

ZoomIn: screening study into hearing impairment in pre-schoolers

Published: 28-09-2023

Last updated: 24-05-2024

Validating toddler and preschool hearing screening by means of a tablet.

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

Summary

ID

NL-OMON56441

Source

ToetsingOnline

Brief title

Tablet-based pre-schoolers hearing screening

Condition

- Hearing disorders

Synonym

hearing impairment, hearing loss

Research involving

Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep

Source(s) of monetary or material Support: Stipendium Wetenschapsraad/Directie van het Reinier de Graaf Gasthuis;Delft

Intervention

Keyword: Audiometry, Hearingscreening

Outcome measures

Primary outcome

Warble-tone hearing thresholds obtained by a self-test with tablet audiometry, duration 10', which will be compared with the results of standard diagnostic hearing tests, requested by an ENT specialist, performed by an experienced acoustician.

Secondary outcome

Not applicable.

Study description

Background summary

At least 10% of all children aged 3-5 years suffer from ear problems with doubts about their hearing. There is no uniform hearing screening at that age.

Study objective

Validating toddler and preschool hearing screening by means of a tablet.

Study design

The attending ENT specialist will perform an otoscopy for all participants. Acousticians will conduct standard hearing tests in a double-walled audiometry booth. In addition, a *self-test* with a tablet will determine the hearing thresholds for warble tones. For simplicity and speed, unmasked air conduction is the only investigational part of this study and binaural testing will be performed on all participants using calibrated headphones. A clinical physicist - audiologist supervises the execution of the tests. One parent/guardian may accompany the child for support during the test. During the examination of the children, one of the parent(s)/caregiver(s) will complete a short questionnaire (1 A4) about the nature of the hearing complaints. Statistical research will determine the reliability of the hearing screening in relation to the regular diagnostic examination.

Study burden and risks

No burden, other than 10' participation in hearing screening, easier to implement in terms of deployment than participation in the regular diagnostic hearing test. No risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Children, 3-5 years old, with complaints of hearing loss, referred by general practitioner to ENT-specialist.

Exclusion criteria

No other health problems.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-08-2023

Enrollment: 185

Type: Anticipated

Medical products/devices used

Generic name: ZoomIn Audiometry

Registration: No

Ethics review

Approved WMO

Date: 28-09-2023

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 15-05-2024

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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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	NL81067.058.23