COGNITIVE BEHAVIOR THERAPY FOR TINNITUS RELATED INSOMNIA: A SINGLE-CASE EXPERIMENT

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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...

Ethical review	Approved WMO
Status	Completed
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49401

Source
ToetsingOnline

Brief title
CBT for tinnitus related insomnia

Condition

- Hearing disorders
- Sleep disorders and disturbances

Synonym
tinnitus and "ringing in the ear"

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: This project has received funding from the

European Union's Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie grant agreement number 722046

Intervention

Keyword: CBT, insomnia, single-case, tinnitus

Outcome measures

Primary outcome

Participants* sleep diary is the main parameter for this study. Sleep onset latency, wake time after sleep onset, number of awakenings and sleep quality can be calculated for each night. The participant completes the diary on paper and delivers to the therapist at each session (treatment as usual).

Secondary outcome

Participants* tinnitus diary will be used to identify changes in tinnitus experience. The diary is composed of 16 questions related to tinnitus experience (e.g. *how annoying was your tinnitus today?*), avoidance (e.g.* What proportion of the day have you used a device / television / radio etc to mask your tinnitus?*), avoidance and emotion (e.g. *how angry did you tinnitus make you today?*).

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 (Bhatt, Lin, & Bhattacharyya, 2016; Cima, Crombez, & Vlaeyen, 2011; Davis & Refaie, 2000; Kim et al., 2015; McCormack, Edmondson-Jones, Somerset, & Hall, 2016). Chronic tinnitus has no cure and sufferers typically experience severe distress and disturbances in many aspects

of daily life (Davis & Refaie, 2000; Hall et al., 2018). Insomnia is one such complaint that is prevalent amongst tinnitus sufferers, with the underlying mechanisms still largely unknown (Langguth, 2011). According to Harvey (2001), 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 (Folmer & Griest, 2000).

Recent meta-analyses have concluded that CBTi has clinically significant effects on primary chronic insomnia (Trauer, Qian, Doyle, Rajaratnam, & Cunnington, 2015) and comorbid insomnia (Geiger-Brown et al., 2015). Moreover, beyond insomnia reduction, CBTi has demonstrated improvements in accompanying complaints such as depression (Jacobs, Benson, & Friedman, 1993), generalized anxiety disorder (Blais, Mineault, & Morin, 2000) and chronic pain (Jungquist et al., 2010). 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 (Marks, McKenna, & Vogt, 2019). 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.

Patients are required for this study as there is no reliable means of simulating the effects of chronic subjective tinnitus in healthy participants. Adults with chronic subjective tinnitus and sleep complaints will be recruited to participate in this study as we are testing the degree of effectiveness of the intervention. These treatment-seeking individuals are already recommended CBTi by the established hospital protocol (a.k.a. treatment as usual), allowing for a minimally invasive and burdensome study design.

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

The study will use a sequentially replicated SCED. This design relies on a series of different participants undergoing the same intervention at different time points. Each participant will act as their own control and will be systematically assessed through daily diaries (already part of the current CBTi intervention). The continuous assessment of each individual participant allows for the exploration of possible relationships between each intervention component (e.g. psycho-education, relaxation) and individual experience (e.g. sleep quality, tinnitus distress) by pinpointing when and if change occurs at different levels.

Data is continuously collected throughout baseline (phase A), treatment (phase B) and follow-up (phase A`), latter analysed within and between participants, allowing causal relations to be established. A sequentially replicated design across subjects increases power by allowing randomization of intervention start (phase B) for every incoming participant.

The treatment as usual for tinnitus related insomnia at Maastricht UMC+ is the CBTi intervention (see section 5.1 and Appendix A) comprised of 9 sessions. The first session (Session 0 in the CBTi protocol) relates to the introduction of the sleep diary. Sessions 7 and 8 are follow-up sessions at the 1 and 3 month marks respectively. Therefore, after the introduction of the sleep diary there are 6 intervention sessions delivered weekly at Maastricht UMC+. Added to treatment as usual are the tinnitus daily diary and other assessments (i.e. ESIT-SQ, FTQ, TCS, HUI-3; see section 8.1) at T0 (screening/pre-treatment), T1 (end of session 6), T2 (1 month follow-up), and T3 (3 month follow-up).

Data collection starts immediately after Session 0. An internet-based application purposely build for single-case experiments (https:tamalkd.shinyapps.io/scda/ - developed by the Methodology of Educational Sciences Research Group and Health Psychology Research Group at KU Leuven) will randomly generate a start date for phase B. The recommended minimum number of measurement points required for a stable baseline varies and primarily depends on the level of variability in the dependent variable. As a minimum it is considered that at least five data points are necessary (Kratochwill et al., 2013) and therefore, randomization of treatment start will take place between 5 and 33 days after Session 0. The study follows a regulated randomization (Koehler & Levin, 1998) where each participant is randomized into a schedule that has the treatment start also randomized, increasing the possible number of combinations and thus, increasing power. Daily data gathering halts at the last follow-up meeting together with all final data points obtained at session 8 (the 3-month follow-up as stablished by the CBTi protocol).

The sleep diary embedded into the CBTi protocol strongly favours the single-case methodology through its sensitivity to therapy related changes and by its daily schedule of data gathering. A tinnitus diary is added in order to capture any daily changes in tinnitus experience. Therefore, detailed assessments on sleep and tinnitus experience are collected daily during phase A, B and A`.

Intervention

The treatment as usual relies on the CBTi protocol (Dutch: *Behandeling van langdurige slapeloosheid*; Verbeek & van de Laar, 2015), which contains 9 sessions carried out by a trained therapist at Maastricht UMC+. Added to the treatment as usual assessments (i.e. sleep diary, TQ, ISI, DBAS, TFI, and HADS) are the tinnitus diary and questionnaires (i.e. ESIT-SQ, FTQ, TCS, HUI-3) at T0 (screening/pre-treatment), T1 (end of session 6), T2 (1 month follow-up), and T3 (3 month follow-up). A brief summary of the sessions* aims follows:
1. Session 0: Sleep anamneses.
Exploration and discussion of sleep history and introduction to the sleep and tinnitus diary as well as assessments (added to treatment as usual).
2. Session 1: Information and sleep hygiene.
Explanation of sleep hygiene and insomnia model (psycho-educational session)
3. Session 2: Sleeping behavior and break moments.
Introduction of two interventions/techniques for insomnia.
4. Session 3: Relaxation and cognitive therapy.
Introduction to relaxation (Jacobson*s technique) and cognitive therapy (i.e. the role of automatic thoughts).
5. Session 4: Working with automatic thoughts.
Carrying out relaxation exercises as well as discussing other techniques (e.g. sleep restriction). The session focuses on challenging automatic thoughts.
6. Session 5: Cognitive therapy (continuation).
Further development of cognitive therapy techniques (e.g. sleep restriction).
7. Session 6: Evaluation.
Discussion of which methods are beneficial to the patient. Administration of assessments (i.e. FTQ, TCS, HUI-3, TQ, ISI, DBAS, TFI, and HADS) added to treatment as usual.
8. Session 7: 1 month follow-up.
Discussion of if sleeping behavior has improved or been maintained. Administration of assessments (i.e. FTQ, TCS, HUI-3, TQ, ISI, DBAS, TFI, and HADS) added to treatment as usual.
9. Session 8:
End of treatment and possible scheduling of booster session or further referral. Administration of assessments (i.e. FTQ, TCS, HUI-3, TQ, ISI, DBAS, TFI, and HADS) added to treatment as usual.

Study burden and risks

There are minimal risks, discomfort and burden associated with the study. Previous CBTi research has demonstrated improvement in sleep as well as comorbidities (e.g. anxiety, depression) with no additional risks to the individual. The sleep diary is a short assessment instrument (under 5-min completion time), which is already an integral part of the clinical treatment. The added tinnitus diary (also under 5-min completion time) does not significantly increase burden. Beyond the regular clinical treatment appointments, participants are not required to stay longer than necessary, neither to make extra visits to the centre.

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:
- Be primarily seeking treatment/help for difficulties caused by tinnitus.
- Additionally complaints of sleep disturbance (e.g. insomnia).
- Recommended to start CBTi protocol.
- Be at least 18 years of age.
- Have at least a score of 47 in the Tinnitus Questionnaire
- Have at least a score of 10 on the Insomnia Severity Index

Exclusion criteria

- Any person who discloses current suicidal intent.
- Severe anxiety or depression (as measured by having at least a score of 14 on 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
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-01-2021
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-06-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 24403
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL68941.068.19
OMON	NL-OMON24403

Study results

Date completed: 11-04-2024

Summary results
Trial ended prematurely