

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of using binaural beats music on the level of anxiety of dental patients

Protocol summary

Study aim

The effect of using binaural beats music on the level of anxiety of dental patients in Sari in test and control groups

Design

The present clinical trial has two groups of test and control with parallel and randomized groups on 80 patients. Quadruple blocking was used for randomization.

Settings and conduct

dental faculty of Mazandaran University of Medical Sciences

Participants/Inclusion and exclusion criteria

not taking psychiatric medication, no epilepsy, no hearing problems

Intervention groups

For the test group, background music will be played after the anesthesia injection, but no music will be played for the control group.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220824055789N1**

Registration date: **2022-09-04, 1401/06/13**

Registration timing: **prospective**

Last update: **2022-09-04, 1401/06/13**

Update count: **0**

Registration date

2022-09-04, 1401/06/13

Registrant information

Name

Pegah Nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3326 1989

Email address

pegah.nasiri75@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using binaural beats music on the level of anxiety of dental patients

Public title

The effect of using binaural beats on the level of anxiety of dental patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are systemically healthy

Exclusion criteria:

Taking psychiatric medication Hearing problems Epilepsy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done using blocks of four with the help of random numbers table of Random Allocation Software and the allocation ratio of samples will be (Allocation 1:1). A total of four blocks were allocated, the first two blocks will belong to the control group and the third and fourth blocks will be placed in the intervention group. And based on the obtained blocks and according to the allocation sequence, the intervention will be done.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Tooba dental clinic, Khazar Blvd

City

Sari

Province

Mazandaran

Postal code

4817846164

Approval date

2022-04-13, 1401/01/24

Ethics committee reference number

IR.MAZUMS.REC.1401.005

Health conditions studied

1

Description of health condition studied

Dental anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Effect of binaural beats music

Timepoint

Before and after anesthesia injection

Method of measurement

Spielberger overt and covert anxiety questionnaire

Secondary outcomes

1

Description

reducing dental anxiety

Timepoint

After anesthesia injection

Method of measurement

Spielberger overt and covert anxiety questionnaire

Intervention groups

1

Description

intervention group: Recording the level of anxiety of the patients and then playing wordless music with a frequency of 200 Hz for the right ear and 209 Hz for the left ear for ten minutes after injecting 2% lidocaine local anesthesia for the patients and then measuring the level of anxiety again after ten minutes using the questionnaire

Category

Treatment - Other

2

Description

control group: Recording the initial anxiety of the patients and then injecting local anesthesia and waiting for ten minutes and not playing any music and then measuring the anxiety again after ten minutes using a questionnaire

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Ebrahimi Saravi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Research and Technology center of Mazandaran
University of Medical Sciences
Street address
Research and Technology center, Moallem Square
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4815733971
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
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Reza Rasti
Position
Student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available