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Can we do a study to prevent cognitive decline with hearing aids?

Submission date	Recruitment status	[ ] Prospectively registered
16/12/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/09/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/04/2025	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Age-related hearing loss is responsible for about 90% of the hearing loss cases in adults. While it is easy to treat hearing loss with hearing aids, about one-third of the adults with hearing loss do not use hearing aids. It is unknown whether hearing improvement for those affected with hearing impairment will result in less cognitive decline (loss of mental abilities). Therefore we will conduct a study to see if it is possible to do a full scale trial assessing the effects of hearing aids on cognitive decline.

Who can participate?
People aged 65 years or older with hearing loss.

What does the study involve?
Participants will be randomized towards a group using hearing aids and a group not using hearing aids. All participants will complete study questionnaires and cognitive tests.

What are the possible benefits and risks of participating?
Benefits: some participants who would not have otherwise sought out treatment with a hearing aid will have one provided
Risks: none

Where is the study run from?
UMC Utrecht (Netherlands)

When is the study starting and how long is it expected to run for?
January 2022 to July 2024

Who is funding the study?
ZonMW (Netherlands)

Who is the main contact?
Dr Stegeman
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Feasibility study for a randomized controlled trial to evaluate the effect of hearing aids on cognitive decline in elderly individuals: Cognition and Isolation in Deafness

Acronym
CognID

Study objectives
Feasibility of an RCT investigating the effect of hearing aids on cognitive decline

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/08/2022 (Medical Research Ethics Committee NedMec (MREC NedMec)) ref:22-697 /H-A
Amendment approved on 25/01/2023

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Cognitive decline

Interventions
Current interventions as of 28/02/2023:

After informed consent of eligible patients, participants will be randomly allocated to one of the two groups; the hearing aid group or the control group. Randomisation will take place by the study management system Castor. Investigators will be blinded of the randomisation sequence. After randomisation, an appointment will be made for an in house-visit or visit to the clinic in order to assess the cognitive functioning of the participants.
After the visit, participants randomized to the intervention group will be referred to a local hearing aid centre to collect and adjust a standard of care hearing aid (no type and brand restrictions) uni- or bilateral. Participants randomized to the control group will continue without a hearing aid.
Six months after inclusion of participants a second visit will be performed by a similar procedure as the first visit to fulfil the test battery again whereafter the study stops.

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Previous interventions:

After informed consent of eligible patients, participants will be randomly allocated to one of the two groups; the hearing aid group or the control group. Randomisation will take place by the study management system Castor. Investigators will be blinded of the randomisation sequence. After randomisation, an appointment will be made for an in house-visit or visit to the clinic in order to assess the cognitive functioning of the participants. Two weeks before this visit participants are asked by email to fill out digital questionnaires. If participants are unable to answer the questionnaires digitally, paper versions will be filled out by the participant during the visit.
After the visit, participants randomized to the intervention group will be referred to a local hearing aid centre to collect and adjust a standard of care hearing aid (no type and brand restrictions) uni- or bilateral. Participants randomized to the control group will continue without a hearing aid.
Six months after inclusion of participants a second visit will be performed by a similar procedure as the first visit to fulfil the test battery again whereafter the study stops.

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Standard of care hearing aid (no type and brand restrictions)

Primary outcome(s)
The willingness of ‘naïve’ patients to be randomized for hearing amplification in a study concerning cognition. Reasons for refusing to take part in the study will be noted. Based on the

resulting number and percentage of eligible patients willing to be randomized we will assess the feasibility to include the intended number of participants for the main CognID study from hearing centers.

Key secondary outcome(s))
1. Feasibility of the test battery for cognitive tests, at baseline and 6 months. Missing data for each outcome measure will be analysed, and reasons for these missing data will be assessed. The number of tests included in the test battery will be reconsidered according to the amount of missing data, retention and dropout rate and reasons for withdrawal/non-completion.
2. Therapy compliance of hearing aid use for individuals willing to be randomized in a RCT. Adherence to the intervention will be noted. The threshold for adherence to hearing aid use will be set to four hours a day and at least four days of usage during the week.

Completion date
17/07/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 27/02/2023:

1. 65 years and older at the time of consent
2. ≥35-<50 dB PTA hearing loss (0.5-4 kHz) uni- or bilateral, as assessed in a recent (less than 6 months old) hearing examination
3. Not using a hearing aid at time of assessment
4. No foreseen surgcal interventions to restore hearing planned during the time of the study follow-up.

Previous inclusion criteria:

1. 65 years and older
2. ≥35-<50 dB PTA hearing loss (0.5-4 kHz) uni- or bilateral, without using a hearing aid at time of assessment and without foreseen surgical interventions to restore hearing planned during the time of the study follow-up.
3. Hearing examination performed in an audiological centre less than 6 months ago

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Sex

All

Key exclusion criteria
1. Severe cognitive impairment before the start of the study
2. Don’t speak the Dutch language

Date of first enrolment
22/08/2022

Date of final enrolment
17/07/2024

Locations

Countries of recruitment
Netherlands

Study participating centre
University medical center Utrecht
Heidelberglaan 100
Utrecht
Netherlands
3584 CX

Sponsor information

Organisation
University Medical Center Utrecht

ROR
https://ror.org/0575yy874

Funder(s)

Funder type
Government

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
Data will be shared upon request to Dr. Inge Stegeman. i.stegeman@umcutrecht.nl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/12/2023	27/12/2023	Yes	No