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Assessing the feasibility of a randomised controlled trial examining the effect of hearing aids on cognitive decline in elderly individuals: a study protocol

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ABSTRACT

Introduction Hearing loss is one of the leading potentially modifiable risk factors for dementia. There is growing evidence suggesting that treating hearing loss with hearing aids could be a relatively low-cost intervention in reducing cognitive decline and the risk of dementia in the long term. However, given the current constraints of the limited evidence, it is premature to draw definitive conclusions about the effect of hearing aids on cognitive functioning. More long-term randomised studies examining this effect would be recommended. Prior to embarking on large-scale lengthy randomised controlled trials (RCTs), it is imperative to determine the viability of such studies. Therefore, the purpose of the current study is to assess the feasibility of a RCT that investigates the effect of hearing aids on cognitive functioning in elderly hearing impaired individuals.

Methods and analysis In this randomised controlled feasibility trial, 24 individuals aged 65 years or older with mild to moderate hearing loss (≥35–<50 dB pure tone average (0.5–4 kHz) unilateral or bilateral) will be included and randomised towards a hearing aid intervention or no intervention. At baseline and at 6-month follow-up, a test battery consisting of cognitive tests and questionnaires will be administered to both groups. The primary outcome of the study is the willingness of hearing impaired individuals to be randomised for hearing amplification in a study regarding cognition. The secondary outcomes are the feasibility of the test battery and the therapy compliance of hearing aid use.

Ethics and dissemination This research protocol was approved by the Institutional Review Board of the University Medical Centre Utrecht (NL80594.041.22, V.3, January 2023). The trial results will be made accessible to the public in a peer-reviewed journal.

Trial registration number ISRCTN84550071.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Procedural, methodological and clinical challenges will be examined to improve and refine the inclusion procedures and study design of a randomised controlled trial on the effect of hearing aids on cognitive functioning.
⇒ The administered test battery consists of cognitive tests that cover multiple cognitive (sub)domains and rely minimally on auditory information.
⇒ As part of the recruitment, advertisement for study participation will be aimed at inviting elderly individuals visiting a hearing centre as well as those without any connection to a hearing or audiological care centre.
⇒ The study's focus on individuals aged 65 and older with mild to moderate unilateral or bilateral hearing loss implies that the findings are primarily applicable to this specific demographic group.
⇒ Adherence to hearing aid usage is assessed through self-report measures, as the lack of brand or type restrictions of the provided hearing aids results in variable availability of data logging capabilities.

INTRODUCTION

In an era of increased longevity, dementia is considered one of the greatest challenges for health and social care. It is estimated that more than 55 million people worldwide were living with dementia in 2019, and this number is expected to increase to 78 million in 2030 and 139 million in 2050.[1] People with dementia, otherwise known as a major neurocognitive disorder,[2] suffer from significant cognitive decline which interferes with their independence in everyday activities.[3] Dementia not only affects the individuals with this condition and people in their immediate surroundings, but also society as a whole due to the required health and social care.[4 5] The total global cost of dementia, which was estimated to be US$1.3 trillion in 2019,[1] will continue to rise as the prevalence increases. This substantial social and economic impact, and the lack of curative treatment, increases

the need to focus on reducing the risk of developing dementia.[6]

In 2017, the Lancet Commission on dementia prevention, intervention and care introduced a model that depicts the life-course risk factors contributing to the development of dementia.[4] While some risk factors, such as genetic predisposition, are not modifiable, it is estimated that around 40% of the risk factors for dementia are modifiable.[7] Hearing loss is the leading potentially modifiable risk factor in this model accounting for more than 8% of the overall modifiable risk.[7]

Several hypotheses about the underlying mechanism linking hearing loss to cognitive decline and dementia have been suggested over the past years. Hypothesised mechanisms include a shared neuropathological aetiology, changes in brain structure and function due to prolonged sensory deprivation and diminished cognitive reserve due to relocation of resources for auditory processing.[8–11] Other risk factors for dementia, such as social isolation and loneliness,[8 12] are also hypothesised to mediate the association between hearing loss and cognitive decline.[8 13 14] While these mechanisms are often presented individually, it is likely that they are not mutually exclusive and several mechanisms are involved in the association.[15]

There is a growing body of evidence suggesting that treating hearing loss with hearing aids could be a relatively low-cost intervention in reducing cognitive decline and risk of dementia.[16 17] Most of this evidence, however, relies on observational studies, which are susceptible to unmeasured confounding. Furthermore, other limitations to these studies apply, such as unknown or poor hearing aid compliance, differences between groups in baseline characteristics, the use of cognitive outcome instruments that rely on auditory information and the use of self-reported hearing loss measures.[16–19] Well-designed randomised controlled trials (RCTs) would be recommended to address some of these limitations. However, RCTs on this topic are notably scarce and often part of a pilot study, characterised by short follow-up periods and small sample sizes.[17 18 20 21]

Recently, Lin *et al* published the results of a RCT, which showed that hearing aid usage was associated with a reduction in cognitive decline in a population at increased risk for cognitive decline, but not in the total cohort population.[22] In this study, the effect of a hearing intervention on cognitive functioning was compared with outcomes in a control group receiving health education during a 3-year follow-up period. Although the results are in favour of the positive effect of hearing amplification to those at risk for cognitive decline, drawing definitive conclusions about the effect of hearing aids on cognitive functioning necessitates the replication of results, inclusion of a broader participant group and incorporation of a no-intervention control group. Therefore, more long-term randomised studies are needed to further investigate this effect.

Prior to embarking on large-scale RCTs, it is imperative to ascertain the viability of such studies. Therefore, the purpose of the current study is to assess the feasibility of a RCT that investigates the effect of hearing aids on cognitive functioning in hearing impaired individuals 65 years of age and older. The primary objective is to examine the feasibility in terms of the willingness of individuals to participate in a RCT. Considering that many patients only seek help after their hearing loss becomes severe and significantly impairs daily life functioning, resulting in the underuse of hearing aids,[23] it is crucial to assess whether individuals with mild to moderate hearing loss are willing to be randomised for hearing amplification. Additionally, the study will assess the feasibility of a test battery consisting of cognitive tests and questionnaires, along with hearing aid compliance. Evaluation of these feasibility aspects will contribute to the viability of a RCT examining the effect of hearing aids on cognitive functioning.

METHODS AND ANALYSIS

Study objectives

The primary objective of this feasibility study is to assess the willingness of individuals with mild to moderate hearing loss to be randomised for hearing amplification in a study regarding cognition. The secondary objectives of the study are to assess the feasibility of the test battery consisting of cognitive tests and questionnaires and to assess the therapy compliance of hearing aid use.

Study design and setting

The study is a monocentre, randomised controlled feasibility trial performed in a tertiary referral clinic (university hospital) in the Netherlands (University Medical Centre (UMC) Utrecht). The protocol is reported according to the Standard Protocol Items: Recommendations for Interventional Trials statement.[24]

In this RCT, participants will be randomised into two groups: a hearing aid group and a control group (figure 1). All participants will be asked to fulfil a test battery consisting of cognitive tests and questionnaires for the baseline measurement. Subsequently, 12 participants (hearing aid group) will receive hearing aids at a local hearing aid centre according to standard care, while the other 12 participants (control group) will continue without hearing aids during the follow-up period of 6 months. Six months after inclusion, all participants will be asked to fulfil the same test battery consisting of cognitive tests and questionnaires using similar procedures as during the baseline measurement.

Study population

24 individuals aged 65 years or older with mild to moderate hearing loss will be included in this feasibility study. Participants will either be recruited at the otorhinolaryngology department of the UMC Utrecht, or will be recruited using flyers that will be distributed outside the UMC in the region of Utrecht, at locations where it is anticipated that they will reach the target population

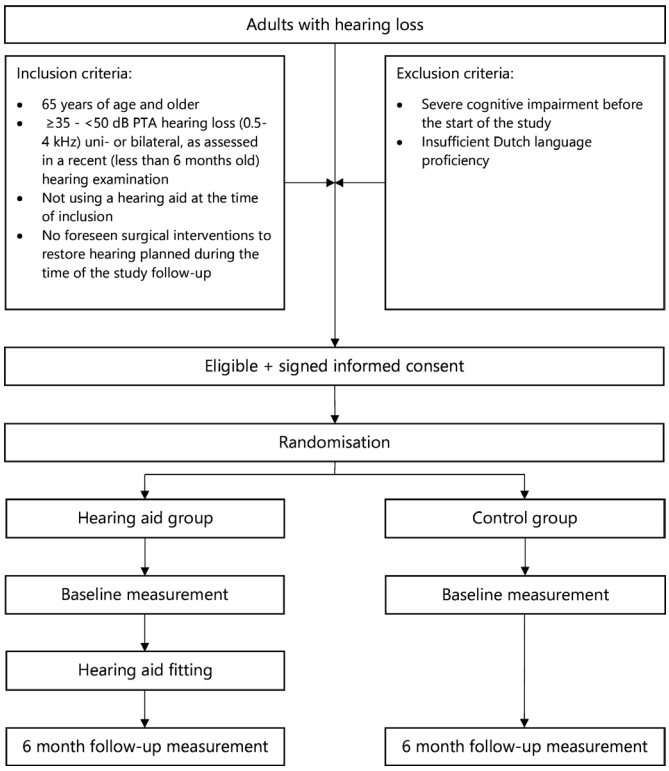

Figure 1 Study flowchart. dB, decibel; PTA, pure tone average.

(eg, community centres, libraries and churches). All of the following criteria must be met to be eligible for inclusion. Individuals who do not have a recent hearing level assessment (less than 6 months old) will be offered an audiological test to assess eligibility.

Inclusion criteria

- 65 years of age and older
- ≥35–<50 dB PTA hearing loss (0.5–4 kHz) unilateral or bilateral, as assessed in a recent (less than 6 months old) hearing examination
- Not using a hearing aid at the time of inclusion
- No foreseen surgical interventions to restore hearing planned during the time of the study follow-up

Exclusion criteria

- Diagnosed with severe cognitive impairment (eg, due to a neurodegenerative disease) by a clinician before the start of the study
- Insufficient Dutch language proficiency

Eligible patients who visited the otorhinolaryngology department of the UMC Utrecht, will be asked by their otorhinolaryngologist or audiologist if a member of the research team may contact them to provide information about the study. If a patient agrees, a member of the research team will give them this information and will recheck if they meet the inclusion criteria.

Individuals who contacted the research team based on the flyer invitations will be contacted for information about the study and to screen for eligibility.

Individuals interested in participating will receive the patient information letter and informed consent (IC) form. If a participant is eligible and willing to participate, they can sign the IC. Signing of the IC will be done in the presence of a member of the research team, after all the questions of the individual have been answered and after a reflection period of at least 48 hours. If someone decides not to participate, they will be asked to share the reason for that decision, which will be noted without including any personal information.

Participants will not receive any compensation for participation in this study. They will, however, be reimbursed for the travel costs if their measurements take place in the UMC Utrecht.

Randomisation

After inclusion, participants will be randomly allocated into one of two groups: the hearing aid group or the control group. Randomisation will take place electronically by the study management system Castor Electronic Data Capture (EDC), using a validated variable block randomisation model. Both groups carry the same weight (1:1). Block sizes will be 2 and 4. Investigators will be blinded of the randomisation sequence. Blinding of participants and investigators regarding the randomisation assignment is not possible due to the nature of the intervention.

Intervention

Participants allocated to the intervention group will receive a hearing aid at the side of hearing loss, which can be unilateral or bilateral. The hearing aid(s) will be provided for a 6-month free-of-charge trial period by affiliated local hearing aid centres, without brand or type restrictions, according to standard care procedures. Within 2 weeks after an initial diagnostic and advisory appointment at the hearing aid centre, participants will receive their hearing aid(s). After a trial period of 1 or 2 weeks, the hearing aid is further adjusted according to standard guidelines in a check-up appointment. Participants allocated to the control group will continue without a hearing aid during the time of the study. After the 6-month follow-up measurement, all participants will be informed about the possibility of starting or continuing hearing aid treatment after the end of the study period according to regular care principles, for which they will be advised to visit their local hearing aid centre. The costs for the continuation of the hearing aid after study participation are at the expense of the participant and depend on their health insurance.

Sample size

In accordance with the recommendations for sample size of pilot studies,[25] 12 participants for each arm of the study will be included, accounting for 24 participants in total. The justification of 12 participants per arm in this recommendation is based on rationale about feasibility, gains in the precision about the mean and variance,

and regulatory considerations.[25] Participants who withdraw from the study will be replaced by newly recruited participants.

Outcomes

During the recruitment period, data regarding the number of individuals who are eligible for this study will be collected. Furthermore, the amount of eligible individuals who are willing to participate will be documented, and reasons for declining to take part in the study will be noted anonymously. Based on the resulting number of eligible individuals willing to be randomised, the feasibility to include the intended number of participants in a future RCT will be assessed.

At baseline and at the 6-month follow-up, a test battery consisting of cognitive tests that measure different domains of cognitive functioning and questionnaires on feelings of loneliness, anxiety and depression will be administered during an in-house visit or visit to the clinic by a psychologist of the research team. Each visit will last between 60 and 90 minutes. Missing data for each outcome measure will be reviewed, and reasons for these missing data will be examined. The number of tests included in the test battery will be reconsidered for application in a future RCT according to the amount of missing data, retention and dropout rate, and reasons for withdrawal/non-completion.

At the follow-up assessment, additional questions regarding the hearing aid adherence will be asked to participants in the hearing aid group. They will be asked if and when they started wearing the hearing aid and for how many days a week and how many hours a day they have worn the hearing aid on average during the study period. The threshold for adherence to hearing aid use will be set to an average of 4 hours a day and at least 4 days of usage during the week. The rationale for this duration is based on half of the working day for at least half of the days of the week, in order for participants to adapt to their hearing aid(s).

Furthermore, the amount of participants in the control group who drop out of the study or deviate from the protocol by obtaining hearing aids outside of the study will be documented.

Explanation of cognitive tests

The cognitive tests in the test battery are included to cover multiple cognitive (sub)domains. Since the tests will be administered to participants with hearing loss, cognitive tests that rely minimally on auditory information are included. To control for learning effects due to retesting, other versions of the same cognitive tests (if applicable) will be used in the follow-up test battery. As the aim of the study regarding the test battery only focuses on its feasibility, no test scores will be calculated and/or reported.

- The Self-Administered Gerocognitive Examination[26] is a cognitive assessment instrument that can be used as a screening tool for mild cognitive impairment and early dementia. The self-administered test consists of 12 items that examine cognitive functioning in the domains of orientation, language, memory, executive function, calculations, abstraction and visuospatial abilities.
- The Letter Digit Substitution Test[27] is a speed-dependent task in which the participant needs to write digits underneath corresponding letters according to a key. After 10 practice items, the participant will be instructed to complete as many substitutions within 60 seconds. The task requires visual scanning, mental flexibility, sustained attention but most of all psychomotor speed and speed of information processing.
- The Location Learning Test[28] is a spatial memory task that consists of a stimulus card with a 5×5 grid in which 10 everyday objects are presented at different locations. In five trials, participants are shown the grid for 15 seconds. After every trial, the participant receives an empty grid and is instructed to relocate the objects in the same position as on the stimulus card. After a delayed interval of 20–30 minutes, the empty grid is shown again and the objects have to be relocated without the presentation of the stimulus card.
- The Corsi Block Tapping Task[29 30] is a visuospatial working memory task in which the experimenter shows nine blocks arranged on a board in front of the participant. In the first condition of the test, the experimenter taps a sequence of blocks, and the participant is asked to tap the blocks in the same order. In the second condition of the test, the participant needs to tap the presented sequence of blocks in reversed order. In both conditions, the sequences gradually increase in length, and the condition is discontinued if the participant fails to reproduce two sequences of the same length.
- The Colour Word Interference Test is part of the Delis-Kaplan Executive Functioning System,[31] a test battery for the assessment of executive functioning. The test consists of four conditions. In the first condition, participants receive a page containing a series of red, green and blue squares and are asked to name the colours as quickly as they can. In the second condition, they receive a page that consists of a series of the words ‘red’, ‘green’ and ‘blue’, which are printed in black ink, and are asked to read these words as quickly as they can. The first and second conditions measure colour naming speed and word reading speed, respectively. In the third condition, the words ‘red, ‘green’ and ‘blue’ are presented printed incongruently in red, green or blue ink. The participant is asked to say the colour of the ink in which each word is printed. The fourth condition is similar to the third, except for some words that are enclosed within a box. In this condition, the participant is asked to say the colour of the ink in which each word is printed but to read the word aloud when a word appears inside a box, as quickly as they can. These conditions measure functions within the executive functioning domain; condition three measures the response inhibition, while

condition four measures both inhibition and cognitive flexibility.

- The Trail Making Test[32] is a neuropsychological test that consists of two parts. In part A, the participant needs to connect a series of 25 encircled numbers, placed semirandomly on a page, in numerical order. In part B, the participant connects 25 encircled numbers and letters in numerical and alphabetical order, alternating between the numbers and letters. Participants are asked to work as quickly as they can. Part A measures visual search and psychomotor speed. Part B measures mental flexibility, which is a component of the executive functioning domain.
- The verbal fluency[33] consists of two tasks: category fluency (also called semantic fluency) and letter fluency (also called phonemic fluency). In these tests, participants are given 1 minute to produce as many unique words starting with a given letter (letter fluency) or within a semantic category (category fluency). This test measures both executive functioning and language.

Explanation of questionnaires

Questionnaires regarding feelings of loneliness and feelings of anxiety and depression have been added to the test battery, as these have been described in the literature as risk factors that might mediate the association between hearing loss and cognitive decline.[8 12–14] As is the case with the cognitive tests, no scores will be reported as we only examine the feasibility of the test battery.

- The Hospital Anxiety and Depression Scale[34] is a 14-item screening instrument for symptoms of anxiety and depression. It consists of two subscales: the anxiety scale (seven items) and the depression scale (seven items).
- The De Jong Gierveld Loneliness Scale[35] is an 11-item instrument measuring loneliness. It consists of two subscales: social loneliness (six items) and emotional loneliness (five items).

Statistical analysis

All data will be analysed with statistics software (IBM SPSS Statistics V.27.0). The demographics of the participants will be expressed as medians with IQR.

Outcomes will be assessed as individuals willing to be included and randomised, missing data and reasons for this missing data per outcome measure and per group in the test battery, and adherence to hearing aid usage. The number of cases and percentages will be presented for these categorical variables in the primary and secondary study parameters. Since this is a feasibility study, the outcomes of the tests in the test battery will not be analysed.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this study.

Ethics and dissemination

The study will be conducted according to the principles of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013) and in accordance with the Medical Research Involving Human Subjects Act (‘Wet medisch-wetenschappelijk onderzoek met mensen’), the ‘gedragscode gezondheidsonderzoek’ and ‘code goed gebruik’. The research protocol was approved by the Institutional Review Board (IRB) of the UMC Utrecht (NL80594.041.22, V.3, January 2023).

All substantial amendments will be notified to the local Medical Research Ethics Committee (MREC). The trial results will be made accessible to the public in a peer-reviewed journal, preferably open access.

The handling of personal data will comply with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation (‘Uitvoeringswet AVG’). All data will be treated confidentially. Only authorised members of the research team will get access to all of the collected data. After IC, participants will receive a unique identification code. Research data will be entered into an electronic case report form through Castor EDC using this identification code. Generated (meta)data will be stored in a secure research folder structure with access control, which ensures only authorised members of the research team have access to personal data, including the key table that links personal data to the identification code. IC forms and paper files will be stored safely in a locked cabinet in a locked room in the study centre. The final trial data set will be safeguarded and available to the principal investigator and approved members of the research team.

The investigator will submit a summary of the progress of the trial to the accredited MREC once a year. Information will be provided on the date of inclusion of the first participant, number of participants included and number of participants that have completed the trial, serious adverse events (SAEs)/serious adverse reactions, other problems and amendments. All adverse events will be recorded in Castor EDC, and SAEs will be reported to the accredited Medical Ethical Committee that approved the protocol. Trial and data quality will be checked by an independent local monitor of the UMC Utrecht.

Trial status

The study is currently in the recruitment phase. Initial approval by the IRB was granted in August 2022. The expected end date for the study is March 2025.

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Contributors All authors (DF, ALS, IMCHW, KSR, IS) developed the protocol. DF drafted the manuscript. All other authors revised the manuscript. All authors read and approved the final version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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