Perceptual and neurophysiological characteristics of intermittent tinnitus

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Aural disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON43168

Source
ToetsingOnline

Brief title
Neural networks in intermittent tinnitus

Condition

- Aural disorders NEC

Synonym
Ringing in the ears

Research involving
Human

Sponsors and support

Primary sponsor: Keel-, Neus- en Oorheelkunde
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Auditory perception, MRI, Psychoacoustics, Tinnitus

Outcome measures

Primary outcome

Part 1: the dynamic characteristics of intermittent tinnitus, such as the

percentage of time the tinnitus is ON, the duration of the ON and OFF

intervals, variability of these parameters within and across participants.

Part 2: The difference between brain connectivity patterns with tinnitus ON and

OFF in participants with intermittent tinnitus and the differences in

comparison to participants with continuous tinnitus.

Secondary outcome

Not applicable.

Study description

Background summary

Tinnitus is a very common and potentially devastating condition. It is related to peripheral hearing loss. A key hypothesis is that tinnitus is caused by changes in brain function as a result of hearing loss. Clinical evidence suggest that tinnitus may not constitute a single entity. Instead, tinnitus may comprise several subgroups of tinnitus, who*s pathophysiology is currently unknown. One specific tinnitus subgroup may be intermittent tinnitus. Participants with intermittent tinnitus describe changes in the loudness of their tinnitus over the course of a day, between days, or from week to week. They may be free of tinnitus on some days (tinnitus *OFF*), and may be heavily bothered on other days (*ON*). Earlier studies, on participants with continuous tinnitus, showed that tinnitus is related to abnormal functional connectivity in the brain. That is, the brain connectivity is abnormal in comparison to participants without tinnitus. This study further investigates whether these abnormalities occur in a similar fashion in intermittent tinnitus, and whether

they appear only when the tinnitus is ON. Alternatively, the abnormal brain activity may not be related to the tinnitus percept itself and simply reflect a brain state that is prone to generate tinnitus.

Study objective

The study consists of two parts.

Objective 1 to document the day by day changes of tinnitus that participants with intermittent tinnitus experience. This objective is aimed for in part 1 of the study. In addition, this part allows the selection of a subgroup that is compatible with the scanning protocol in part 2.

Objective 2: to document whether the changes in tinnitus co-occur with changes in functional brain connectivity, and whether brain connectivity patterns differ from those in participants with continuous tinnitus.

Study design

Observational study.

Study burden and risks

Part 1: Participants receive an iPhone/Android app, which they use for 30 days. The app prompts them 3 times per day to fill in a brief questionnaire on their tinnitus. Filling in the questionnaires takes about 15 seconds. This has no benefit to the participant, except that the app provides an overview of results to the participants that is informative about their own tinnitus characteristics.

Part 2: A subgroup of participants from part 1 will be invited to participate in an fMRI experiment. This involves filling in 5 standard clinical questionnaires (30 minutes), 1 standard MRI compatibility questionnaire (5 minutes), measuring an audiogram (20 minutes) and two fMRI session in a 3.0 Tesla MRI scanner (30 minutes each). This part provides no individual benefit to the patient. We rate the inconvenience as mild. None of the procedures expose the participants to known risks.

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

Aged 18 - 75 years. Experiencing intermittent tinnitus for group 1. Experiencing continuous tinnitus for group 2. Written informed consent.

Exclusion criteria

Non-compatibility with MRI e.g. pacemaker, neurostimulator, insulinpump, stents, clips, any metal implants, an implanted hearing aid etc. Non conformance to inclusion criteria. Reported medical, neurological, or psychiatric disorders (excluding tinnitus and hearing loss).

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:	Will not start
Enrollment:	220
Type:	Anticipated

Ethics review

Approved WMO

Date:	16-08-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	18-12-2017
Application type:	Amendment
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	NL58152.042.16
Other	NTR nummer is nog niet toegekend, de studie is aangemeld en in afwachting van toekenning van NTR nummer