

Perception of pronouns and reflexives by children: How can an elephant help?

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

Summary

ID

NL-OMON38537

Source

ToetsingOnline

Brief title

Perception of pronouns and reflexives

Condition

- Hearing disorders

Synonym

deafness, hearing loss

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: VIDI;VICI;Rosalind Franklin Fellow

Intervention

Keyword: cochlear implants, hearing-impaired, pronouns, reflexives

Outcome measures

Primary outcome

The main outcome of this study will be the difference in performance on the perception of reflexives and pronouns between children with one or two CIs, and matched hearing-impaired and normal-hearing children. This performance is expressed in percentage correct.

Secondary outcome

Furthermore, the effects of age and age at implantation will be examined as probable influencing factors on the performance of the test. The potential benefits of two CIs compared to one CI, and of having a CI over a hearing aid will be investigated as well. As it becomes a longitudinal study, the development of the children will be followed for a period of 5 years.

Study description

Background summary

Cochlear implants (CIs) are prosthetic devices that restore hearing to profoundly deaf individuals. When implanted young, pediatric CI users greatly benefit from the implants, especially in terms of language development. When implanted at an older age, deficits in speech and language tests can be observed. Given the importance of identifying linguistic milestones with pediatric patient population, we propose a new way of measuring language comprehension, based on the Delay of Principle B Effect (DPBE) in language acquisition. We specifically propose to implement a new linguistic test, namely perception of pronouns (*The elephant is hitting him.*) and reflexives (*The elephant is hitting himself.*), two linguistic milestones that occur at different ages between 5 and 8 years.

Study objective

The main goal of the study is to characterize the perception of reflexives and pronouns in normally developing normal-hearing, hearing-impaired and cochlear implanted children. The proposed project consists of a longitudinal study spreading over 5 years.

Study design

The study is an observational study, with both within-subject and across-group comparisons. The children will be presented with one sentence at a time, either in the pronoun or the reflexive form. Simultaneously, one picture will be shown on a screen. The children will be asked to push a green button when what they heard was similar to what they saw on the screen, and an orange button when these were different. All included children are normal-developing. Therefore, the children will perform various cognitive tests for working memory, inhibition to distraction/attention, and a theory of mind task.

Study burden and risks

The total testing time per subject is 3 hours, including breaks. During these 3 hours, the children perform various cognitive tests, speech audiometry and a linguistic test. This testing requires concentration of the subject, and is therefore fatiguing. Therefore, frequent breaks will be included. If necessary, the session can be split in two sub-sessions. The decision therefor is made based on the attention span of the child. The testing will be repeated every 6 months over a period of 5 years. Participation in this study offers no known risk to participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

- Be aged 5 to 13 years.
- Participants must be generally in good health.
- Monolingual (Dutch); children who use NmG (Nederlands met Gebaren) or children who use sign language
- Normal cognitive development

Exclusion criteria

- Non-native Dutch speakers, native Frisian speakers, or bilingual children will be excluded from the study.
- Children with cognitive disabilities
- Children with multiple developmental problems and physical disabilities

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:	Recruitment stopped
Start date (anticipated):	11-06-2013
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO	
Date:	12-04-2013
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	NL42971.042.12