

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of psychological pretreatment on anxiety level in patients undergoing dental surgery

Protocol summary

Study aim

The effect of psychological pretreatment on anxiety level in patients undergoing dental surgery

Design

This study included 30 subjects in both control and intervention groups. Patients will randomly be divided into two groups. Simple randomization will be performed by using a random number table. The trial is phase 2-3

Settings and conduct

This study will be performed at the Dental Clinic of Ahvaz Jundishapur University of medical sciences with no blinding.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: age 18-80 years: Able to speak Persia: the ability to communicate verbally: a consent to enter the scheme Exclusion Criteria: mental retardation, distinctive physical problems that interfere consultation, history of major psychiatric disorders, dementia

Intervention groups

Intervention group: Pre-treatment training will be performed for 20 minutes before the procedure begins and in a separate room in the dental room. Training includes psychological preparation that includes behavioral control, cognitive control, and information control. Control group: The control group will be given a pamphlet on the general informations (about fruits and vegetables).

Main outcome variables

State Anxiety Trait Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161228031626N4**

Registration date: **2019-11-02, 1398/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-02, 1398/08/11**

Update count: **0**

Registration date

2019-11-02, 1398/08/11

Registrant information

Name

Hatam Boostani

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3038

Email address

tabibi.y@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of psychological pretreatment on anxiety level in patients undergoing dental surgery

Public title

The effect of psychological pretreatment on anxiety level in patients undergoing dental surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
age between 18-80years Able to speak Persian the ability to communicate verbally a consent to enter the scheme

Exclusion criteria:
mental retardation An obvious physical problem A history of major psychiatric disorders Dementia

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was done by random number table

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

157945-6135

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.AJUMS.REC.1397.349

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

State Anxiety

Timepoint

Before intervention- After intervention

Method of measurement

Spielberg questioner

Secondary outcomes

1

Description

Trait Anxiety

Timepoint

Before intervention- After intervention

Method of measurement

Spielberge questioner

Intervention groups

1

Description

Intervention group: A Spielberg questionnaire for measuring level of anxiety will be use and fill out by patients. Pre-treatment training will be provided for 20 minutes before the procedure begins and in a separate room in the dental room. Behavioral control includes the ability to take action to reduce stress, such as relaxation and distraction. Cognitive control involves the ability to use thought processes and strategies, such as thinking about the positive outcome of an event.

Category

Behavior

2

Description

Control group: The control group will be given a pamphlet on the general informations (about fruits and vegetables)

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Fatemeh Davoodi Koorani

Street address

Ahvaz,Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd,

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f.davoodi.k@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

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badavi.m@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Hatam Boostani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Siroos Pak seresht

Position

Assistant Professor استادیار

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Davoodi Koorani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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

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

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available