CBT for tinnitus related insomnia

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24403

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Chronic Tinnitus

Ondersteuning

Primaire sponsor: Maastricht University Faculty of Psychology and Neuroscience
Overige ondersteuning: European Union’s Horizon 2020 research and innovation programme under Marie Sklodowska-Curie grant agreement number 722046

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sleep quality as measured by the sleep diary

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Cognitive Behavior Therapy for Insomnia (CBTi)

Contactpersonen

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Deelname eisen

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:
- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2019
Aantal proefpersonen:	6
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49401
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten