# A treatment components analysis of a stepped-care, CBT based treatment for adults with tinnitus: a replicated single-case experimental approach

Published: 04-12-2018
Last updated: 19-03-2025

Primary Objective: To investigate, in a series of studies, what effect the elements of CBT for tinnitus have on tinnitus distress. Study 1: The objective of study 1 is to examine the effects of audiological assessment, psychological assessment and a…

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Hearing disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON46739

**Source**
ToetsingOnline

**Brief title**
Components analysis of stepped-care CBT for tinnitus

### Condition

- Hearing disorders

**Synonym**
Tinnitus: ringing of the ears

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** SWOL Limburg Fonds voor Revalidatie;Veni Grant;Marie Curie;Adelante Centre for Expertise in Rehabilitation & Audiology(see document C1.)

## Intervention

**Keyword:** CBT, Tinnitus

## Outcome measures

### Primary outcome

The primary study endpoints will include measures related to cognitive, emotional and behavioural responses to living with tinnitus. For example, ratings of annoyance, depression, anxiety, stress, fear related cognitions about tinnitus, catastrophizing about living with tinnitus, acceptance of tinnitus, and quality of life. This data will be collected on a daily basis via the smartphone app. See document C1 for details.

### Secondary outcome

The secondary study outcome is the Tinnitus Functional Inventory (TFI; Meikle et al., 2012) which is a measure of the level of interference tinnitus causes in a person*s daily activities. It has been assessed and recommended as being a suitable outcome measure for tinnitus related treatments and is responsive to change (Fackrell, Hall, Barry, & Hoare, 2014).

# 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). Tinnitus sufferers typically experience severe distress and disturbances in many aspects of daily life (Davis & Refaie, 2000; Tyler & Baker, 1983). Consensus has not been reached on the exact physiological mechanisms causing tinnitus (Baguley et al., 2013)

Currently, a cognitive and behavioural theoretical framework is used to understand how tinnitus negatively impacts on peoples* lives. It also provides the foundation on which psychological strategies for management and treatment of tinnitus related distress are built. In particular, the Fear Avoidance Model (FA; Lethem, Slade, Troup, & Bentley, 1983; Vlaeyen, Crombez, & Linton, 2016; Vlaeyen & Linton, 2000, 2012) and the Neurophysiological (NP; Jastreboff & Hazell, 1993; Jastreboff, Hazell, & Graham, 1994), are used to explain emotional and behavioural responses to tinnitus. The principles and techniques of cognitive behavioural therapy (CBT; Beck, 1979; Clark & Fairburn, 1997; Ellis & Grieger, 1986) are used as a basis for the psychological treatment of tinnitus related distress and address the cognitive (e.g. catastrophising about the meaning of tinnitus), emotional (e.g. fear, anxiety, depression) and behavioural (e.g. avoidance) effects of the condition.

A recent high quality randomised controlled trial (RCT) found that a combined psychological and audiological treatment using a stepped-care approach was highly effective at reducing psychological distress and improving quality of life (Cima et al., 2012). Those with relatively mild levels of tinnitus related distress only received Step 1, while those with higher levels of distress and impairment received an additional and more intense level of treatment (i.e. Step 2). While the intervention is highly effective as a whole, further research is required to discover what elements of it are most effective.

**Study objective**

Primary Objective: To investigate, in a series of studies, what effect the elements of CBT for tinnitus have on tinnitus distress.

Study 1: The objective of study 1 is to examine the effects of audiological assessment, psychological assessment and a tinnitus related information session and whether the order in which they are delivered makes a difference.

Study 2: The objective of study 2 is to examine the effects of receiving treatment individually compared with in a group setting.

Study 3: The objective of study 3 is to study the effectiveness of exposure to tinnitus and a relaxation exercise.

Secondary Objective: To examine whether there are differences/benefits between daily diary compared with Ecological Momentary Assessment (EMA) methods with

regard to predicting and measuring responses to treatment.

## Study design

The three studies will use a single-case experimental design. The single case experimental design (SCED; also known as n = 1 design) is a method in which intervention components can be examined, and is particularly useful in studying interventions with large effect sizes (Baer, 1977) such as that reported in the RCT of specialised CBT for tinnitus (Cima et al., 2012).

Part 1 - Examining Step 1 of Specialised Care
Study 1 will use an ABCD design, where A = a no intervention phase, B = audiological assessment, C = tinnitus information session, and D = psychological assessment. The order of components B, C and D will be varied as described above. These elements make up Step 1 of specialised CBT for tinnitus.

Patients will be actively involved in this study 7 weeks and then for one day at three months follow-up (from the date of the end of treatment).

Part 2: Examining Step 2 of Specialised Care
Study 2 will use an ABACA design, where A = no intervention phase, B = individual intervention, and C = group intervention. The order of components B and C will be changed.

Patients will be actively involved in this study 12 weeks and then for one day at three months follow-up (from the date of the end of treatment).

Study 3 will use an ABCD design, where A = a no intervention phase, B = exposure sessions, C = relaxation exercises, D = exposure and relaxation sessions combined. The order of components B, C and D will be switched as described above.

Patients will be actively involved in this study 12 weeks and then for one day at three months follow-up (from the date of the end of treatment).

## Intervention

Specialised stepped-care CBT for tinnitus.

## Study burden and risks

The burdens and risks associated with participation in this study are non-existent. The study-specific unique additional activity we ask from participating patients is for them to respond to a set of brief questions 7 times per day about their current state (that is, ecological momentary assessment), and complete a daily-diary once per day during a pre- intervention

(baseline) period, the active treatment phase and a post intervention (post-test) period (that is a total of 12 weeks).

The use of ecological momentary assessment and daily diaries, and the strain it might pose on patients has been considered thoroughly and the effects are twofold: 1) it is possible that patients might feel inconvenienced at times due to the prompts to respond to the questionnaires, 2) on the other hand, patient-reports suggest that the actual activity of monitoring and describing their functioning by the end of the day has increased their learning-ability and increased insights in their own 'illness behaviour' favourably, which is especially helpful in these types of interventions.

The benefits for patients are:
1. Patients will be enrolled in treatment fairly quickly
2. Patients will receive continuous feedback on their progress.

# Contacts

**Public**
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229ER
NL
**Scientific**
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229ER
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

### Age

Adults (18-64 years)
Elderly (65 years and older)

### Inclusion criteria

• Be primarily seeking treatment/help for difficulties caused by subjective tinnitus
• Be at least 18 years of age
• Have moderate tinnitus related distress (i.e. TQ score > 30);Additional inclusion criteria specific to Study 2 and 3: Completed Step 1 of specialised care and eligible to continue with Step 2 of specialised care for tinnitus.

### Exclusion criteria

• 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 TRT, medication) 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 antidepessants, 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.;• Receiving psychological or any other kind of therapy addressing 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

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |

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| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 28-05-2019 |
| Enrollment: | 24 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 04-12-2018 |
| Application type: | First submission |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |

## 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: 21248
Source: Nationaal Trial Register
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL63262.015.18 |
| OMON | NL-OMON21248 |
| OMON | NL-OMON23156 |