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

Published: 01-08-2022
Last updated: 21-12-2024

To assess the feasibility of an RCT assessing the effects of hearing aids on cognitive decline.

Ethical review	Approved WMO
Status	Completed
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON53912

Source
ToetsingOnline

Brief title
CognID

Condition

- Hearing disorders

Synonym
Cognitive decline, hearing

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cognition, Hearing, Hearing Aid, Social Isolation

Outcome measures

Primary outcome

• Assess the willingness of *naïve* individuals to be randomized in a study

concerning cognition

Secondary outcome

• Assess the feasibility of the test battery for cognitive tests, at baseline

and six months

• Assess the therapy compliance of hearing aid use for individuals willing to

be randomized in an RCT

Study description

Background summary

In an era of increased longevity, society is facing new health care issues. Considering the wide range of degrees of cognitive impairment with implications for people*s life, cognitive decline is considered one of the greatest global challenges for health and social care in the 21st century. Hearing loss is recognized as one of the risk factors for developing cognitive decline.
Several hypotheses about the reasons for the relation between hearing loss and cognition have been developed over the past years. Core to these is the theory that the diminished auditory input profoundly affects speech processing capabilities and consequently, impairs social functioning. Therefore, individuals with hearing loss exhibit accelerated brain atrophy compared with normal hearing adults, especially within the right temporal lobe structures, that are critical for many cognitive functions.
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, only about one third of the adults with hearing loss use hearing aids. It is unknown whether hearing improvement for those affected with hearing impairment will

result in less deterioration of cognitive decline by ageing. Therefore we will conduct a feasibility study of an RCT assessing the effects of hearing aids on cognitive decline.

Study objective

To assess the feasibility of an RCT assessing the effects of hearing aids on cognitive decline.

Study design

Feasibility study for a randomized controlled trial

Intervention

Conventional type hearing aid

Study burden and risks

The participants will be asked for their willingness to be randomized to hearing aids or not. After randomization participants receive a hearing aid in the intervention and no treatment in the control group. At baseline and after 6 months of hearing aid use they will be asked to perform a cognitive test battery to assess the feasibility of the tests and to assess therapy compliance whereafter the study stops. The burden for the participant is low and there are no risks associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- 65 years of age or older at the time of consent
- >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
- Not using a hearing aid at time of assessment
- No foreseen surgical interventions to restore hearing planned during the time of the study follow-up.

Exclusion criteria

Participants will be excluded if they have severe cognitive impairment before the start of the study or if they don*t speak the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-06-2023
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-01-2023
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN84550071
CCMO	NL80594.041.22

Study results

Date completed:	17-07-2024
Actual enrolment:	5

Summary results
Trial ended prematurely