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Measuring the anxiety-reducing effects of Tibetan singing bowls

Submission date	Recruitment status	[ ] Prospectively registered
01/02/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/02/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/02/2022	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Anxiety is one of the major topics in mental health, representing a relevant societal problem. Although significant advances have been made, anxiety continues to be a major challenge and innovative approaches are still required. Preventive treatments are gaining significant relevance due to their effectiveness, suggesting that anxiety prevention programs should be further developed. The main aim of this study is to compare the magnitude of the relaxation response caused by a new sound-based treatment (Tibetan Singing Bowls [TBS]) against the well-validated Jacobson's progressive muscle relaxation (PMR) and a control waiting list (CWL) group.

Who can participate?
People aged over 18 and under 60 years old with non-clinical anxiety

What does the study involve?
Participants will be randomly allocated to either Tibetan singing bowl treatment (TSB), progressive muscle relaxation (PMR) or a control waiting list (CWL).
Tibetan singing bowl treatment is provided live by an expert in a 30-min session. Four TSBs are used and participants are asked to sit in a comfortable armchair with their eyes closed while TSB sounds are smoothly provided. Heart rate and brain activity are continuously recorded.
In the PMR group instructions are provided using professional audio and speakers. A PMR 30-min session consists of tensing and relaxing groups of muscles in a bottom-up direction (feet, legs, chest, shoulders, arms, neck and face) following the instructions of the audio. Participants are asked to sit in a comfortable armchair with their eyes closed while following the instructions
Participants in the CWL group are asked to sit in a comfortable armchair with their eyes closed for 30 min. No treatment is delivered. After the session is over, participants in the CWL group choose between PMR or TSB treatment, which is provided on another day.

What are the possible benefits and risks of participating?
There is no risk in participating in this study. Participants will receive a treatment that should elicit a relaxation response, which might be of benefit to anyone.

Where is the study run from?
Austral University of Chile (Chile)

When is the study starting and how long is it expected to run for?
June 2019 to October 2024

Who is funding the study?
National Fund for Scientific and Technological Development (Chile)

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
Fondecyt 11190240

Study information

Scientific Title
Preventing effects of the relaxation response induced by a sound-based treatment in human anxiety: physiological, electroencephalographic and psychological outcomes

Study objectives
Tibetan singing bowls (TSB) induce a more evident relaxation response in comparison with Jacobson's progressive muscle relaxation. Specifically, TSB should induce increases in heart rate variability, reductions in the alpha band (EEG) and reductions in self-report anxiety questionnaires in a more evident manner in comparison with Jacobson's progressive muscle relaxation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/11/2019, Ethical Committee of Bioethics on Human Research of the Austral University of Chile (Campus Isla Teja s/n, Valdivia, Region de Los Ríos, Chile; +56 (0)632444314 Anexo (4314); comiteeticocientifico@uach.cl), ref: 0041/19

Primary study design
Interventional

Study design
Single-blind prospective randomized control trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of anxiety

Interventions
Participants will be randomly assigned to either Tibetan singing bowl (TSB), progressive muscle relaxation (PMR) or control waiting list (CWL). The experimental session consists of a 30-min session in which heart rate variability (HRV) recorded with a Polar Q10 device, EEG recorded with the Emotiv device and pre/post self-report anxiety will be measured. Participants allocated to the CWL are able to choose PMR or TSB once their experimental session is over.

TSB methodology:
TSB is provided live by an expert in a 30-min session. Four TSB are used and participants are asked to sit in a comfortable armchair with their eyes closed while TSB sounds are smoothly provided. During the TSB session, EEG and HRV parameters are continuously recorded.

PMR methodology:
PMR instructions are provided using professional audio and Bose soundlink speakers. A PMR 30-min session consists of tensing and relaxing groups of muscles in a bottom-up direction (feet, legs, chest, shoulders, arms, neck and face) following the instructions of the audio. Participants are asked to sit in a comfortable armchair with their eyes closed while following the instructions

CWL:
Participants in the CWL group are asked to sit in a comfortable armchair with their eyes closed for 30 min. No treatment is delivered. After the session is over, participants in the CWL group choose between PMR or TSB treatment, which is provided on another day.

Intervention Type
Behavioural

Primary outcome(s)
Self-reported anxiety measured with the Spielberger State Anxiety Inventory (SAI) pre-experiment (SAI-1; 24 h before the experimental session) and post-experiment (SAI-2; immediately after the experimental session is over)

Key secondary outcome(s)
1. Spectral power of theta, alpha and beta neuroelectric bands measured using Emotiv Epoc Flex gel-based sensors at T1 (baseline), T2 (10 min), T3 (20 min) and T4 (30 min)
2. Heart rate variability (HRV) recorded using a Polar Q10 device at T1 (baseline), T2 (10 min), T3 (20 min) and T4 (30 min)
3. EEG recorded with the Emotiv device at T1 (baseline), T2 (10 min), T3 (20 min) and T4 (30 min)

Completion date
30/10/2024

Eligibility

Key inclusion criteria
1. Over 18 and under 60 years old
2. No regular practice of relaxation techniques
3. Without any pharmacological treatment on course
4. Over 39-40 points on Spielberg´s state anxiety inventory as a measure of state anxiety

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Key exclusion criteria
1. Under 18 and over 60 years old
2. Previous experience with relaxing techniques (yoga, tai-chi, meditation, etc)
3. Being under current pharmacotherapy

Date of first enrolment
30/06/2020

Date of final enrolment
30/10/2024

Locations

Countries of recruitment

Chile

Study participating centre
Austral University of Chile
Department of Psychology
Campus isla teja s/n
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Sponsor information

Organisation
Austral University of Chile

ROR
https://ror.org/029ycp228

Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)
National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication