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Subjective and objective evaluation of acoustic therapies for tinnitus patients

Submission date
24/10/2017

Recruitment status
No longer recruiting

Registration date
31/10/2017

Overall study status
Completed

Last Edited
18/07/2022

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
A large number of acoustic therapies (sound therapy) are used to treat tinnitus (a condition where a person hears sounds that come from inside the body). At present, the only way to evaluate acoustic therapies is by means of subjective methods such as analog visual scale and questionnaires. This study, consequently, seeks to establish an objective methodology to treat tinnitus with acoustic therapies based on electroencephalographic (EEG) activity recordings (the recordings of the electrical activity in the brain). The aim of this study is to examine how acoustic therapies can improve the quality of life and is there is way to correlate the objective and subjective data from patients EEGs and questionnaires.

Who can participate?
Patients aged 18 with tinnitus.

What does the study involve?
Participants are randomly allocated to one of five groups. There are four acoustic therapy groups and one control group. Participants in the acoustic therapy groups, each group using different acoustics and effects, undergo EEG recordings at the beginning of the treatment, one week of treatment, five weeks of treatment and at eight weeks of treatment. Those in the control group listen to relaxing music and do not receive any acoustic therapy. Participants are assessed for their effectiveness of the treatments.

What are the possible benefits and risks of participating?
Participants may benefit from decreases in their tinnitus symptoms. There are no expected risks however it could increase the tinnitus symptoms.

Where is the study run from?
Tecnológico de Monterrey (Mexico)

When is the study starting and how long is it expected to run for?
June 2016 to December 2017

Who is funding the study?
Tecnológico de Monterrey (Mexico)

Who is the main contact?
Dr Luz María Alonso Valerdi

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CONBIOETICA19CEI00820130520

Study information

Scientific Title
Electroencephalographic evaluation of acoustic therapies for the treatment of chronic and refractory tinnitus

Study objectives
Research questions:
1. How can acoustic therapies improve the quality of patients life?
2. How can we correlate objective and subjective data from patients EEG and questionnaires?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee of Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey, 20/06/2016, ref: COFEPRIS register number 13CEI19039139
2. Research Committee of Escuela de Medicina del Instituto Tecnológico y de Estudios Superiores de Monterrey with the National Commission of Bioethics register number, 20/06/2016, refs: COFEPRIS register number 13CI19039138 and CONBIOETICA19CEI00820130520

Study design

Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic and refractory tinnitus

Interventions
Participants are randomly allocated to one of five different acoustic therapies (control and 4 other standard ones).

The acoustic therapies used in the study are the ones found up to now as the most effective. These are tinnitus retraining therapy, auditory discrimination therapy, tinnitus retraining therapy, therapy for enriched acoustic environment, and binaural. All of them are acoustically different and reach different effects. For example, binaural therapy attempts to reduce the stress level and thereby to reduce the tinnitus perception. Auditory discrimination therapy attempts to redirect the patient attention towards therapy instead to tinnitus, and thus diminishing the mental resources used to perceive tinnitus.

The control therapy includes relaxing music instead of any acoustic therapy. It is used as reference to compare the other acoustic therapies.

All participants are made aware of the procedure and signed a consent form. Acoustic therapies are personalized for each patient and their head physician followed-up the experiment. Participants are instructed to use their therapies every day for one hour, at any time of the day. Assistance during the experiment are provided.

In 1st step, evoked activity are considered (EEG data recorded in passive mode) since auditory ERPs have been formerly investigated in patients with tinnitus, as well as in those with tinnitus treated with acoustic therapies. For each experimental session in passive mode, patients will be asked to close their eyes, relax and pay attention to their stimulus. All the stimuli are 1 second long, repeated 50 times, and have an inter-stimulus interval of 2.5 seconds.

In the 2nd step of the same session, active mode is recorded. A usual acoustic environment are played, whilst five associated auditory stimuli are randomly played. Participants are instructed to identify the randomized stimuli by pressing a keyboard button. The three acoustic environments along with their related stimuli in each session are standardised to 1 second and repeated 50 times at a random rate.

In total, four sessions are recorded: at the beginning of the experiment, at one week of treatment, at five weeks of treatment, and at eight weeks of treatment.

To record the data, 17 EEG channels are recorded at 256Hz by using the g.USBamp (g.tec medical enginnering, Austria).

Intervention Type
Other

Primary outcome(s)
Effectiveness of each therapy is assessed using the EEG registration at the beginning of the procedure, one week after beginning, five weeks after beginning, and eight weeks

Key secondary outcome(s))
State and therapy effectiveness is measured using validated patient questionnaires at week one, week five and week eight

Completion date
31/07/2019

Eligibility

Key inclusion criteria
1. Patients adults (>18 years old)
2. Accept voluntarily to participate in the project
3. Sign a consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
102

Key exclusion criteria
1. Without any history of otitis
2. Cerebellopontine angle tumours
3. Psychiatrist pathologies
4. Demyelinating diseases of the nervous system
5. Epilepsy

Date of first enrolment
01/07/2017

Date of final enrolment
20/11/2017

Locations

Countries of recruitment
Mexico

Study participating centre
Tecnologico de Monterrey
Av. Eugenio Garza Sada 2501 Col. Tecnologico Sur
Monterrey
Mexico
64849

Study participating centre
Instituto Nacional de Rehabilitación (INR)
Calzada México Xochimilco No. 289
Colonia Arenal de Guadalupe
Alcaldía Tlalpan
Mexico City
Mexico
14389

Sponsor information

Organisation
Tecnológico de Monterrey

ROR
https://ror.org/03ayjn504

Funder(s)

Funder type
Government

Funder Name
Instituto Tecnológico y de Estudios Superiores de Monterrey

Alternative Name(s)
Tecnológico de Monterrey, Tec de Monterrey, Monterrey Institute of Technology, Monterrey Institute of Technology and Higher Education, ITESM, Tec

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Mexico

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date. Once we have completed our registrations (possibly by the end of this year) and we have published our first results (possibly by June 2018), we'll share our databases.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2022	18/07/2022	Yes	No
Results article		26/01/2022	18/07/2022	Yes	No
Results article		01/01/2022	18/07/2022	Yes	No
Results article		01/11/2021	18/07/2022	Yes	No
Protocol article	protocol	28/11/2017		Yes	No
Basic results		30/09/2019	30/09/2019	No	No
Participant information sheet			18/07/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes