Characteristics of intermittent tinnitus

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON27744

Source
Nationaal Trial Register

Brief title
intermittenttinnitus

Health condition

Intermittent tinnitus

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: NWO

Intervention

Outcome measures

Primary outcome

Objective 1 to document the day by day changes of tinnitus that participants with intermittent tinnitus experience.

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.

Secondary outcome

Not applicable

Study description

Background summary

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.

Study objective

Objective 1 to document the day by day changes of tinnitus that participants with intermittent tinnitus experience.

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

01-10-2016

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

- Adult, 18-75 years of age;

- Written informed consent.

- Group 1: participants with intermittent tinnitus.

- Group 2: participants with continuous tinnitus

Exclusion criteria

-Non-conformance to any of the inclusion criteria stated above

-Contraindications for MRI according to the MRI checklist

-Reported medical, neurological, or psychiatric disorders (excluding tinnitus and hearing loss);

Study design

Design

Intervention model: Parallel

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2016
Enrollment:	220
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5951
NTR-old	NTR6132

Register	ID
Other	: METc 2016/293

Study results