

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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)

Phone

+98 914 575 8663

Email address

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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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

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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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