Auditory perception in early-deafened, late-implanted cochlear-implant users

Published: 14-09-2016
Last updated: 16-04-2024

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

Summary

ID

NL-OMON43156

Source
ToetsingOnline

Brief title
EDLI-CI

Condition

- Hearing disorders

Synonym
Cochlear Implant, Severe deafness

Research involving
Human

Sponsors and support

Primary sponsor: Keel, Neus- en Oorheelkunde en hoofdhalschirurgie
Source(s) of monetary or material Support: Ministerie van OC&W,VIDI grant 016.096.397 from the Netherlands Organization for Scientific Research (NWO) and the Netherlands Organization for Health Research and Development (ZonMw)

Intervention

Keyword: Auditory perception, Cochlear Implant, Deafness

Outcome measures

Primary outcome

The main study parameters are the percent correct scores for the different tests for speech perception, pitch-related speech perception and music perception. Furthermore, just-notable-differences (JND*s) for the vocal tract length and the fundamental frequency in the gender categorization task will be measured. For the subjective outcomes we will use the total outcome scores per questionnaire for quality of life, hearing ability and music enjoyment. The speech production will be scored using the speech intelligibillty ratio.

Secondary outcome

Not applicable

Study description

Background summary

Speech communication is crucial to social interactions, but deafness can seriously hinder this. Cochlear implants (CIs) are prosthetic auditory devices that restore hearing in severely hearing deprived and deaf individuals. They are very successful in providing good speech perception in quiet, yet there remain many unsolved auditory problems. These come mainly from the fact that the sound signal delivered by the device is degraded compared to normal hearing especially for pitch perception and speech perception in more complex listening environments. The success and limitations of the device, namely are largely known for traditional patients; individuals who became deaf early or late (pre- or post-lingually deafened, i.e., before or after language acquisition, respectively), and who received a CI in a relatively short period of time after the deafness onset (Ba*kent et al. 2016).

This project is about a relatively new implantable group that constitutes an

understudied clinical population: the early-deafened, late-implanted (EDLI) CI users. EDLI is defined as severe hearing loss at least since preschool (onset six years of age or earlier), meaning deafness onset during language acquisition, and implanted at sixteen years of age or later (Fuller et al. 2013; Mallinckrodt et al. (in preparation); Goorhuis-Brouwer et al 2000). Clinics traditionally have not implanted this group, due to the potential negative effects of auditory deprivation, but our own clinic at UMCG has a special protocol developed for EDLI users. This gives the unique opportunity to study this group which, combined with limited knowledge from previous literature (Houston and Miyamoto 2010; Santarelli et al. 2008; De Raeve 2010; Most, Shrem, and Duvdevani 2010; Yoshida et al. 2008), indicate potential benefits of implantation. To fill in the gap in our knowledge on the implantation outcome for EDLI, this study will systematically investigate the perception of speech in quiet, noise or in concurrent speech and the perception of pitch-related tasks, such as music, tasks that are known to be particularly difficult for thenormal group of CI users.

Study objective

Our expectation that the EDLI group may positively benefit from CI comes from a small number of studies, due possibly to the very small size of this implantee population worldwide. Despite a delay between the onset of deafness and the implantation, which has negative consequences for the speech perception outcome in general (Blamey et al. 2013), and a potential deficit in language skills due to the onset of deafness during speech language development in early childhood, a subgroup of EDLI CI users has been observed to benefit from implantation regarding speech perception (Houston and Miyamoto 2010; Santarelli et al. 2008; De Raeve 2010; Most, Shrem, and Duvdevani 2010; Yoshida et al. 2008).

Regarding other outcomes of implantation, our lab investigated the subjective music perception and appreciation in post-lingually implanted and EDLI CI users and the outcomes for health-related quality of life (QoL) (Fuller et al. 2013). EDLI showed an improvement in quality of life after implantation (Mallinckrodt et al. (in preparation)). A surprising finding was that the EDLI CI users, in contrast to post-lingually deafened CI-users, find listening to music pleasant. Also the quality of the sound of music was rated positively subjectively, whereas post-lingually deafened CI users rated the quality negatively. There are a number of potential explanations for the differences between these groups: 1) EDLI might simply lack previous exposure to music with acoustical hearing, and hence may appreciate music input, even if it is degraded in quality, due to the lack of a reference for good quality. 2) Our clinical protocol calls for implanting most promising candidates, and it is possible that the protocol works effectively and is successful in maximizing implantation outcome. Then we would expect our EDLI group to perform well in speech and sound perception tasks. 3) EDLI group does not perform well for sound perception, but they are still satisfied with their device as it still provides some improvement in hearing. It is hence timely to find the

differences and the possible positive outcomes for both speech and music, to give extra support for making an evidence-based decision on implant candidacy of early-deafened individuals.

Our research will provide a better understanding of the effect of cochlear implantation in this understudied group of CI users, the EDLI. Not only will we learn more about the effect of the duration of deafness, the project might also lead to new implantation programs for CI users. Lastly, the differences between the three known groups of implantees give comprehensive insight in the influence of for example a period of deafness on outcomes of implantation and/or the plasticity of the human brain.

The objective of this study is to identify the perception of speech in quiet and in noise or in speech, as well as sensitivity to pitch-related speech and music-related stimuli, such as emotion identification, gender categorization and melodic contour identification. Furthermore, subjectively the quality of life, hearing ability and speech production will be tested.

Study design

Behavioural, case-control study. The participants listen to acoustic stimuli in a sound-treated room and the perception is measured via percent correct scores per test.

Study burden and risks

There are no known risks or benefits associated with the participation in the experiment. There will be one session that last for about three hours. Adequate breaks are built into the experiment and no food or drinks will be provided.

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

Early-deafned, late-implanted CI users
Post-lingually deafened, late implanted CI users
Normal hearing listeners

Exclusion criteria

Congenitally deafened
Neurological diseases that possibly interferes with speech and music perception or intelligence
Non-native Dutch speakers

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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2018
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL57829.042.16