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Use-induced reorganisation of the central auditory system in tinnitus

Submission date	Recruitment status	[_] Prospectively registered
11/01/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/04/2005	Completed	[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

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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
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Sponsor information

Organisation
German Research Foundation (Deutsche Forschungsgemeinschaft) (Germany)

Sponsor details
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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