Sound-Ear-Check: analysis and validation of screening tests for hearing using non-speech sounds in noise.

Published: 30-11-2016
Last updated: 11-04-2024

The purpose of this study is the improvement of sound material for the Sound-Ear-Check by focusing on the acoustical analysis and the validation of the Sound-Ear-Check, among adult participants and children with normal-hearing abilities and hearing-...

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

Summary

ID

NL-OMON43325

Source
ToetsingOnline

Brief title
Validity of Sound-Ear-Check (SEC) as a hearing screening method.

Condition

- Hearing disorders

Synonym
hearing impairment, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hearing, screening, sound-in-noise, tests

Outcome measures

Primary outcome

Test results of the Sound-Ear-Check will be compared with the results of the standard pure-tone audiogram and conventional internet screening tests. The sensitivity and specificity can be assessed to investigate whether the Sound-Ear-Check is a valid screening method to diagnose hearing problems.

Secondary outcome

Secondary study parameters that will be studied are differences in S/N score between test and retest, the correlation between S/N scores of test and retest in order to estimate the test-retest reliability and the learning effect.

Furthermore we will investigate the effect of age in the outcomes of the test.

Study description

Background summary

Early hearing screening at children is of great importance, because hearing loss may cause difficulties to their speech perception, language and social-emotional development. Online screening gives an estimation of auditory functioning quickly and easily at home with minimal instructions. The Children*s Hearing Test is an online screening test developed for primary school children. The disadvantage of this test is that the sound material is based on words and makes the test language dependent. Results of non-native speaker children or children with a reduced understanding of the test language may be less reliable. The Sound-Ear-Check is an objective screening test based on sounds and appropriate for screening hearing function of children. It may also be a tool for screening noise-induced hearing loss in young adults.

Study objective

The purpose of this study is the improvement of sound material for the Sound-Ear-Check by focusing on the acoustical analysis and the validation of the Sound-Ear-Check, among adult participants and children with normal-hearing abilities and hearing-impaired abilities by means of psychophysical testing.

Study design

In this study, a hearing screening test, the Sound-Ear-Check will be validated. First an acoustical analysis via principal component analysis will be performed on the stimuli to improve the sound material of the Sound-Ear-Check. In the second part of the study the test will be performed among a group of adult participants with normal-hearing and hearing-impaired abilities. Participants will be performing both tests two times (test and re-test). Being the clinical standard for measuring auditory functioning, pure-tone audiometry will also be performed. The test results of the sound-in-noise test will be compared with current available internet screening tests, for example the National Hearing Test for Adults and pure-tone audiometry to check whether the Sound-Ear-Check is a valid method for screening the hearing function. In the third part of the study, the test will be performed on normal-hearing and hearing-impaired children to check whether the Sound-Ear-Check is also an appropriate test for screening hearing function of children. The test results will be compared with the Children*s Hearing Test and pure-tone audiometry.

Study burden and risks

Since this study is observational, the burden for the patient is minimal and no risks are associated with this study. The participants will undergo one-time pure-tone audiometry and a sound-in-noise test in the clinical practice. To reduce the load to a minimum, the duration of the tests will be as short as possible and several short breaks will be taken.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Group I: Aged >18 years old
Group II: children 6-12 years old
Normal hearing ability (hearing threshold levels at octave frequencies *20 dB HL) or mild to moderate sensorineural hearing loss)
Native speaker

Exclusion criteria

Language problems
Conductive hearing loss, as expressed by an air-bone gap > 15 dB HL

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):	23-01-2017
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL59554.018.16