Improving adult Cochlear Implant users* speech recognition by optimizing fitting parameters.

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

Summary

ID

NL-OMON49674

Source
ToetsingOnline

Brief title
Optimizing CI users' speech recognition

Condition

- Hearing disorders

Synonym
hearing impairment, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Opleidingsbudget van de uitvoerend onderzoeker

Intervention

Keyword: Cochlear Implant, fitting, Optimisation, speech recognition

Outcome measures

Primary outcome

Speech intelligibility test results with optimized MAP parameters, compared to

the speech test intelligibility results with standard MAP parameters.

Secondary outcome

not applicable.

Study description

Background summary

In a previous study by de Graaff et al. (2019)(NL.51919.029.15) several fitting parameters were identified that may improve speech recognition in quiet and speech recognition in noise in adult cochlear implant (CI) users. The results suggest that optimizing these parameters in CI users with a non-optimal fitting could result in improved speech recognition.

Study objective

The aim of the current study is to examine whether it is possible to improve speech recognition in specific CI users by optimizing dynamic range and mean aided thresholds. Furthermore, we want to investigate to what extent patient counselling and acclimatization can help in accepting these optimal CI settings by the CI user.

Study design

Single-center experimental study.

Intervention

not applicable.

Study burden and risks

Compared to care as usual, participants will have to pay two additional visits to the department of audiology for extra speech recognition tests or extra fitting sessions. Immediate benefits for individual subjects are to be expected from participation in this study. Furthermore, the knowledge on the technical innovations for fitting and rehabilitation of cochlear implant users is expected to contribute to the improvement of the therapy for cochlear implant users.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients aged 18 years or older (all study parts); Patients with at least 1 year of CI experience after activation; Patients with onset of severe hearing impairment after the age of 7 years (all study parts); Native Dutch speakers;

Patients using a Nucleus 5, 6 of 7 CP800 or CP900 or CP1000 processor and the Freedom implant, with full insertion and 22 active electrodes.

Exclusion criteria

Disability which could interfere with the completion of the tests (i.e. psychiatrie problems, dyslexia or severe health problems); Additional handicaps that may prevent participation in evaluations; Patients with deviating map parameters (i.e., number of maxima, or pulses per second (PPS)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Cochlear implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	20-04-2020
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL70082.029.20