ISRCTN27770434 https://doi.org/10.1186/ISRCTN27770434

Normal hearing tinnitus sound therapy

Submission date	Recruitment status	[_] Prospectively registered
23/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2019	Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims
There are plenty of studies that investigate how relief sounds for tinnitus sound therapy work for patients with hearing loss. The purpose of this study is to see how sounds can be used effectively with normal-hearing patients, using the Tinnitus Retraining Therapy (TRT) treatment approach.

Who can participate?
Normal-hearing patients with tinnitus symptoms can participate if they are between age 18-75.

What does the study involve?
The study involves the patient coming to a tinnitus clinic and being fit with a set of hearing aids that have a built-in sound generator (combination device). Patients will all follow the TRT fitting and treatment protocol and they will be asked to fill out questionnaires at a 3-month and a 6-month visit. Patients will be fit using non-traditional relief sounds and the results will be compared to patients who have been fitted with white noise relief sound.

What are the possible benefits and risks of participating?
The benefit is the elimination or reduction of tinnitus symptoms in patients with normal hearing. The risk may possibly be prolonged exposure to loud sounds. Patients will be counseled on the safe use of devices and how to avoid excessive noise exposure during the study. The risk is minimal.

Where is the study run from?
Fondazione Ascolta e Vivi (Italy).

When is the study starting and how long is it expected to run for?
From May to December 2015.

Who is funding the study?
Oticon A/S in Denmark and the Oticon filial in Italy.

Who is the main contact?
Luca Del Bo

Contact information

Type(s)
Scientific

Contact name
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20123

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Normal hearing tinnitus sound therapy: an interventional single-centre study

Study objectives
The aim of this study is to investigate whether or not Tinnitus Retraining Therapy (TRT) using complex sounds such as red noise or pink noise or other sounds provided by the open ear hearing aids (Oticon Alta2 Pro Ti) can be equally or more effective in the rehabilitation of tinnitus than the classical white noise sound generator for a subgroup of patients with normal hearing up to at least 2 kHz.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fondazione Ascolta e vivi (FAEV) (Internal Scientific Board) – approval pending

Study design
Interventional single-centre study

Primary study design

Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Normal hearing persons with tinnitus symptoms

Interventions
The intervention is the type of tinnitus relief sound used in the treatment of tinnitus. In this study, the plan is to compare traditional white noise to non-traditional relief sounds (pink noise, red noise, nature sounds, modulated sounds). All sounds are integrated in a sound generator which is part of an Oticon Alta2 Pro Ti hearing aid.

Intervention Type
Device

Primary outcome measure
1. Demonstrate that the Oticon device is at least as effective as other combination/sound generator devices that are used currently
2. Demonstrate that the Oticon device is more effective than other combination/sound generator devices that are used currently

In other words, to understand what makes the Ti different (better?) in comparison with other devices.

Secondary outcome measures
New sounds: red or pink noise, modulated sounds, and/or ocean sounds are appreciated and preferred by patients

Overall study start date
01/05/2015

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Normal hearing or hearing loss not more than 25 dB between 250 Hz and 2 kHz
2. Minimum 6 months tinnitus (no upper limit)
3. Category 1 (Jastreboff & Hazell, 2004) patients with normal hearing and severe tinnitus

4. Age 18-75 years
5. Inclusion of mono or bilateral tinnitus and with moderate hyperacusis (up to 6 in VAS scale), exclusion of pathological severe anxiety and depression (THI >= 80)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
All tinnitus aetiology excluding: Meniere, middle-external ear desease, somatosensory tinnitus under physical therapy

Date of first enrolment
07/04/2015

Date of final enrolment
01/08/2015

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione Ascolta e Vivi
Italy
-

Sponsor information

Organisation

Oticon A/S

Sponsor details
Kongebakken 9
Smoerum
Denmark
2765

Sponsor type
Industry

ROR
https://ror.org/05mwsq745

Funder(s)

Funder type
Industry

Funder Name
Oticon A/S (Denmark)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2017	24/01/2019	Yes	No