Innovative Hearing Aid Research - Ecological Conditions and Outcome Measures (HEAR-ECO)

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

Summary

ID

NL-OMON52431

Source
ToetsingOnline

Brief title
HEAR-ECO

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: Europese Commissie,Oticon Foundation

Intervention

Keyword: hearing impairment, listening effort, pre-ejection period, pupillometry

Outcome measures

Primary outcome

The main study parameters include the pupil dilation response and cardiovascular response (pre-ejection period [PEP] and respiratory sinus arrhythmia [RSA]) during listening to speech, as well as speech perception performance. Furthermore, subjective rating scales (experienced effort, estimated performance, and tendency to give up listening), the data of two validated questionnaires (subjective hearing difficulties, need for recovery, inclusion of other in self and group feeling) and the performance on a verbal working memory test and a symptom-validity test are part of the study parameters.

Secondary outcome

Blood pressure and hearing acuity.

Study description

Background summary

In today*s ageing European population, hearing impairment is an increasing concern for public health and societal participation. The percentage of hearing-impaired people will rise from around 16% of the adult EU population now to around 40% in 2030. Hearing aid (HA) fitting is the most widely prescribed solution for hearing impairment. However, only around 30%-40% of adults with hearing impairment use HAs in daily life. One of the reasons for this is that methods used to develop and evaluate HAs are still not based on conditions in which HAs are actually used. Thus the potential of improved HA technology to meet the needs of individual users in their daily lives is acutely underexploited. The science in HEAR-ECO will help to facilitate the

paradigm shift which is needed to bridge the gap.

Study objective

The primary aim of this study is to develop ecologically valid listening tests with realistic social consequences of speech understanding difficulties in which physiological outcome measures are applied. Specifically, we aim to develop a speech perception tests in which feedback is provided. We will manipulate the task auditory demands by manipulating sentence complexity. The outcome measure includes physiological measures of the pupil dilation response and cardiovascular measures. These measures are associated with the sympathetic and parasympathetic activity of the autonomous nervous system, and are sensitive to listening effort. We hypothesize that increased auditory task demands and social feedback will increase the listening effort as reflected by the physiological measures.

Study design

Experimental study

Study burden and risks

Participating in this study does not involve any health risks. Participants have to perform one test session (site visit to VUmc) of 1.5-2.5 hours, respectively.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: aged between 18 and 80 years of age, native speakers of Dutch, normal or corrected-to-normal eyesight. Listeners with hearing loss should have average pure tone hearing thresholds (across 1000, 2000 and 4000 Hz) of at least 35 dB HL in both ears. We aim to include an equal number of female and male participants in each of the studies in order to improve the generalizability of the results.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: Listeners with normal hearing should have age-normal hearing (ISO 7029, 2000). General exclusion criteria: having a history of a neurological, psychiatric disease or using psychoactive drugs. Additional exclusion criteria for Studies 2, 4 and 5 (related to the cardiovascular measures collected in these studies): having a history of cardiovascular diseases, anatomic abnormalities such as: aortic valve regurgitation and defect of septum, aortic prosthesis, cardiac shunts, severe aortic sclerosis, and intra-aortic pumps or having a pacemaker. Severe hypertension (MAP > 130 mmHg), cardiac arrhythmia, tachycardia with a heart rate higher than 200 bpm, aortic balloon or aortic balloon pump. These abnormalities and dysfunctions may impede the reliable measurement of the ECG and ICG.
The exclusion criteria for each of the studies except Study 2 also include (eye-) diseases such as diabetes mellitus and cataract that may influence the pupil dilation response. Additional exclusion criteria for Study 5 entail psychological disorders that may affect social skills such as disorders on the autistic spectrum and any disorders that affect social perception such as

social anxiety. Furthermore, participants that have experienced extreme nausea when using virtual reality technology before this experiment will be excluded as well. Finally, because of limited space in the virtual reality head-mounted display participants cannot wear glasses. Participants who normally wear glasses and cannot substitute with contact lenses have to be 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):	04-02-2019
Enrollment:	191
Type:	Actual

Medical products/devices used

Generic name:	Eye-tracker;Monitor for Electrocardiogram (ECG) and Impedancecardiogram (ICG)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-09-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	07-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-02-2022
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	NL66213.029.18