across groups. A constrained linear mixed model is used to analyse the outcome of change in SSQ12 score between baseline and follow-up. The model will include randomisation group (UAud/control), time (baseline/follow-up) and their interaction as fixed effect 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 treatment (groups). Model validation will be performed by visual inspection of residuals, fitted values and random effect estimates.

A one-way analysis of variance will be used to compare the mean in SRT in the two groups. The model will include randomisation group as the independent factor and SRT as the dependent factor.

Correlations between UACT results and DS will be investigated. Furthermore, correlations between UACT results and SRT will be compared with the correlation between DS and SRT. Likewise, correlations between UACT results and SSQ12 scores at baseline and post-test will be compared with correlations between DS scores and SSQ12 scores at baseline and follow-up.

Bias

All enrolled patients who meet the inclusion and escape the exclusion criteria will be included in the study to avoid selection bias. The study will report missing data as recommended for clinical trials,[49] by following the Consolidated Standards of Reporting Trials statement.[50] At the end of the study, a drop-out analysis will be conducted, to check if drop-out participants differ from the rest of the enrolled participants in terms of age, sex and over/under PTA=45 dB HL to avoid attrition bias.

DATA MANAGEMENT

Handling of person-sensitive data that is governed by General Data Protection Regulation (GDPR) will be conducted using the respective partner's preapproved GPDR-compliant IT systems. Appropriate data manager agreements will be made with researchers from all partners that need access to the data.

The study will use REDCap as the data collection tool whenever it comes to personal sensitive data governed

by GDPR. The research project is registered at OUH, Region of Southern Denmark (20/50524). When data will be analysed, the analysis of personal sensitive data will be through Odense Patient Explorative Network (OPEN) and the OPEN Analyse platform. In this way, personal sensitive data are kept on secure servers and not personal computers. OPEN storage can be used to store personal sensitive information as well.

An elaborate data management plan is available at https://dmponline.deic.dk/plans/4500/export.pdf.

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Acknowledgements We would like to thank Louise T. Smidt for her contribution to the article preparation. Carsten Daugaard of Force Technology (Odense) measured the ambient noise level at the test side. Furthermore, we are deeply grateful for the interim BEAR data shared by Sabina S. Houmøller and Oscar Cañete.

Contributors JHS initiated the collaborative study. All authors participated in the conceptualisation of the study. CCP wrote the original draft of the manuscript. JHS, ERP, CBS, SL, RS-L, JN, CBS and RGP all reviewed and edited the manuscript. All authors agreed with the final version of the manuscript.

Funding The project is funded by Innovation Fund Denmark Grant no. 9090-00089B and the William Demant Foundation Grant no. 19-1251. Additionally, the project is a collaboration between the University of Southern Denmark, Odense University Hospital, Interacoustics and Oticon.

Competing interests SL has stocks in Demant A/S, who owns Interacoustics A/S, who manufactures the equipment used to implement the UAud system. RS-L and SL who both are employed at the Interacoustics Research Unit, have a patent considered for the technical details of the UACT procedure. All the other authors report no conflicts of interest.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval The project was evaluated by the Research Ethics Committee of Southern Denmark and judged not to need approval.

Provenance and peer review Not commissioned; externally peer reviewed.

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