Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of meditation on anxiety and pain in patients undergoing implant placement with bone grafting

Protocol summary

Study aim
Evaluation of the effect of meditation on anxiety and pain in patients undergoing implant placement with bone graft

Design
A parallel intervention group, single-blind, randomized, phase two clinical trial on 28 patients. The sampling method is random. The randomization method is simple with a table of random numbers.

Settings and conduct
Among the patients referred to the periodontics department of Tabriz Faculty of Dentistry who need tooth replacement using bone graft, they participate in the study. Patients are randomly assigned to one of the groups. The first group is exposed to meditation practice and listening to Alpha music half an hour before surgery. In the second group (control), there is no intervention. Pain measures and bleeding rate will be taken from all people during and after the surgery after the removal of anesthesia and anxiety measures before and during the surgery using standard protocols. The evaluator is not aware of the application or non-application of meditation.

Participants/Inclusion and exclusion criteria
Including criteria: requires implants and bone grafting of mild and moderate levels (three- and four-wall defects). Excluding criteria: no need for bone grafting or extensive bone grafting and surgery longer than one hour.

Intervention groups
Intervention: using meditation practice and listening to alpha music half an hour before surgery Control: not using meditation practice before surgery

Main outcome variables
The level of anxiety The amount of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220712055445N1**
Registration date: **2022-07-26, 1401/05/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-26, 1401/05/04**
Update count: **0**

Registration date
2022-07-26, 1401/05/04

Registrant information

Name
Leyla Basirat

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 914 575 8663

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leylabasirat@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-13, 1401/04/22

Expected recruitment end date
2022-07-30, 1401/05/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of meditation on anxiety and pain in patients undergoing implant placement with bone grafting

Public title

Evaluation of the effect of meditation on anxiety and pain in patients undergoing implant placement with bone grafting

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients whose surgery takes less than an hour. The surface of the area requiring surgery should be small and about one to three teeth. Patients with good health condition and index plate less than 30% Patients over 50 years old

Exclusion criteria:

Taking blood thinners such as NSAIDs and anticoagulants History of blood pressure, leukemia, diabetes and other diseases that affect the normal physiology of blood, vessels and heart. Statement of Dentophobia It requires extensive bone grafting and surgery lasting more than an hour Patients with mental problems such as depression and anxiety disorders and people who take psychiatric drugs. No need for bone grafting Smoking patients Patients with hearing problems

Age

From **50 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random sampling is among the people who refer to the maxillofacial surgery department of the Faculty of Dentistry in Tabriz. The randomization method is simple and individual. Our tool for randomizing a table of random numbers. Also, the allocation of treatment to patients will be done randomly. In such a way that the type of treatment is specified with the code A (with meditation) and B (without meditation) and will be placed inside the sealed envelopes; Then the envelopes will be placed in a bag and mixed. Then it will be randomly removed from the bag and after seeing the code, the treatment will be given to the patient. None of the patients will be informed about the treatment of another patient.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator who will record the level of pain, bleeding and anxiety will not be aware of whether or not meditation was applied before surgery.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Golgasht St., Tabriz University of Medical Sciences,

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2022-02-02, 1400/11/13

Ethics committee reference number

IR.TBZMED.REC.1400.1144

Health conditions studied

1

Description of health condition studied

Dental implants require bone grafting

ICD-10 code

Z96.5

ICD-10 code description

Presence of tooth-root and mandibular implants

Primary outcomes

1

Description

The level of anxiety

Timepoint

Before and after surgery

Method of measurement

Complete the Spielberger questionnaire (manifest anxiety scale form y-1 of STAI) before surgery. Also, in both groups, systolic, diastolic and heart rate blood pressure, and oxygen saturation are measured using pulse oximetry before and after surgery.

2

Description

The amount of pain

Timepoint

After surgery

Method of measurement

VAS(Visual analog scale)

Secondary outcomes

1

Description
Bleeding rate
Timepoint
During surgery
Method of measurement
Based on the number of gases soaked in blood and the amount of bleeding in suction, it will be calculated according to the following method: The number of blood-soaked 4x4 gauzes and the volume of blood sucked are recorded separately for each patient. Each blood-soaked gauze contains 10 ml of blood, so the number of blood-soaked gauzes is multiplied by 10 ml and the result is added to the volume of blood sucked. Since this obtained volume includes the volume of the washing fluids in the surgical area, we also subtract the volume of the consumed fluid from it, and the result will be equal to the actual blood loss of the patient.

Intervention groups

1

Description
Intervention group: half an hour before the implant and bone graft surgery, the patient is exposed to meditation practice and listening to alpha music. Pain measures after surgery, bleeding rate during surgery and anxiety measures before and after surgery will be obtained using standard protocols.
Category
Other

2

Description
Control group: The patient will perform his implant and bone graft surgery without any intervention. Pain measures after surgery, bleeding rate during surgery and anxiety measures before and after surgery will be obtained using standard protocols.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Tabriz
Full name of responsible person
Atabak Kashfi Mehr
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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farhadif@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Farrokh Farhadi
Position
Assistant Professor
Latest degree
Specialist
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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
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable