The melody of speech in children with cochlear implants

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21603

Source
NTR

Health condition

Early (under 2 years) and late (after 2 years) unilateral or bilateral cochlear implantation
Vroege (onder de 2 jaar) en late (na de 2 jaar) unilaterale of bilaterale cochleaire implantatie

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

percentage correct; reaction time; Percentile score; acoustic analysis of speech: means and standard deviations of fundamental frequency measures; in Hz) intensity masures (in dB), jitter (as ppq5), shimmer (a quotient of amplitude variablity)

Secondary outcome

Same as the primary outcomes

Study description

Background summary

Rationale: Prosody, both linguistic and emotional, is essential in the acquisition and usage of language and socio-emotional development, but it proves difficult for CI users because of their relative inability to hear spectral and, to a lesser degree, dynamic differences. Temporal differences, however, are not particularly problematic. The left cerebral hemisphere specializes in both types of prosody and in temporal cues, the right hemisphere in emotional prosody and spectral cues. We hypothesize later implanted children to have a delayed prosody development, to rely more on dynamic temporal than on spectral cues, and to find differential success and cue reliance for left- and right implanted children.
Objective: Main: determine competence difference, if any, between (early and late) implanted and normally hearing children on prosody processing. Secondary: determine competence differences between emotional and linguistic prosody; between left- and right implanted children; between dynamic temporal and spectral cues; between production and perception; between combinations of these conditions.

Study design: Intervention study with patients and controls

Study population: Early-implanted (implanted around 1 year old; chronological age 4 years) and late-implanted (4 years; 7 years) Dutch children with cochlear implantation; hearing age matched normally hearing children; chronological age matched normally hearing children.

Intervention (if applicable): 45 general cognitive base (‘pre-’) tests and 4 tests of prosody perception and production

Main study parameters/endpoints: Percentage correct and reaction times

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: This study is non-therapeutical and involves no medical treatment or physical contact whatsoever. Participation in this study involves no risks. Intervention consists of 5 cognitive and psychoacoustic baseline tests of about 2 minutes each and 4 experimental tests of around 5 minutes each, 2 of which involve perception (1 for emotional and 1 for linguistic prosody) and 2 of which involve elicited production (1 for emotional and 1 for linguistic prosody) of prosody. Parents/caretakers will be allowed to accompany their child during the experiment. Only positive feedback will be given, so the child will never feel it is performing badly. Parents and children are allowed to withdraw their participation before or during the experiment without any consequences. The only burden for the participants in this study consists of the time they have to spend, around one hour and a half altogether. This study can only be performed on children with CIs, because n order to know if CI children develop differently than their normally hearing (hearing or chronological-age matched) peers, real patients are needed. Second, it is the only way to test the role of the sensitive period in early natural language acquisition (between 0 and 4 years). This is because CI children are the only population experiencing delayed verbal language acquisition. Third, the outcomes

could have implications for the way language and speech therapy for CI children is designed.

Study objective

Prosody, both linguistic and emotional, is essential in the acquisition and usage of language and socio-emotional development, but it proves difficult for CI users because of their relative inability to hear spectral and, to a lesser degree, dynamic differences. Temporal differences, however, are not particularly problematic. The left cerebral hemisphere specializes in both types of prosody and in temporal cues, the right hemisphere in emotional prosody and spectral cues. We hypothesize later implanted children to have a delayed prosody development, to rely more on dynamic temporal than on spectral cues, and to find differential success and cue reliance for left- and right implanted children.

Study design

Single sessions or two separate sessions with as short an interval as possible

Intervention

The intervention consists of 4 experimental behavioural psycholinguistic tests of 2-3 minutes (on average) each consisting of practice and experimental trials. This series of tests is preceded by a maximum of 4 general cognitive and perception tests of 20-25 minutes together. For the tests that will be performed on a computer, participants will be seated in front of a computer screen at a distance of around 60 cm. Pausing time is provided between test blocks within and between tests, such that resting time is assured approximately every couple of minutes. Only positive feedback is provided and only in the practice trials . The whole procedure will take about one two hours and a half including the time to instruct and pay the participants and to have them sign the informed consent and including pauses between the tests/test blocks.

Contacts

Public
Daan van de Velde
[default]
The Netherlands
Scientific
Daan van de Velde
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

a) Early Implanted Group. Having undergone cochlear implantation before the age of 1;6; having used the implant for a gross duration of between 3;0 and 3;6 years. Half of them are left implanted and half right implanted.

b) Late Implanted Group. Having undergone cochlear implantation before the age of 3;0 and 4;0; having used the implant for a gross duration of between the 3;0 and 3;6 years. Half of them are left implanted and half right implanted.
c) Hearing-Age Matched Group. Aged between 3;0 and 3;6; Dutch nationality.

d) Younger Chronological-Age Matched Group. Aged between 4;0 and 4;6; Dutch nationality.

e) Older Chronological-Age Matched Group. Aged between 7;0 and 7;6; Dutch nationality.

Exclusion criteria

a/b) Early Implanted Group. Reported medical problems related to the CI; multilingual development; bilateral implantation.
c/d/e) Control groups. Reported audiological or psychosocial problems; multilingual development

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	22-04-2015
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion Date:	14-04-2015
Application type:	First submission

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
NTR-new	NL4815
NTR-old	NTR5316
CCMO	NL46060.098.13

Study results