Which treatment works for whom? A comparison of sound-exposure therapies

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Primary research questions:1. Does tinnitusspecific- behavioural exposure-treatment (T-BET) decrease tinnitus-related fear, tinnitus-severity and enhance recovery, when compared to a masking-therapy with use of personalised on-ear masking-devices,...

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

Summary

ID

NL-OMON44287

Source
ToetsingOnline

Brief title
A fear-conditioning approach to chronic tinnitus suffering

Condition

- Hearing disorders
- Somatic symptom and related disorders

Synonym
Tinnitus: Ringing of the ears

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: VENI scheme Dossier nummer 016.165.105

Intervention

Keyword: CBT, Fear-avoidance, Masking, Tinnitus

Outcome measures

Primary outcome

1. Tinnitus-disability: Tinnitus Handicap Inventory

2. Tinnitus-severity: Tinnitus questionnaire (TQ)

3. Health related QoL: HUI, SF36

Secondary outcome

4. Tinnitus-fear: FTQ; Fear of Tinnitus Questionaire (FTQ)

5. Catastrophic thoughts: Tinnitus Catasstrophising Scale (TCS)

6. Tinnitus variability

7. Threat expectancies

8. Negative emotional status

9. Avoidance behaviour (safety-seeing) (behavioural task/Inventory of Tinnitus

Avoidance Behaviours (ITAB)

10. Daily diaries (including 3 weeks pre- and post intervention): 10a) Tinnitus

loudness & maskability Questionnaire (LMI) 10b)Tinnitus-related fear-responding

and tinnitus-intensity

Study description

Background summary

Tinnitus, or the ringing of the ears, is defined as the perception of a continuous sound, in the absence of a corresponding acoustic stimulus in the external environment. It is estimated that in Europe over 70 million people experience tinnitus and that for 7 million it creates a chronic incapacitating

condition, tenaciously haunting them up to the point where it interferes with every aspect of their daily living. Residing within and confined to the individual*s subjective and perceptual experience, tinnitus is not measurable or quantifiable by objective physical recordings, and is furthermore not traceable to disease, injury, or pathology in the brain or elsewhere.
Empirical evidence for either the effectiveness of curative tinnitus treatments or for audiological interventions, such as hearing aids, and sound-generating devices to mask the sound, is lacking. Moreover, the audiometric characteristics of the tinnitus sound (loudness/pitch) hardly predict severity of the condition, or treatment outcomes. Contrary to scientific evidence, the clinical practice of masking/attenuating the tinnitus-sound is still the most widespread tinnitus-treatment approach.
Presently I propose the counterintuitive conjecture that it is not the sound itself which is so devastating, but it is rather threat-appraisals and fear-conditioned responses as a result, which cause the chronic condition. Indeed, empirical evidence is growing for the effectiveness of a cognitive behavioral approach; i.e. fear-reducing exposure based therapies not only decrease tinnitus severity and impact on daily life, but also contribute to general well-being of patients. Our recent findings support the importance of addressing tinnitus-related fear and fear-responses in the management of patients with disabling tinnitus. In this project we will experimentally test the idea that initial threat-appraisal and fearful responses, not only predict increased tinnitus suffering, but also that a sound-based approach is counterproductive in managing tinnitus complaints. Moreover, a recently developed (and validated) Tinnitus-specific Behavioural Exposure Treatment (T-BET), will be tested. This study may provide important input for existing and novel tinnitus-treatment approaches.

Study objective

Primary research questions:
1. Does tinnitusspecific- behavioural exposure-treatment (T-BET) decrease tinnitus-related fear, tinnitus-severity and enhance recovery, when compared to a masking-therapy with use of personalised on-ear masking-devices, or vice versa?
2. Can we identify different sub-groups of patients who benefit more from one approach over the other?
Secondary:
3. Can we identify clinically relevant behavioural/emotional markers by daily assessments?
4. Can we identify risk/resilience factors in the patient group suffering from mild- to severe tinnitus disability?

Study design

In a RCT, minimally 208 tinnitus-patients (N= 244, including 15% loss to

follow-up) recently diagnosed with tinnitus will be randomized (stratified on severity TQ<= 46; and hearing level: PTA on 1, 2, and 4 Khz of 25 dB worst ear) in a masking or exposure condition, with tinnitus-disability and severity as independents and tinnitus-related fear, threat-appraisal, avoidance/safety behaviour, and psychoacoustic measures (Andersson, 2003) as dependent variables, at baseline, pre-/post-treatment, and follow-up at 3 and 6 months. Tinnitus-related fear-responding and tinnitus-intensity (using self-report diaries) during masking-exposure procedures during 12 weeks (6 weeks masking-exposure procedures; 3 weeks pre-/post-measurements) will be assessed daily.

Intervention

Masking- and exposure-procedures will follow previously developed and validated guidelines (Cima et al., 2012; Henry, Jastreboff, Jastreboff, Schechter, & Fausti, 2003; Jastreboff, 2012).

Study burden and risks

The burdens and risks associated with participation in this study are non-existent. The study-specific unique additional activity we standardly request from all participating patients is for them to fill in a daily-diary during a 3-week pre-intervention (pre-test) period, the active treatment phase (6 weeks in both treatment arms), and a 3 week post intervention (post-test) period, for a total of 12 weeks. The use of daily diaries, and the strain it might pose on patients has been considered thoroughly and effects are two-fold: 1) patients will be requested to fill in a short daily-diary assessment, therefore they might feel inconvenienced at some times, 2) on the other hand, patient-reports suggest that the actual activity of monitoring and describing their functioning by the end of the day has increased their learning-ability and increased insights in their own 'Illness behaviour' favourably, which is especially helpful in these types of interventions.

The benefits for patients are:
1. Patients will receive continuous feedback on their progress and functioning: they are to receive weekly individualised treatment feedback from the treatment-teams in both conditions.
2. Patients will have a chance to receive (in the experimental arm) a new and promising innovative Tinnitusspecific Behavioural Exposure Treatment (T-BET)
3. Patients in the control arm will be enabled to also receive this T-BET, after they completed the final follow-up assesment and flow out of the trial.

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

- Score on Tinnitus questionnaire of TQ>30
- No previous masking or exposure therapy of minimally 5 years before inclusion
- Hearing aids are allowed
- Aged 18 plus

Exclusion criteria

- Hearing loss of more than 40 dB in either/both ears
- Limited knowledge: reading and writing skills in Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	31-08-2017
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO Date:	17-08-2017
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	04-02-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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: 27634
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61673.015.17
OMON	NL-OMON27634