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Can music at a frequency of 432 Hz reduce dental anxiety in patients undergoing tooth extraction?

Submission date
11/12/2018

Recruitment status
No longer recruiting

Registration date
23/01/2019

Overall study status
Completed

Last Edited
10/09/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
It has been observed that music therapy allows controlling the clinical levels of anxiety of patients undergoing several treatments. However, there is still controversy regarding the effects of music at a frequency of 432 Hz, and the real difference discernible with the music at 440 Hz.
The aim of this study is to compare the effects of music at 432 Hz on the clinical perception of anxiety and levels and salivary cortisol in patients undergoing a surgical procedure like a tooth extraction.

Who can participate?
Patients over the age of 15 to 3 5who attend the Austral University of Chile dental service.

What does the study involve?
Participants are asked to join this study while they are at the Austral University of Chile dental clinics. Participants must score 9 or higher in MDAS anxiety score. Participants are randomly allocated to one of three groups (432 Hz, 440Hz or control), and they will be exposed to relaxing piano music (Giorgio Constantini album "Dreamers") 432 Hz or 440 Hz, during 15 minutes. Saliva samples are taken before and after the music stimulation, participants also complete the anxiety questionnaires after the music stimulation.

Where is the study run from?
At the Dental clinics of the Austral University of Chile, Valdivia.

When is the study starting and how long is it expected to run for?
January 2019 to March 2019

Who is funding the study?
Austral University of Chile, Valdivia, Chile.

Who is the main contact?
Dr. Pedro Aravena
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
195/2018

Study information

Scientific Title
Effect of music at 432 Hz in dental anxiety and salivary cortisol levels in patients undergoing tooth extraction. A randomized clinical trial.

Acronym
N/A

Study objectives
Musical stimulation at a frequency of 432 Hz is more effective in decreasing salivary cortisol levels and dental anxiety compared to music at a frequency of 440 Hz in patients undergoing tooth extraction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Scientific Ethics Committee of the Valdivia Health Service in Chile, 05/07/2018, ref. 95/2018.

Study design
Interventional, randomised parallel clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Dental anxiety

Interventions
The study will consist of three arms, the participants of the three groups will be randomized by a simple randomization using an online randomizer. All the participants will be intervened once, when they come to the clinics for a tooth extraction. Each participant before the tooth extraction will answer the CORAH MDAS anxiety scale, and those who obtain a score of 9 or above will apply. A saliva sample will be collected from each participant before the intervention. The first group will receive music (Giorgio Constantini “Dreamers”) at a frequency of 432 Hz during 15 minutes with headphones at a moderate volume, then a second saliva sample will be taken and he will answer the anxiety questionary again. The second group will receive music (Giorgio Constantini “Dreamers”) at a frequency of 440 Hz during 15 minutes with headphones at a moderate volume, then a second saliva sample will be taken and he will answer the anxiety questionary again. The third group will not be exposed to music, patients will be set in the dental unit during 15 minutes after the first saliva sample, then a second saliva sample will be taken and he will answer the anxiety questionary again. Then the profesional will proceed with the tooth extraction as normal.

Intervention Type
Other

Primary outcome measure
1. Dental anxiety will be measured using the CORAH- MDAS questionnaire before and after music stimulation.
2. Salivary Cortisol will be measured using 3 ml of unstimulated saliva before and after music stimulation.
2.1. Saliva samples will be transported under refrigeration conditions and then frozen at -20 ºC

until laboratory analysis.
2.2. For statistical analysis, the amount of saliva secreted will be expressed in mL / min and cortisol expressed in ug / dl.

Secondary outcome measures
N/A

Overall study start date
01/04/2018

Completion date
01/03/2019

Eligibility

Key inclusion criteria
1. A Modified Dental Anxiety Scale in Spanish (MDAS) score greater > 9 points
2. 15 to 30 years of age
3. ASA I
4. Requiring simple tooth extraction.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25 patients

Total final enrolment
42

Key exclusion criteria
1. Suffering from systemic diseases
1.1. Diabetes
1.2. Immunosuppression
1.3. Hypertension
1.4. Thyroid pathology
1.5. Heart disease
1.6. Alcoholism
1.7. Pheochromocytoma
1.8. Cushing's syndrome
2. Heavy smokers (consumption of > 10 cigarettes a day)
3. Receiving permanent pharmacological treatment
3.1. Tricyclic antidepressants,
3.2. Anticholinergics

3.3. Benzodiazepines
3.4. Antihypertensives
3.5. Diuretics
3.6. Phenothiazines
3.7. Narcotics
3.8. Synthetic glucocorticoids (prednisone and prednisolone)
3.9. Phenytoin
4. Pregnant women
5. Pericoronitis or infection at the time of surgery or 10 days before surgery.

Date of first enrolment
01/01/2019

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
Chile

Study participating centre
Austral University of Chile Dental Clinics
Rudloff 1640, Valdivia, Chile.
Valdivia
Chile
5111710

Sponsor information

Organisation
Universidad Austral de Chile

Sponsor details
Campus Isla Teja S/N. Valdivia. Chile.
Valdivia
Chile
5111434

Sponsor type
University/education

ROR
https://ror.org/029ycp228

Funder(s)

Funder type
University/education

Funder Name
Universidad Austral de Chile

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/04/2019

Individual participant data (IPD) sharing plan
Data will be shared on OSF https://osf.io/ya3dx from 05/04/2019. Data will be exported in CVS anonimized by R package Anonimizer and will not have restriction for access by a GNU General Public License (GPL) 3.0.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/05/2020	10/09/2021	Yes	No