Optimization of remote assessment in cochlear implant recipients.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56547

Source
ToetsingOnline

Brief title
ORACI1

Condition

- Hearing disorders

Synonym
deafness, Perceptive hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Advanced Bionics verleent technische ondersteuning (vragen beantwoorden over bijvoorbeeld kalibratie).

Intervention

Keyword: Cochlear implant, Digits-in-noise, Matrix test, Remote testing

Outcome measures

Primary outcome

Outcomes on audiological tests: NVA phoneme scores, DIN test, and Matrix test.

Secondary outcome

The secondary study parameters are comparisons between scoring mechanisms (clinician vs. self-scoring) of the tests mentioned above. We will also compare outcomes on the different tests both within-subjects and between subjects.

Additionally, secondary study parameters are subject characteristics possibly influencing performance and discrimination abilities. Demographic data will be gathered to accurately describe the study sample, such as type of implant, experience with implant, duration of deafness etc.

Study description

Background summary

Cochlear implantation is the established standard of care for rehabilitation of patients with severe to profound hearing loss. Patients getting an cochlear implant (CI) follow an intensive rehabilitation program in order to make optimal use of the implant. After this rehabilitation phase, patients need aftercare and monitoring for the rest of their lives. Patient management and monitoring therefore leads to an increasing cumulative workload for CI-centers. Additionally, technological advances have led to expanding cochlear implant candidacy in recent years (Snel-Bongers et al., 2018), contributing to a furtherly increased workload.

A visit to the clinic generally consists of subjective testing (e.g. a speech recognition test), objective testing (e.g. impedance measurements) and the

patients* evaluation of, for example, sound quality or hearing performance by a clinician. Based on the gathered information, the clinician adjusts the settings of the processor.

In managing the increasing workload, growing interest has been shown in remote hearing care, also for cochlear implants. Researchers have shown that remote testing of speech recognition (De Graaff et al., 2016; de Graaff et al., 2018, 2019; Goehring et al., 2012; Hughes et al., 2012) and evaluation of objective parameters such as impedances or electric compound action potentials (eCAPs) (Hughes et al., 2012; Parreño et al., 2020) is feasible. Regarding remote speech recognition testing, which is of paramount importance in clinical care, it was found that background noise and reverberation had a severe influence on speech recognition scores in remote sites compared to the clinic (Goehring et al., 2012; Hughes et al., 2012). This problem can be circumvented by making use of increased connectivity capabilities of modern CI processors, where audio input can be presented through dedicated audio cables (De Graaff et al., 2016; de Graaff et al., 2018, 2019) or, in newer generations of sound processors, direct streaming. In these studies, it was found that clinical results sometimes deviated when measured via loudspeaker compared to direct audio input. Additionally, patients in general were positive about remote testing but sometimes had difficulty using the experimental setup.

Study objective

A future project will focus on a new platform for at-home monitoring and testing of cochlear implants, developed by one of the manufacturers of cochlear implants, Advanced Bionics (AB). Their Research Application allows for clinicians to read out the technical status of the implant and sound processor, but can also be used for audiological testing using direct Bluetooth streaming, or perform a subjective rating of hearing performance by the patient by means of questionnaires. Before studying the at-home application, it must be determined whether results that are obtained via direct Bluetooth streaming and self-scoring are the same, and as reliable, as clinical testing. Moreover, this needs to be evaluated thoroughly for multiple tests that are done in our clinic, which earlier studies did not include.

Study design

This study is a prospective, single-centre, cross-sectional study. The total duration of the study is estimated to be 1 year. Cl users and normal-hearing subjects are included as study groups. The CI subjects will participate in a maximum of 4 test days. The normal hearing controls in one to two test days. Each test day consists of a test session that lasts for approximately 2 hours, with breaks between if needed. The setting is the LUMC ENT department, where the CI subjects have already followed similar procedures as part of their regular clinical program.

Study burden and risks

There is minimal risk involved. Subjects use their regular clinical programming. The only predictable risk, for both the CI users and normal hearing subjects, is that they have to listen in a challenging listening environment, potentially leading to mild fatigue.

Benefits to the Cl population would be 1) an extra test moment, adding to the monitoring that is done as part of their regular clinical follow-up, 2) extra insight in their own performance with CI, as the clinical test battery is extended with extra tests and 3) in case there are equivalent results between the two presentation modes, this might allow the bulk of CI patients to self-test at home in the future, reducing the need to come into the clinic. There is no direct benefit for normal hearing subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)

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

Inclusion criteria

CI-users:
• Postlingually deafened adults (>16 years).
• Legally capable
• Excellent spoken and written Dutch, at the level of a *native*.
• Implanted with a cochlear implant of Advanced Bionics at least on one side.
• Using the AB Naida M90 sound processor.
• At least 3 weeks experience with their CI (subjects in rehabilitation).
• At least 12 months experience with their CI (experienced subjects).
• Speech scores in quiet of at least 50%.

Normal hearing:
• >16 years
• Legally capable.
• Excellent spoken and written Dutch, at the level of a *native*.
• Hearing threshold averaging <20dB HL for frequencies 500-4000Hz.

Exclusion criteria

• Disorders other than a hearing impairment that could affect the study results.
• Not able to complete 2 hours of testing.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2024
Enrollment:	44
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	30-01-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL85074.058.24