Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 grops :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 duo 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 mesiangular 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
he 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
City
karaj
Province
Alborz
Postal code
3198684868
Phone
+98 26 3355 5110
Email
melikaalishahi1373@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
dr seyed mostafa mortazavi
Street address
dental clinic, katoeizade street, golshahr
City
karaj
Province
Alborz
Postal code
3198684868
Phone
+98 26 3355 5110
Email
melikaalishahi1373@gmail.com
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
Street address
dental clinic, katoeizade street, golshahr
City
Karaj
Province

Alborz
Postal code
3198684868
Phone
+98 26 3355 5110
Email
melikaalishahi1373@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
dr seyed mostafa mortazavi
Position
professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
dental clinic, katoeizade street, golshahr
City
Karaj
Province
Alborz
Postal code
3198684868
Phone
+98 26 3355 5110
Email
Drmo_mortazavi@yahoo.com

Person responsible for updating data

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
Street address
dental clinic-katoeizade street-golshahr
City
karaj
Province
Alborz
Postal code
3198684868
Phone
+98 26 3355 5110
Email
melikaalishahi1373@gmail.com

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