Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of the music therapy with and without virtual reality in reducing the anxiety of patients undergoing implant surgery in a parallel randomized controlled trial

Protocol summary

Study aim

General purpose: Comparing the effectiveness of music therapy with and without virtual reality glasses in reducing anxiety in patients undergoing Implant surgery in the Department of Dental Implants of Tehran School of Dentistry in a parallel randomized clinical controlled trial study.

Design

Clinical trials with control group, with parallel groups, one-blind, randomized, were used on 28 patients, for randomization of Microsoft Excel software.

Settings and conduct

This study is conducted in the Implant Department of Tehran University of Medical Sciences. Patients are selected randomly divided into control or intervention group. Patients receive relaxing music during surgery. Patients in the intervention group, in addition to relaxing music, also receive nature video by VR glasses. The anxiety score of patients in both groups is measured by MDAS questionnaire before and after surgery. Blood pressure of patients before and after surgery is measured. The heart rate of patients before, during and after surgery is measured. In this study, analyzers are blinded. In this way, data is delivered to the analyzers as A and B codes.

Participants/Inclusion and exclusion criteria

exclusion criteria: the age of the patient is between 18 and 70 years and the patient is satisfied with the study. exclusion criteria: Mental Disease; Synchronous treatment with sinus surgery; Consumption of all types of blood pressure controllers or cardiac drugs or types of benzodiazepines everyday; Need to treat broad bone marrow; Complex surgicals such as the number of implants above 4 and more than one hour and a half

Intervention groups

Control group: Perform implant surgery with sedative music playback intervention group: Perform implant surgery with sedative music playback and video playback from nature by virtual reality glasses(VR)

Main outcome variables

.Blood pressure; Heartbeat; Questionnaire MDAS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240714062433N1**
Registration date: **2025-04-23, 1404/02/03**
Registration timing: **retrospective**

Last update: **2025-04-23, 1404/02/03**
Update count: **0**

Registration date

2025-04-23, 1404/02/03

Registrant information

Name

Zahra Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-02, 1403/08/12

Expected recruitment end date

2024-11-17, 1403/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of the music therapy with and without virtual reality in reducing the anxiety of patients undergoing implant surgery in a parallel randomized controlled trial

Public title

Comparison of the effectiveness of the music therapy with and without virtual reality in reducing the anxiety of patients undergoing implant surgery in a parallel randomized controlled trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients undergoing implant surgery (18 to 70 years old) if the patient consents to participate in the study.

Exclusion criteria:

The patient is being treated for any type of mental illness, especially anxiety. Patients undergoing closed sinus transplant treatment with the osteotom method (due to the use of trauma). Patients who take blood pressure control drugs or heart drugs or benzodiazepines on a daily basis. Patients who need extensive bone grafting during surgery. (Because the dimensions of the VR glasses may hinder the comfortable operation of the surgeon.) Patients who need more than 4 implants. Complex surgeries that require more than an hour and a half from the start of surgery.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

How to prepare the randomization list: Random allocation is done by balanced block allocation method. The software used will be Microsoft Excel. The size of the blocks will be determined by the generator of the random allocation list without informing others. How to hide: The allocation code of the patients to the two studied groups is placed in invisible numbered envelopes. This envelope is opened for each patient before anesthesia. To analyze random allocation data, it is entered into the software with random code A and B. This code is decoded after statistical analysis and interpretation of the findings by a person unrelated to the study. Randomization implementation process: The envelope is opened by the person responsible for allocating the code to the patients. Random allocation and entering the allocated data is done by a person unrelated to the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyzer is masked. The data is delivered to the analyst with statistical codes of A and B, so only the data of A and B are delivered to them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Faculty of Dentistry, Tehran University of Medical Sciences. North kargar Ave. Tehran

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2024-10-20, 1403/07/29

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1402.103

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score based on MDAS questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and after the end of the surgery, until half an hour later

Method of measurement

modified dental anxiety scale questionnaire

Secondary outcomes

1

Description
heartbeat
Timepoint
After the patient sits on the unit, before anesthesia injection and immediately after surgery
Method of measurement
pulse oximeter

2

Description
blood pressure
Timepoint
After the patient sits on the unit, before anesthesia injection and immediately after surgery
Method of measurement
pressure gauge

Intervention groups

1

Description
Intervention Group: This group uses music therapy (a number of pre -defined relaxing music by the Bluetooth headset for the patient) and the distribution of nature by virtual reality glasses VR) are used to reduce patients' anxiety.
Category
Behavior

2

Description
Control Group: This group uses music therapy (a number of pre -determined relaxing music by Bluetooth headset for the patient) to reduce patient anxiety.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry Tehran University of Medical Sciences
Full name of responsible person
Soolmaz Akbari
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Faculty of Dentistry Tehran University of Medical Sciences, North Kargar St. , Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Sixth Floor Research and Technology, The central organization of the university, Qods St, Keshavarz Blvd, Tehran
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Zahra jafari
Position
Student

Latest degree
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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
I don't want to
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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available