CBT for tinnitus related insomnia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24403

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Chronic Tinnitus

Sponsors and support

Primary sponsor: Maastricht University Faculty of Psychology and Neuroscience
Source(s) of monetary or material Support: European Union’s Horizon 2020 research and innovation programme under Marie Sklodowska-Curie grant agreement number 722046

Intervention

Outcome measures

Primary outcome

Sleep quality as measured by the sleep diary

Secondary outcome

Tinnitus experience as measured by the tinnitus diary

Study description

Background summary

Tinnitus is the perception of sound (excluding voices), often described as a “ringing” or a high frequency tone, which occurs in the absence of an identifiable source. Although approximately 20% of the adult population has tinnitus, between 1-6% suffer from it. Chronic tinnitus has no cure and sufferers typically experience severe distress and disturbances in many aspects of daily life. Insomnia is one such complaint that is prevalent amongst tinnitus sufferers, with the underlying mechanisms still largely unknown. Insomnia may not be a secondary complaint and may be the cause, maintainer and generator of disorders, distress and dysfunction. Given the dynamic relationship between insomnia and tinnitus, insomnia is likely a comorbid clinical complaint. As such, comorbid insomnia must be treated directly. Recent meta-analyses have concluded that CBTi has clinically significant effects on primary chronic insomnia and comorbid insomnia. Moreover, beyond insomnia reduction, CBTi has demonstrated improvements in accompanying complaints such as depression, generalized anxiety disorder and chronic pain. More recently, a small trial has suggested that the same improvements might be true for tinnitus patients with half of the participants showing improvements in tinnitus distress. The trial was the first ever conducted with CBTi on tinnitus patients. Despite the small number of participants (n=24) and lack of control condition, the findings are an important first step in understanding insomnia in tinnitus patients. Further research into the effects of CBTi on tinnitus is needed. As an alternative and complementary approach to Randomized Control Trial (RCT), Single-Case Experimental Design (SCED) offers high degree of internal validity, vital for establishing causal relations between intervention and changes within patients. SCED also enables for an in depth exploration of change mechanisms within the intervention, allowing for the emergence and exploration of possible mediators and moderators. This research utilizes the SCED methodology to investigate CBTi for tinnitus patients allowing a more precise and controlled evaluation of the treatment protocol and enabling causal relationships to be established. A positive and reliable effect of CBTi on insomnia and tinnitus distress may provide a concrete path to treatment and indicate future directions for intervention designs.

Study objective

Primary Objective: This study aims to investigate the positive, negative or lack of effect that CBTi has on insomnia in tinnitus patients. Secondary Objective(s): Investigate the positive, negative or lack of effect that CBTi has on tinnitus experience.

Study design

Start at introduction (session 0) to 3-month follow-up (session 8).

Intervention

Cognitive Behavior Therapy for Insomnia (CBTi)

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Be primarily seeking treatment/help for difficulties caused by tinnitus.
- Additionally complaints of sleep disturbance (e.g. insomnia) as measured by the Insomnia Severity Index.
- Recommended to start CBTi protocol.
- Be at least 18 years of age. - Have at least moderate tinnitus (as defined by the Tinnitus Questionnaire)

Exclusion criteria

- Any person who discloses current suicidal intent.
- Severe anxiety or depression (as measured by the HADS-A and/or HADS-D.)
- Pregnancy of potential participant or partner.
- Currently undergoing any treatment for tinnitus (e.g. Tinnitus Retraining Therapy).
- Reported to have commenced or ceased a course of antidepressants [i.e. selective serotonin re-uptake inhibitors (SSRIs); selective serotonin and norepinephrine re-uptake inhibitors (SNRIs); atypical antidepressants, tricyclic antidepressants, or monoamine oxidase inhibitors], antipsychotics [Aripiprazole (Abilify), Asenapine (Saphris), Brexpiprazole (Rexulti), Cariprazine (Vraylar), Clozapine (Clozaril), Iloperidone (Fanapt), Lurasidone (Latuda), Olanzapine (Zyprexa), Paliperidone (Invega), Quetiapine (Seroquel), Risperidone (Risperdal), Ziprasidone (Geodon), Haloperidol], anxioltytics [beta blockers, benzodiazepines], Ritalin, hormone replacement therapy, or medication to lower high blood pressure (i.e. thiazide diuretics, ACE inhibitors, angiotensin II receptor blockers, beta blockers, calcium channel

blockers, renin inhibitors] within the previous 3 months
- Unable to read and write fluently in Dutch.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	6
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 49401
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7841
CCMO	NL68941.068.19
OMON	NL-OMON49401

Study results