Components analysis of stepped-care CBT for tinnitus

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21248

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: 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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Adelante, Centre of Expertise in Rehabilitation and Audiology
NWO Veni grant number 016.165.105.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Tinnitus Functional Inventory (TFI)

Study description

Background summary

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.

Study objective

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

Study design

From inclusion to 3 month follow-up assessment.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-05-2019
Enrollment:	6
Type:	Actual

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: 46739
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

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

Study results