

Use-induced reorganisation of the central auditory system in tinnitus

Submission date 11/01/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/01/2021	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Thomas Elbert

Contact details
Department of Psychology
University of Konstanz
P.O. Box D25
Konstanz
Germany
78434
+49 (0)7531 883363
Thomas.Elbert@uni-konstanz.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DFG/EL 101/20

Study information

Scientific Title

Use-induced reorganisation of the central auditory system in tinnitus

Acronym

Tinnitus training

Study objectives

Chronic subjective tinnitus is the perception of a (usually high-frequency) sound in the absence of an objective physical source. Up to now, there is no generally accepted view how these phantom sounds come about, and also no cure. A broadly accepted view states that this symptom is not only reflected but caused by changes in the central nervous system. Based on a recent study (Weisz et al), we argue that tinnitus is related to changes in spontaneous activity patterns, that is an Alpha reduction and Delta enhancement (A/D) over temporal regions.

The enhancement of the A/D ratio, respectively the delta band - by means of several neurofeedback training protocols - results in ameliorations of the psychoacoustical (perceived loudness) and psychological (subjective distress) tinnitus variables.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics information provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Chronic subjective tinnitus

Interventions

In this trial we will investigate how different neurofeedback protocols affect distress variables and psychoacoustic measures. One group has to enhance alpha and reduce delta, the other group will only reduce delta. The neurofeedback training consists of ten sessions over three or four weeks.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Measured quantity of alpha and delta band frequency ranges (e.g. the alpha/delta ratio, or the delta band only) in the Electroencephalogram (EEG)

Secondary outcome measures

1. Perceived loudness of the tinnitus (matched to a 1 kHz pure tone)
2. Tinnitus related distress (operationalised with a standard German questionnaire, Goebel et al., 1998)

Overall study start date

01/06/2004

Completion date

30/04/2006

Eligibility**Key inclusion criteria**

Two groups consisting of ten tinnitus sufferers each will be treated with a neurofeedback training. Any tinnitus sufferer can participate with no need to exclude subjects.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

20

Total final enrolment

21

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/06/2004

Date of final enrolment

30/04/2006

Locations

Countries of recruitment

Germany

Study participating centre**Department of Psychology**

Konstanz

Germany

78434

Sponsor information

Organisation

German Research Foundation (Deutsche Forschungsgemeinschaft) (Germany)

Sponsor details

Kennedyallee 40

Bonn

Germany

53170

+49 (0)228 8851

postmaster@dfg.de

Sponsor type

Research organisation

ROR

<https://ror.org/018mejw64>

Funder(s)

Funder type

Research organisation

Funder Name

German Research Foundation (Deutsche Forschungsgemeinschaft) (Germany)

Funder Name

Eldith (Electro-Diagnostic & Therapeutic Systems GmbH, Ilmenau, Germany) lends a neurofeedback system (NEUROPRAX)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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	01/02/2007	12/01/2021	Yes	No