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Notched music against total tinnitus

Submission date
13/06/2013

Recruitment status
No longer recruiting

Registration date
25/06/2013

Overall study status
Completed

Last Edited
21/03/2016

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tinnitus is defined as the perception of noise without an external source. About 10 - 15% of the general population suffers from this symptom/syndrome. Despite its high prevalence (percentage of a population affected with disease in a given time) , there is currently no effective standardized treatment for tinnitus. We developed a new treatment strategy, the tailor-made notched music training (TMNMT), to treat chronic tinnitus. In TMNMT the music is modified individually according to the patient's tinnitus frequency (the frequency which sounds like the tinnitus) by applying a filter which cancels out frequencies in the music corresponding to the tinnitus frequency. We hypothesize that this music modification results in an inhibition (blocks) of certain auditory neurons (nerve cells that process and transmit information through electrical and chemical signals) which are assumed to be involved in the tinnitus perception. This theory was strongly confirmed in two previous studies demonstrating that regular listening to tailor-made notched music reduces the tinnitus related cortical activity and perceived tinnitus loudness. The aim of this study is to transfer our previous results into clinical practice by investigating the treatment effect of TMNMT on a large number of tinnitus patients. Our data will verify more securely and reliably the effectiveness of this kind of completely non-invasive, and low-cost treatment on tonal tinnitus.

Who can participate?
Adult patients aged between 18 and 70 years with chronic tonal (i.e. peep- or whistle-like) tinnitus, and without severe hearing loss.

What does the study involve?
We will include 100 patients into the clinical trial and they will be randomly allocated to either a target or a control group. Participants in the target group will listen to tailor-made notched music, while the control group will receive placebo music. All participants will listen to the music (either tailor-made notched music or placebo) daily in a quiet environment through a supplied closed headphones with convenient loudness over the course of 3 months. Listening times and duration will be documented on a daily basis by a specially developed application.

What are the possible benefits and risks of participating?
The possible benefits of participating in the clinical trial are reductions in tinnitus loudness, and annoyance. There are no known risks, however, all participants in the trial are continuously monitored over the time of the trial.

Where is the study run from?
The study has been set up by the Interdisciplinary Center for Clinical Research (IZKF) of the Medical Faculty of the University of Münster, Germany.

When is the study starting and how long is it expected to run for?
The patient recruitment will be completed by end of June 2013 and the study is scheduled to run one year.

Who is funding the study?
Funding has been provided by Interdisciplinary Centre for Clinical Research Münster.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CRA05

Study information

Scientific Title
Münster tinnitus randomized controlled clinical trial-2013 based on Tailor-Made Notched Music Treatment (TMNMT)

Acronym
TMNMT

Study objectives
The null hypothesis of our clinical trial is that there will be no statistical significant difference between the target and placebo groups after TMNMT.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Association of Westphalia-Lippe and the Medical Faculty of the University of Münster, 03/05/2011, Ref: 2011-109-fs

Study design
Parallel-group double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Optimal individual matching of the TMNMT profile

Interventions
The choice of the intervention we are going to apply is based on two 'proof of concept' studies in humans and on a recent animal study.
Patients are randomised to two groups:
1. Target condition:
In the target condition, the frequency band centered at the individual tinnitus frequency of each tinnitus patient is removed from the music energy spectrum. The music that is delivered to both ears simultaneously is modified identically. The patients listen to their individually modified treatment music daily in a quiet environment via supplied closed headphones (model: Sennheiser HD 201) with convenient loudness over the course of 3 months. Listening times and duration are documented on a daily basis by a specially developed iOS application. The derived data are sent to the tinnitus research team as an email attachment.
2. Control (placebo) condition:
In the placebo condition, a moving notch filter having the same bandwidth as in the target condition but omitting the tinnitus frequency region is applied. The moving filter randomly chooses a frequency band outside of the tinnitus frequency region. After 5 seconds of filtering, the center frequency of the filter randomly jumps either 1/18 octave up or down and continues jumping in the same direction every 5 seconds until its lower or higher edge reaches a predefined border, at which point it changes direction.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Visual Analogue Scale (VAS) total score (loudness, annoyance, awareness, and tinnitus handicap)
2. Tinnitus Handicap Questionnaire (THQ) (total score)

These outcomes are measured after participants education and final pitch match, after three months of training and after one month follow-up.

Key secondary outcome(s))
1. Tinnitus Handicap Inventory (THI) score
2. Subscales THQ
3. Tinnitus Questionnaire (TQ)
4. VAS subscales

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Adult patients with chronic (≥ 3 months) tonal (i.e. peep- or whistle-like) tinnitus, and without severe hearing loss (≤ 65 dB HL) in the frequency ranges of one half octave above and below the tinnitus frequency.
2. Aged between 18 and 70 years
3. Written informed consent to participate in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Tinnitus patients who do not have severe neurological or psychiatric disorders (e.g. amnesia, dementia, depression, epilepsy, etc) that could limit their capability or result in major difficulties regarding the patients' motivational compliance or limit their ability to follow instructions or to participate in the training.
2. Planned start of other rehabilitation therapies that might interfere with this trial, or participation in another clinical trial, or insufficient motivation to participate.

Date of first enrolment
01/07/2013

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Germany

Study participating centre
IBB, Malmedyweg 15
Münster
Germany
48149

Sponsor information

Organisation
University of Münster (Germany)

ROR
https://ror.org/00pd74e08

Funder(s)

Funder type
University/education

Funder Name
Interdisciplinary Centre for Clinical Research Münster (IZKF) (Germany) ref: CRA 05

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/03/2016		Yes	No
Protocol article	protocol	02/03/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes