Hearing aids and tinnitus

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Using hearing aids that either boost or filter out the frequencies around the tinnitus pitch might ameliorate the patient's tinnitus to a larger extent compared to standard amplification.

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

Summary

ID

NL-OMON28370

Source
NTR

Brief title
HEARANDTINN

Condition

- Hearing disorders

Health condition

Tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: This project has received funding from the European Research Council (ERC) under the European Union’s Horizon 2020 research and innovation program (grant agreement no. 722064, ESIT) and the Heinsius Houbolt Foundation.

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome
There was a small reduction of the TFI score after the adaptation process, possibly due to a placebo effect. The TFI score did not differ significantly from the standard setting after using the notched or the boosted settings. Regardless of the TFI outcomes, most participants had an individual preference for a particular setting. Notch-filtered and boosted amplification did not provide better tinnitus suppression than standard amplification, although notched amplification performed better than boosted amplification. The individual preferences highlighted the importance of tailor-made approaches to hearing aid amplification in clinical practice. Further studies should explore the differences among patient’s tinnitus and their preference for a hearing aid setting.

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

Study description

Background summary

Rationale: 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 (Stein et al., 2016). This study is designed to compare three amplification approaches, whether amplification at the tinnitus frequency is either increased, reduced, or at a standard predescribed level. 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 13 weeks, testing each approach for 4 weeks. 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. Study population: 18 subjects with tinnitus will undergo the study. Dropouts will be replaced by new participants. Intervention: Each subject will be fitted with the 3 different amplification schemes in the same model of hearing aids, switching scheme every 4 weeks. Main study parameters/endpoints: 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. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There is no known 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 total duration of the trial is 13 weeks, which involves 5 visits to the lab of around 1 hour each, to change the hearing aids' features, fill in questionnaires and perform psychoacoustic tests.

Study objective

Using hearing aids that either boost or filter out the frequencies around the tinnitus pitch might ameliorate the patient's tinnitus to a larger extent compared to standard amplification.

Study design

Baseline and after 4, 8 and 12 weeks.

Intervention

During 13 weeks, participant will use hearing aids with 3 different amplification techniques: standard amplification, notched amplification and boosted amplification. After a week of adaptation, participants will be fitted with one of this approaches for 4 weeks. ● “Standard” amplification. In this approach, all frequencies in the hearing loss region are amplified according to the standard clinical fitting using the formulae NAL-NL2. This approach is based on the regular recommendation for patients with tinnitus and hearing loss. Hearing aids might act as a tinnitus masker by enhancing the natural environmental sounds. ● “Notched” amplification. Following the TMNMT (Pantev et al., 2004), this scheme follows the previous fitting formulae, but is filtering out the frequencies around the participant’s tinnitus pitch. The rationale of this approach is based on lateral inhibition, by which tinnitus might be suppressed more efficiently by inhibition between neurons whose characteristic frequency is close. ● “Boosted” amplification. Similar fitting formulae but boosting the frequencies around the tinnitus pitch. This approach is similar to the first one, but with the addition of enhancing further the frequencies to better mask the tinnitus percept.

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
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 ≤ 6 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 phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	12-07-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen De Brug, kamer 7.067 / Huispostcode LA15 Postbus 30001 9700 RB Groningen 050 361 4204 metc@umcg.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 50937
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9424
CCMO	NL76499.042.21
EudraCT	2021-001848-10
OMON	NL-OMON50937

Study results