Use-induced reorganisation of the central auditory system in tinnitus

Submission date	Recruitment status No longer recruiting	Prospectively registered		
11/01/2005		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
04/04/2005		[X] Results		
Last Edited	Condition category	[] Individual participant data		
12/01/2021	Ear, Nose and Throat			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s))

- 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)

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

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

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