Auditory Diagnostics and Error-based Treatment

Published: 29-03-2022
Last updated: 21-09-2024

The main objective of this study is to assess the effectiveness of an integrated program of fitting and training interventions aimed at reducing unexpected variability and addressing the specific error patterns of each recipient.

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

Summary

ID

NL-OMON51557

Source
ToetsingOnline

Brief title
AuDiET

Condition

- Hearing disorders

Synonym
deafness, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: This project has received funding from the European Union□s Horizon 2020 research and innovation programme under the Marie Sk□odowska-Curie grant agreement No 860718.

Intervention

Keyword: cochlear implant, diagnostic, fitting, rehabilitation

Outcome measures

Primary outcome

The primary endpoint is the level of improvement of phoneme and word recognition score on the individual scale after the interventions.

Secondary outcome

The secondary endpoints are:

1. the results of the exploratory analyses performed on the correlation between the spectrotemporal assessment test and the subjects* error profile.

2. the results of the exploratory analyses performed on the differences between error patterns in phoneme and word recognition tests, both between and within subjects.

3. The results of the SUS/IMI questionnaires concerning the individualized training app

Study description

Background summary

Some adult Cochlear Implant recipients have markedly poorer speech recognition scores than what can be expected from the known predictive factors. This study aims to better understand what type of errors in speech understanding is being made by those users and what tests are sensitive for mapping out user-specific error patterns. The ultimate aim of the AuDiET study is to pave the way to novel, innovative fitting and training interventions which could help improve the performance of CI recipients.

Study objective

The main objective of this study is to assess the effectiveness of an integrated program of fitting and training interventions aimed at reducing unexpected variability and addressing the specific error patterns of each recipient.

Study design

Pre-post study design

Intervention

Two distinct interventions are planned for the lower performing CI users, one concerning adjustments to their CI fitting and one concerning personalized auditory training.

Study burden and risks

Study subjects will undergo a number of non-invasive tests, some of the tests are standard audiometric tests part of routine clinical visits such as Tonal Audiometry and Speech Audiometry, others are specific phoneme recognition tests or psychophysical tests measuring spectral and/or temporal acuity. Due to the number of measurements needed, the subject may experience fatigue: the tests will be accordingly spread out and there will be opportunities to rest and recover. We foresee no risks associated with this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* Adult (over 18 years old at the time of inclusion)
* Post-lingually deafened (the subject had a good mastery of spoken language before onset of deafness)
* Native Dutch speaker
* Implanted, either unilaterally or bilaterally, with a Cochlear Implant manufactured by Cochlear Ltd (i.e., a Nucleus ® implant).
* Implanted with one of the following implants: CI422, CI512, CI522, CI532, CI24R, CI24RE.
* Implanted for at least 12 months.

Exclusion criteria

A potential subject for the CI user group who meets any of the following criteria will be excluded from participation in this study:
* Known abnormally formed cochlea
* Known pre-implantation ossification of the cochlea
* Severe cognitive disorders affecting their ability to understand spoken language
* Intense facial nerve stimulation
* Unaddressed electrode tip foldover
* More than 4 electrodes deactivated because of malfunction (open/short circuit) or lack of response
* Additional illnesses or handicaps that could impact the ability to participate in the study, at the clinician*s discretion.

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):	30-05-2022
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	29-03-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-05-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-12-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80521.091.22