Phase Out as a treatment for chronic untreatable Tinnitus

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The major aim of this study is changes in tinnitus loudness (daily report mark) and annoyance (daily report mark) and the duration of this change (time).

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31257

Source
ToetsingOnline

Brief title
Phase Out as a treatment for Tinnitus

Condition

- Other condition

Synonym
noise in the head, tinnitus

Health condition

tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Phase Out, tinnitus

Outcome measures

Primary outcome

The major aim of this study is changes in tinnitus loudness (daily report mark)

and annoyance (daily report mark) and the duration of this change (time).

Secondary outcome

Besides the mojor aims, different questionnaires will be used to determine for

which kind of tinnitus patients, this treatment is most effective (THI, TRQ,

VE, HADS, SF-36, Eysenck, type D personality, SSQ and TCSQ).

Study description

Background summary

Approximately 10-15% of the general population complains about tinnitus. In spite of the investigations of many years, little is known about the pathophysiology and the treatment of tinnitus. A new therapy was developed and called *Phase Out*. This therapy is based on the physical mechanism of sound. In physics, sound is a wave and can shift in phase over 360 degrees. The hypothesis is that, shifting phase provides a better residual inhibition. Following the hypothesis there is a better efficacy in comparison with placebo sound. This means that the intensity and frequency of tinnitus are decreased with the Phase Out treatment and effects will be sustained.

Study objective

The major aim of this study is changes in tinnitus loudness (daily report mark) and annoyance (daily report mark) and the duration of this change (time).

Study design

Prospective, double blind, randomized placebo controlled crossover trail.

Intervention

A subject will receive Phase Out treatment for thirty minutes three times a week for one week and placebo sound treatment on the same regime during another. One month interval is in between these two stets of treatment. If a treatment is started, the subject fills in a report mark on the *tinnitus loudness* and *tinnitus annoyance* in the tinnitus diary every evening till three weeks after the treatment session. One week after each week of therapy a subject receives the evaluating questionnaires and will sent them back after filling in.

Study burden and risks

The study will take 9 weeks and comprises 6 meetings. The patient selection will be done during the tinnitus consultation, which includes an interview and examination of the Ear-, Nose-, Throat (ENT) area, filling out questionnaires and audiologic examination. A participating subject will receive a week with Phase Out treatment (three treatments of thirty minutes) and a week with placebo sound (three treatments of thirty minutes), with an interval of one month. Placebo sound and Phase Out treatment gives a tone at tinnitus frequency and matches the tinnitusintensity by means of a headphone. The phase of the sound wave shifts every 30 seconds with 6 degrees. A subject will keep a tinnitus diary and fill in specific questionnaires one week after both intervention weeks to evaluate the changes. If the treatment is effective, the treated subjects and patients with the same complaints will benefit with Phase Out treatment. The headphone is uncomfortable with hearing aids, so subjects will be asked to remove the hearing aid during the treatment session. One patient is known with a temporarily tinnitus increasing during the treatment. The tinnitus normalized within a month after treatment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

subjects > 18 years
unilateral or bilateral tinnitus
predominant tone tinnitus by history
tinnitus for minimum of 3 months

Exclusion criteria

acoustic neurinoma
aortic/ outflow tract stenosis
pulsatile tinnitus
pregnancy
inability to correct use of test equipment: unable to cooperate during audiologic examination.
known tinnitus etiology, which would demand other treatment
Hearing loss greater than 60 decibel

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	phase shifting sound therapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ISRCTN	ISRCTN17631678
CCMO	NL16807.042.07