Investigating the benefit and relevance of the automatic classifier Autosense Sky in various complex acoustic conditions in CI children

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Gaining insight in the potential benefit and relevance of the automatic classifier in various acoustic conditions for children using Advanced Bionics Sky CI(s).

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

Summary

ID

NL-OMON56575

Source
ToetsingOnline

Brief title
CI-Sky

Condition

- Hearing disorders

Synonym
severe-to-profound hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Advanced Bionics,bedrijf

Intervention

Keyword: automatic classifier, cochlear implant, virtual reality

Outcome measures

Primary outcome

Difference in speech recognition score and sound detection/identification score

in the virtual classroom setting between Autosense on and off.

Self/parent-rated difference in auditory performance between the two CI

settings that are tested during the take-home period (Autosense on and off).

Secondary outcome

Difference in speech recognition score and sound detection/identification score

in the virtual classroom setting between Autosense off and remote microphone

condition. Head movements and response times are logged, because they are known

secondary measures of listening effort/attention.

Study description

Background summary

More and more modern hearing devices are equipped with an automatic classifier, which uses signal processing and machine learning techniques to categorize an acoustic environment into one of several general categories. Based on the selected category, different hearing device settings, such as the microphone directivity, are activated. The requirements that such an automatic classifier has to fulfil are different for children than for adults, because of the different listening situations that children encounter. For example, children are more often addressed from other directions than the frontal direction, when they are playing or in the classroom. Whereas a directional microphone can improve speech perception from the front in noisy situations, it also attenuates sounds coming from other directions and should therefore only be turned on in appropriate situations, especially for children with severe hearing loss using a cochlear implant (CI). AutoSense Sky OS is an automatic classifier designed especially for children and is used in Phonak Sky hearing

aids and Advanced Bionics Sky cochlear implants. This study tests the hypothesis that AutoSense Sky OS improves speech perception from the front and does not impair localization ability or sound identification from other directions in CI children.

Study objective

Gaining insight in the potential benefit and relevance of the automatic classifier in various acoustic conditions for children using Advanced Bionics Sky CI(s).

Study design

The study is a double-blinded crossover intervention study. Children test two different settings of their CI(s) during the study: their current setting (Autosense is turned off), and a new setting where Autosense is turned on. They test the two settings (blindly) at home for two weeks each. For each of the two take-home periods, they fill out a questionnaire and diary about their auditory performance together with their parents. Furthermore, the children do listening tests when they come back to the clinic, to compare their performance with each of the two settings. These listening tests take place in a virtual classroom, using a VR headset and loudspeaker ring. Speech recognition from the front is tested using stimuli from the clinically-used digit-in-noise test. Furthermore, sound detection/identification from other directions is tested, by letting the children push a button when the hear an animal name (one button for tiger, another button for rabbit). In these listening tests, a third condition is included, which is the condition where a remote microphone is used by the speaker from the front. Moreover, a technical evaluation is done to check how Autosense reacts to the virtual test environment.

Intervention

The automatic classifier Autosense Sky is turned on in the CI processor.

Study burden and risks

The participants need to visit the Erasmus MC twice, with four weeks in between. After two weeks, the CI processor with the second program can be picked up or send to their home address, and participants fill out a diary and questionnaire with their parents to describe their experience in different listening situations. During both visits, speech tests will be done, and each visit will take 1-1.5 hours. After the second visit, the participants decide together with their parents which program they want to keep. The sound of the CI programs in the study will be very similar to the programs that the participants are used to, so we expect no problems with acceptance of sound or

deterioration of daily auditory functioning during the study.

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

Children with one or two Advanced Bionics Sky CI(s), aged between 5 and18 years, who have used their CI(s) for a period longer than 6 months.

Exclusion criteria

Additional disabilities that are expected to interfere with VR evaluation

Vision problems that prevent subjects from seeing 3D through the VR headset
Epilepsy (visual effects of VR headset may trigger a seizure)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2024
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	cochlear implant (processor)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-01-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL85237.078.23