Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
The effect of psycological 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)
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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 psycological pretreatment on anxiety level in patients undergoing dental surgery

Public title
The effect of psycological 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
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Ahvaz,Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
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Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
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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

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Ahvaz University of Medical Sciences
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Position
Assistant Professorاستادیار
Latest degree
Medical doctor
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Person responsible for updating data

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Resident
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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