Influence of attention on sensory processing in the presence of distracting stimuli in tinnitus subjects and healthy controls.

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

Summary

ID

NL-OMON34519

Source
ToetsingOnline

Brief title
Attention and Sensory Processing.

Condition

- Hearing disorders
- Neurological disorders NEC
- Disturbances in thinking and perception

Synonym
ringing in the ears

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Fundação para a Ciência e a Tecnologia (FCT)

Intervention

Keyword: Attention, Functional Magnetic Resonance Imaging, Sensory processing, Tinnitus

Outcome measures

Primary outcome

Audiometric and psychometric values obtained by means of questionnaires and

audiological exams, parameters related to task performance and stimulus-evoked

BOLD fMRI signals in the brain.

Secondary outcome

not applicable

Study description

Background summary

Tinnitus is a prevalent hearing disorder that affects millions of people and has a severely disabling impact on life in about 1-3% of the general population. It is characterized by the perception of sound in the absence of any external sound sources. Attention deficit is part of the psychopathological profile of tinnitus patients, which have difficulty to focus on task performance. Whether this deficiency is maintained across sensory modalities or is mainly present within the auditory domain remains unclear. This study aims to achieve further knowledge on the neural correlates of the pathophysiology of this condition. Neuroimaging studies on tinnitus rarely address activity in higher brain areas, beyond the classical auditory brain centers. In particular, neuroimaging studies on attention and tinnitus have never been carried out.

Study objective

The present study intends to perform functional magnetic resonance imaging (fMRI) in order to obtain further insight in effects of selective attention on

sensory processing. This study aims to compare subjects with normal hearing to patients that suffer from tinnitus.The effects of distractors on task performance will be assessed. We will determine brain areas and networks involved in auditory and visual perception and compare their function in the presence or absence of distractor stimuli in the other modality. In addition to such cross-modal effects, we will also assess unimodal effects by studying sound-evoked responses in the presence or absence of distractor auditory stimuli (i.e., in the same modality). This will be approached through neuroimaging methods allowing access to functional interactions between higher and lower brain areas (e.g. related to attention and audition, respectively).

Study design

Two-group exploratory study.

Study burden and risks

The audiological and psychometric assessment involve several audiometric tests, and the administration of questionnaires (approx. 2 hours). Two fMRI scanning sessions will take place on separate days (approx. 1 hour each). None of the procedures expose the subject to known risks or major burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient group:
Report of mild to moderate subjective tinnitus, characterized by a score of 18-56 on the Tinnitus Handicap Inventory;
No reported medical, neurological, or psychiatric disorders (excluding tinnitus);
Adult, 18-60 years of age;
Normal hearing thresholds or mild hearing loss (average threshold <60 dB @ 500-2000 Hz);
Symmetrical hearing thresholds (<20 dB difference between both ears for all frequencies);
No contraindications for fMRI according to the MRI-checklist; ;In healthy group:
Healthy subjects (i.e., no medical, neurological, or psychiatric disorders);
Adult, 18-60 years of age;
Normal hearing thresholds or mild hearing loss (average threshold <60 dB @ 500-2000 Hz);
Symmetrical hearing thresholds (<20 dB difference between both ears for all frequencies);
No contraindications for fMRI according to the MRI-checklist;

Exclusion criteria

Non-conformance with any of the inclusion criteria.

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:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL33326.042.10