Listening effort in the European population: A new innovative program of research and training

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

Summary

ID

NL-OMON44463

Source
ToetsingOnline

Brief title
LISTEN

Condition

- Hearing disorders

Synonym
Hearing impairment, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: EU en Oticon (experiment 4c),Oticon A/S Denemarken

Intervention

Keyword: effort, perception, pupillometry, speech

Outcome measures

Primary outcome

Performance on a speech perception in noise test, pupil response.

Secondary outcome

Performance on the cognitive tasks and questionnaires.

Study description

Background summary

Hearing loss is one of the most prevalent European disabilities. It is associated with increased levels of distress, fatigue and need for recovery. This causes withdrawal from major social roles, such as the occupational role and imposes a risk for the ageing European population. LISTEN aims to examine which current and new hearing aid technologies can successfully decrease listening effort required during speech perception.

Study objective

The aim of the study is to strengthen the basis for a new application of pupillometry (i.e., the measurement of pupil dilation) within the field of Audiology. An innovative method to quantify listening effort (pupillometry) will be further developed. Novel concepts translating laboratory findings back to daily life practice will be explored and validated.

Study design

The main study parameters in the study are:(1) The percentage of auditory sentences perceived correctly, (2) the peak pupil dilation (PPD) in response to the cognitive processing load during listening to speech presented in a background of interfering speech and (3) the pupil light reflex (PLR), the pupil response to brief exposure to light.
The PPD will be expressed relative to the pupil size during listening to interfering speech or silence (baseline pupil size). We will assess to what extent the speech and signal characteristics (e.g., signal levels) influence the PPD. We will additionally assess the pupil light reflex (PLR; the

constriction of the pupil when exposed to bright light as compared to darkness). We will also examine group effects (e.g., effects of hearing loss) on the test performances, PPD and PLR.
Subjects additionally perform working memory and verbal inference-making tests and complete questionnaires about daily-life (hearing) functioning and stress.
We will examine the correlation coefficients between the test performances and speech intelligibility (percentage correct word repetition) and the pupil parameters.

Study burden and risks

Participating with this study does not involve any health risks with careful observation of approved safety procedures for audiological testing and pupillometry. Pupillometry is based on recordings of a camera emitting infra-red light at a power well below the standard safety guidelines.
Participants will perform a speech comprehension test in which they are asked to repeat speech presented in background noise. In addition, participants will perform several cognitive tests (reading aloud of partly masked sentences, working memory).

Participants will spend a total of 4 hours to this study (30 minutes for those participating in the pilot study and 60 minutes for those participating in Exp 4c).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age between 18 and 80 years, native Dutch speaker, normal or corrected to normal eyesight, for normally hearing listeners: age -normal hearing according to ISO 7029, 2000, for listeners with hearing loss: pure tone hearing thresholds (average across 1, 2, 4 kHz) of at least 25 dB HL in at least one ear. ;For experiment 4C: Aged 12 years up to and including 16 years, native speakers of Dutch, normal or corrected-to-normal eyesight. Listeners with hearing loss should use at least one hearing aid in daily-life. Furthermore the hearing-impaired children should have a moderately to severe binaural sensorineural hearing loss (* 35 dB HL and * 70 dB HL for both ears), and be experienced hearing aid users. Children with normal hearing should have air-conduction pure-tone thresholds of max. 20 dB HL at the octave frequencies between 500 and 4000 Hz.

Exclusion criteria

dyslexia or other reading problems, history of neurological or psychiatric diseases, eye diseases such as caused by diabetes mellitus and cataract.;Supplementary for experiment 4C: General exclusion criteria: not being able to attend regular education schools. For the hearing impaired children unilateral and conductive hearing losses are excluded.

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2015
Enrollment:	171
Type:	Actual

Medical products/devices used

Generic name:	Hearing aid: "Open Sound Navigator"
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-11-2016
Application type:	Amendment
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	NL49302.029.14