

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of music therapy effect on anxiety and pain level in impacted mandibular third molar surgery

Protocol summary

Study aim

Evaluation of music therapy effect on anxiety and pain level in impacted mandibular third molar surgery

Design

clinical trial has control group and also has parallel groups/single blinded/ on 102 patients/ randomised with statistical software

Settings and conduct

Location: Special clinic of Alborz Dental School Patients are placed in one of three groups :1-control groups 2- Western classical music or 3- Iranian music. after Completing the CORAH Dental Anxiety Assessment Questionnaire they will be assessed for heart rate, blood pressure, and blood oxygen levels(5 minutes before surgery, at the start of surgery, and in the middle of surgery).24 and 48 hours after surgery, the level of perceptual pain will be recorded for them through oral and numerical pain scales.The surgeon will be blind in this study (all patients will have headphones.

Participants/Inclusion and exclusion criteria

inclusion criteria : patient in the age range of 18-30 - candidate for in impacted mandibular third molar surgery(mesioangular) exclusion criteria:patient who is candidate for impacted wisdom tooth surgery and is out of the age range of 18-30 or the tooth is diagnosed as a C group and third class of Pell & Gregory's classification.also patients with systemic complications will be excluded due to probable errors

Intervention groups

1-Intervention group 1 includes patients who are candidates for mandibular impacted wisdom tooth surgery who receive western classical music 2- Intervention group 2 includes patients who are candidates for mandibular impacted wisdom tooth surgery who receive Iranian classical music 3-The comparison group (control group) includes patients who are candidates for mandibular impacted wisdom tooth surgery who do not receive music.

Main outcome variables

heart rate-blood pressure-blood oxygen-pain perception level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210708051818N1**

Registration date: **2021-08-31, 1400/06/09**

Registration timing: **prospective**

Last update: **2021-08-31, 1400/06/09**

Update count: **0**

Registration date

2021-08-31, 1400/06/09

Registrant information

Name

iran Alishahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3350 5372

Email address

melikaalishahi1373@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of music therapy effect on anxiety and pain level in impacted mandibular third molar surgery

Public title

Evaluation of music effect on anxiety and pain level in wisdom tooth surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being in the age range of 18-30 years impacted mandibular third molar (mesioangular) Absence of active cardiovascular disease Absence of normal auditory respiratory disease Lack of disability and mental retardation

Exclusion criteria:

Age under 18 and over 30 years Implanted wisdom tooth that is not mesioangular and is in group C and class 3 of Pell and Gregory classification Existence of acute infection or swelling at the site during removal Sensitivity to local anesthetic solution Phobia and severe fear of the environment and dental treatment Existence of active cardiovascular disease Existence of active respiratory disease Hearing problems Disability and mental retardation Prolonged surgical time longer than average minutes

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of samples to each of the three groups will be done by block randomization method with not similar blocks and randomization list using web at <https://www.sealedenvelope.com/simple-randomiser/v1/> lists will be provided

Blinding (investigator's opinion)

Single blinded

Blinding description

Surgeon: All patients will have headphones and the surgeon will not know which group the patient is in (We have three study groups in which patients in all three groups put headphones on their ears during surgery, music is played for two groups, and the control group does not receive music, so the surgeon does not know if the patient is receiving music or not because all patients have headphones)

Placebo

Not used

Assignment

Parallel

Other design features

The two intervention groups listen to music from different cultures, by analyzing the data, the cultural pre-familiarity with music on the surgical results is also examined.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

Street address

Dentistry faculty-Katoeizade Street-Golshahr-Karaj

City

Karaj

Province

Alborz

Postal code

3198684686

Approval date

2021-06-19, 1400/03/29

Ethics committee reference number

IR.ABZUMS.REC.1400.101

Health conditions studied**1****Description of health condition studied**

Impacted mandibular third molar

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes**1****Description**

pain

Timepoint

12.24 hrs after surgery

Method of measurement

NRS and VRS

2**Description**

anxiety

Timepoint

5 minutes before surgery-at the start point of surgery-10 minutes after starting surgery

Method of measurement

heart rate and blood pressure: Digital
sphygmomanometer -level of the blood oxygen:digital
pulse oximeter(Physiological indicators of anxiety have
been selected based on similar previous studies)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients who are candidates for impacted wisdom tooth surgery and will receive Western classical music. Patients will receive Western classical music, which averagely has 60-80 beats per minute(5 minutes before the start of surgery until the end of it)

Category

Treatment - Other

2

Description

Intervention group: Patients who are candidates for impacted wisdom tooth surgery and will receive Iranian classical music. Patients will receive Iranian classical music, which averagely has 60-80 beats per minute(5 minutes before the start of surgery until the end of it)

Category

Treatment - Other

3

Description

control group:Candidate patients for mandibular impacted wisdom tooth who do not receive music (this group only puts headphones on their ears during surgery to blind the surgeon)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

dental clinic of alborz university of medical sciences

Full name of responsible person

Dr.Seyed Mostafa MOrtazavi

Street address

dental clinic, katoeizade street, golshahr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

alborz university of medical sciences

Proportion provided by this source

1

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

Karaj University of Medical Sciences

Full name of responsible person

melika alishahi

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more informations are available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available