

# The cost-effectiveness of multidisciplinary management of Tinnitus at a specialised Tinnitus Center.

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The main objective of this study proposal is to examine the effectiveness, costs, and cost-effectiveness of an integral treatment provided by a specialised tinnitus center.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Aural disorders NEC
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON31662

### Source

ToetsingOnline

### Brief title

Multidisciplinary tinnitus management and effectiveness

### Condition

- Aural disorders NEC
- Somatic symptom and related disorders

### Synonym

ringing of the ears, Tinnitus

### Research involving

Human

### Sponsors and support

**Primary sponsor:** SRL, Stichting Revalidatie Limburg

**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Cost-effectiveness, Randomised Clinical Trial, specialised treatment, Tinnitus

## Outcome measures

### Primary outcome

Quality of life

### Secondary outcome

Negative affect, severity of tinnitus, illness cognitions, fear of tinnitus, and costs.

## Study description

### Background summary

Tinnitus is the involuntary perception of the concept of a sound without the presence of an external source. Little is known about the pathophysiology and consequently few treatments are standardized or evaluated. In the Netherlands about 2 million persons experience tinnitus. In a minority (approximately 3%: ca. 60.000 individuals) it causes severe affective problems and a decrease in quality of life. The lack of correct information, appropriate guidance and multidisciplinary treatment creates undue frustration, anxiety and deterioration of the condition, which in turn leads to increased health services utilization and prolongation of the referral trajectory. Evidence suggests that an integral multidisciplinary approach in treating tinnitus is effective. The Tinnitus Center Limburg (TCL) founded within Hoensbroeck Audiological Center, offers evidence-based specialised integral tinnitus management programs, executed by several disciplines.

### Study objective

The main objective of this study proposal is to examine the effectiveness, costs, and cost-effectiveness of an integral treatment provided by a specialised tinnitus center.

### Study design

In a randomised controlled trial 394 tinnitus patients will be randomly assigned to a

specialised tinnitus care group or a usual care group. The duration of follow-up is 12 months. Inclusion: 18 years or older experiencing subjective tinnitus. Exclusion: Not able to read and/or write in the Dutch language.

## **Intervention**

Treatment is based on a stepped-care approach, tailored to individual patient needs, with key elements from cognitive behavioural therapy, education, relaxation techniques, attention diversion, exposure to daily live situations, and tinnitus retraining therapy.

## **Study burden and risks**

Burden or risk associated with participation is expected to be minimal. Subjects are asked to fill in a number of questionnaires, which are next to research purposes, necessary for treatmentdiagnostics, except for the cost-questionnaire.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Subjective tinnitus

### Exclusion criteria

Not able to read and/or write in Dutch

## Study design

### Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Health services research

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	394
Type:	Anticipated

## Ethics review

Approved WMO

Application type:

First submission

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

No registrations found.

### In other registers

**Register**

**ID**

CCMO

NL12965.022.06