Personalized hearing aid amplification to ameliorate tinnitus

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON50937

Source
ToetsingOnline

Brief title
Hearing aids and tinnitus

Condition

- Hearing disorders

Synonym
tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ESIT

Intervention

Keyword: hearing aids, notch, tinnitus

Outcome measures

Primary outcome

The main parameters to evaluate amelioration of tinnitus are: tinnitus intrusiveness, ability to ignore the tinnitus percept, concentration, quality of sleep and sense of control.

Secondary outcome

Additionally, the following psychoacoustic measures will take place:

- Changes in tinnitus pitch

- Changes in tinnitus loudness

- Auditory Handicap

- Hours of hearing aid use

Hearing aid benefit and hyperacusis will be assessed by means of questionnaires.

Study description

Background summary

Around 10% of the population suffer from tinnitus and in some cases their quality of life can be adversely affected. In most cases tinnitus is associated with hearing loss, and it might be triggered by related changes in the brain, as it has been observed in several animal studies. At the same time, deafferentation produced by acoustic trauma can lead to a decrease of spontaneous firing rates in the auditory nerve. Since these changes are observed after a reduced auditory input, it can be assumed that a sensory restoration might reverse the process. Hearing aids increase the volume of

external sounds, improving the communication of users while helping to mask tinnitus. Potentially, hearing aids also revert the abnormal brain activity that could be originated by acoustic deprivation.
There is a lack of high quality evidence to support the clinical efficacy and effectiveness of hearing aids for tinnitus (Hoare et al., 2014; Shekhawat et al., 2013), especially when it comes to randomized controlled trials (RCTs). Well-designed randomized controlled trials are necessary in tinnitus research to provide the higher grade of evidence quality for treatment efficacy, as it described in clinical guidelines (Tunkel et al., 2014).
There is an increasing interest in sound-based therapies for tinnitus treatment (Henry and Meikle, 2000; Hobson et al., 2007)Previous studies suggested that the perceived tinnitus pitch usually corresponds to frequencies where hearing is impaired (König et al., 2006; Norena et al., 2002; Roberts et al., 2008).
The tinnitus literature has shown that masking is more likely to be achieved when the frequency range of hearing aid amplification includes the tinnitus pitch (McNeill et al., 2012).
There is a great need for further studies involving RCTs with hearing aids in tinnitus patients, exploring different amplification schemes that are adjusted to the individuals* tinnitus pitch.
Some evidence suggest that details of the sound amplification strategy in the hearing aid are key in the success in suppressing tinnitus. Specifically, it was suggested that the amount of amplification that the hearing aid provides at the tinnitus frequency may be a determining factor. This study is designed to compare three amplification approaches, whether amplification at the tinnitus frequency is either increased, reduced, or at a standard pre-described level.

Study objective

The main objective of this study is to conduct a double-blind randomized control trial to assess the efficacy of 3 different amplification schemes of hearing aids in tinnitus patients. The schemes will be adjusted to the individual*s tinnitus characteristics to potentially optimize the outcome.

Study design

The project will consist of a randomized controlled trial, designed as a Latin square balanced crossover study. The design is balanced to avoid undesired carryover effects. Patients will be fitted with hearing aids using 3 different amplification schemes over the total period of 3 months, testing each approach for a month. Questionnaires and psychoacoustic measurements will be used to assess the outcomes of each scheme. Comparisons will be drawn across schemes and correlations across measurements will be made within subjects.

Intervention

Each subject will be fitted with the 3 different amplification schemes in the

same model of hearing aids, switching scheme every month.

Study burden and risks

There is no known high risk associated with participation. The only risk associated with participation is that, with one of the amplification strategies, tinnitus might get worse, but this situation is temporal. Patients experience changes in their tinnitus every month, week, and sometimes every day, and this can be related to the therapy or to different factors, such as stress levels or psychological status. The experiment is non-invasive in nature. Potential benefits with one, two or the three schemes of hearing aids are: better tinnitus maskability, reduction of tinnitus intrusiveness, concentration improvement, help with habituation/adaptation to tinnitus and placebo effect. The stimulus sound level using tinnitus pitch and loudness matching will always be adjusted by the participant and it will never reach uncomfortable levels. The duration of the trial is 13 weeks, which involves 5 visits to the lab of around 2 hours each, to change the hearing aids* features, fill in questionnaires and perform psychoacoustic tests.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- No reported neurological or psychiatric disorders (excluding tinnitus and hearing loss);
- High frequency hearing loss;
- Moderate- to moderate-severe- degree of hearing loss (PTA of 1, 2 and 4 kHz * 35 dB);
- Chronic tinnitus (lasting more than 6 months);
- Tinnitus percept described as tonal (or at least being able to perceive a pitch during a tinnitus matching);
- Tinnitus pitch * 8 kHz, and in the hearing loss region;
- Using hearing aids for at least the last 6 months;
- Written informed consent;

Exclusion criteria

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

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2021
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	02-06-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-07-2021
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

ID: 28370
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL76499.042.21
Other	UMCG Research Register, number 202000728
OMON	NL-OMON28370