Assessment of listening effort in tinnitus patients

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We aim that by assessing listening effort subjectively with an adaptive categorical listening effort scale (ACALES) we can demonstrate the possibly increased listening effort in tinnitus patients.

Ethical review	Approved WMO
Status	Completed
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53978

Source
ToetsingOnline

Brief title
Listening effort in tinnitus patients

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Listening effort, Tinnitus

Outcome measures

Primary outcome

Listening effort scale (ACALES) determined during speech-in-noise tests with

signal-to-noise ratios around the subject*s speech reception threshold (SRT).

Secondary outcome

Evaluate the relative importance of (subscales of) the tinnitus related

questionnaires (TQ, TFI, HADS) on the listening effort.

Study description

Background summary

About 5-15% of the general population experience a chronic ringing, buzzing, hissing or roaring sound in one or two ears, without any external source. This so-called tinnitus can be present in people with normal hearing, but often coexists with hearing loss. Most people suffering from tinnitus can cope with it, however a minority experiences emotional distress or cognitive dysfunction as a result of the tinnitus, called tinnitus disorder. People suffering from tinnitus disorder regularly complain about an increased experienced effort when listening to speech or other sounds in daily life situations. As this has never been proven scientifically, we aim in this pilot study to evaluate the effect of the tinnitus percept and tinnitus disorder on experienced listening effort by comparing listening effort between a population with tinnitus disorder and a population without tinnitus.

Study objective

We aim that by assessing listening effort subjectively with an adaptive categorical listening effort scale (ACALES) we can demonstrate the possibly increased listening effort in tinnitus patients.

Study design

Observational pilot study.

Study burden and risks

There are no substantial health risks specifically associated with study participation. Several audiological tests will be performed that are used in standard clinical care. Participation however takes time, effort and attention form subjects. Specifically, patients need to come to the hospital for a test session.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

POPULATION WITH TINNITUS DISORDER
• Adults, i.e. 18-70 year old;
• PTA4 better than/equal to 35 dB HL (PTA4 = average of hearing thresholds at

frequencies 0.5, 1, 2 and 4 kHz);
• Proficient and native speaker of Dutch language;
• Severe unilateral or bilateral tinnitus disorder (TQ > 46).

POPULATION WITHOUT TINNITUS
• Adults, i.e. 18-70 year old;
• PTA4 better than/equal to 35 dB HL (PTA4 = average of hearing thresholds at frequencies 0.5, 1, 2 and 4 kHz);
• Proficient and native speaker of Dutch language;
• No tinnitus.

Exclusion criteria

POPULATION WITH TINNITUS DISORDER
• Significant asymmetric hearing loss (|PTAright - PTAleft| > 15 dB);
• Significant loss of vision (text on screen at 70 cm should be readable);
• Frequent user of any of the following devices: Hearing Aid, Bone Conduction Device, Cochlear Implant, Tinnitus masker;
• Additional mental or physical disabilities that may prevent active participation and testing as per protocol.

POPULATION WITHOUT TINNITUS
• Significant asymmetric hearing loss (|PTAright - PTAleft| > 15 dB);
• Significant loss of vision (text on screen at 70 cm should be readable);
• Frequent user of any of the following devices: Hearing Aid, Bone Conduction Device, Cochlear Implant, Tinnitus masker;
• Additional mental or physical disabilities that may prevent active participation and testing as per protocol.

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:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	07-06-2023
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	13-02-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-01-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL82108.068.22

Study results

Date completed: 30-10-2024

Summary results
Trial ended prematurely