Components analysis of stepped-care CBT for tinnitus

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To explore the positive, negative or lack of effect that these components have (isolated and combined) on tinnitus disability.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21248

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Chronic tinnitus

Ondersteuning

Primaire sponsor: Maastricht University Faculty of Psychology and Neuroscience
Overige ondersteuning: SWOL Limburgs Fonds voor Revalidatie and Netherlands Organisation for Health Research and Development (ZonMW), Netherlands. Research programme: Health Care Efficiency, Subprogramme: Effects & Costs, Grant number: 945-07-715.
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tinnitus disability as measured through daily diaries and ecological momentary assessments.

Toelichting onderzoek

Achtergrond van het onderzoek

Specialised cognitive behavioural therapy (CBT) for tinnitus is a complex intervention comprised of many components. Recent research has demonstrated that it is effective in significantly reducing the impact tinnitus has in daily life for people suffering from it. What is unknown is the impact that the respective components have on reducing distress and interference in daily activities. In this project, comprised of three studies, components of specialised CBT for tinnitus (e.g. audiological and psychological assessment, education, relaxation, exposure and group effects) will be closely examined to reveal what role they play in facilitating change in patients' thoughts, emotions and behaviours. In this particular study, exposure and relaxation components are isolated to assess the positive, negative or lack of effect that these components have on tinnitus disability.

Doel van het onderzoek

To explore the positive, negative or lack of effect that these components have (isolated and combined) on tinnitus disability.

Onderzoeksopzet

From inclusion to 3 month follow-up assessment.

Onderzoeksproduct en/of interventie

Exposure and relaxation protocols of the established CBT for Tinnitus intervention.

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 person must meet all of the following criteria. That is they must:
• Be primarily seeking treatment/help for difficulties caused by subjective tinnitus
• Be at least 18 years of age
• Have at least moderate tinnitus related distress (i.e. TQ score > 30)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential participant who meets any of the following criteria will be excluded from participation in this study:
• Severe depression or anxiety as measured by Dutch version of DASS-21.
• Any person who discloses current suicidal intent.
• Currently or undertaken any treatment for tinnitus (e.g. CBT, tinnitus retraining therapy) within the previous 5 years (including the aforementioned RCT)
• Potential participant has 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.
• Currently receiving psychological or any other kind of therapy addressing psychological, social, emotional, and or behavioural problems

• Unable to read and write fluently in Dutch
• Commenced the use of a hearing aid in the previous 3 months
• Has hearing loss greater than 40dB in one or both ears
• Having previously participated in a study from this project.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	26-05-2019
Aantal proefpersonen:	6
Type:	Werkelijke 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: 46739

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7826
CCMO	NL63262.015.18
OMON	NL-OMON46739

Resultaten