Gehoorapparaten en 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.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Gehoorstoornissen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28370

Bron
NTR

Verkorte titel
GEHOORTINN

Aandoening

- Gehoorstoornissen

Aandoening

Tinnitus

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: 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.

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten
Er was een kleine vermindering van de TFI-score na het aanpassingsproces, mogelijk als gevolg van een placebo-effect. De TFI-score verschilde niet significant van de standaardinstelling na gebruik van de ingekorte of versterkte instellingen. Ongeacht de TFI-resultaten had de meerderheid van de deelnemers een individuele voorkeur voor een bepaalde instelling. Inkepinggefilterde en versterkte versterking boden geen betere onderdrukking van tinnitus dan standaardversterking, hoewel ingekorte versterking beter presteerde dan versterkte versterking. De individuele voorkeuren benadrukten het belang van op maat gemaakte benaderingen voor gehoorapparaatversterking in de klinische praktijk. Verdere studies zouden de verschillen tussen het oorsuizen van patiënten en hun voorkeur voor een gehoorapparaatinstelling moeten onderzoeken.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline and after 4, 8 and 12 weeks.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Fase onderzoek:	3
Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	28-10-2021
Aantal proefpersonen:	18
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Goedgekeurd WMO

Datum:	12-07-2021
Soort:	Eerste indiening
Toetsingscommissie:	METC Universitair Medisch Centrum Groningen
	De Brug, kamer 7.067 / Huispostcode LA15 Postbus 30001 9700 RB Groningen 050 361 4204 metc@umcg.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50937
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten