

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effectiveness of acceptance and commitment therapy and cognitive-behavioral therapy on dental anxiety, cognitive emotion regulation and oral health-related quality of life in patients with dental anxiety

Protocol summary

Study aim

Determining and Comparing the effectiveness of therapy based on acceptance and commitment and cognitive-behavioral therapy on dental anxiety, cognitive emotion regulation and quality of life associated with oral health in patients with dental anxiety

Design

Controlled clinical trial, with parallel groups, double blinded, randomized design

Settings and conduct

Forty-eight participants who were eligible for inclusion in the study were randomly classified into three groups by a statistics consultant. The groups included acceptance and commitment therapy, cognitive-behavioral therapy, and control. Then, the participants who were blind to the intervention were invited to attend separate sessions at the dental research center of Isfahan University of Medical Sciences. The assessors, except for the researcher, gave the encoded dental anxiety scale, cognitive emotion regulation questionnaire, and oral health-related quality of life scale to the participants to complete at pretest, posttest, and three-month follow-up. Each therapy included ten 90-minute sessions per week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 19-50 years old; Having the dental anxiety. Non-inclusion criteria: need for emergent dental care.

Intervention groups

Intervention group1: In this group the treatment will be done according to acceptance and commitment therapy using the model presented by Haze 2016. Intervention group2: In this group the treatment will be done according to cognitive-behavioral therapy using the model presented by Ost, Öst & Skaret 2013. control group: patients will not receive any treatment during the study

Main outcome variables

Dental anxiety; cognitive emotion regulation; oral health-related quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190505043473N1**

Registration date: **2019-06-27, 1398/04/06**

Registration timing: **retrospective**

Last update: **2019-06-27, 1398/04/06**

Update count: **0**

Registration date

2019-06-27, 1398/04/06

Registrant information

Name

Elham Binandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of acceptance and commitment therapy and cognitive-behavioral therapy on dental anxiety, cognitive emotion regulation and oral health-related quality of life in patients with dental anxiety

Public title

Comparison of the effectiveness of "ACT" and "CBT" on dental anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

People living in Isfahan age between 19-50 years old higher education level than middle school Willingness to attend intervention sessions and giving written consent minimum physical and cognitive abilities for participating in psychological interventions Supplementary studying of psychiatric criteria using SCL-90-R self-report questionnaire Having the dental anxiety using Stouthard dental anxiety Inventory Having at least 20 natural teeth Additional confirmation of dental anxiety will report by pulse oximeters by a dentist. Heart rate of each patient will be measured after relaxing for 5 minutes in the waiting room for 2 times. Then it will be measured twice during the dental treatment, and the mean values will be compared. If the second measure was at least 5 beats per minute higher than the first one, the patient will participate in the study Having at least one treated teeth

Exclusion criteria:

systemic diseases or congenital syndromes approved by an internal specialist sensation of pain by VAS (score higher than 1) psychiatric disorders except dental anxiety according to DSM-5 criteria need for emergent dental care approved by a dentist Graduated in any fields of dentistry and psychology receiving psychiatric therapies and chemical drugs in the last six months

Age

From **19 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual randomization will be implemented by blinded statistician, using the block randomization method and black concealed pocket

Blinding (investigator's opinion)

Double blinded

Blinding description

participants, Evaluators and statistical consultant Will be unaware of the type of intervention

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University - Ahvaz Branch

Street address

Islamic Azad University - Ahvaz Branch, Farhangshahr, Golestan Blvd

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Postal code

6134937333

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.IAU.AHVAZ.REC.1398.005

Health conditions studied**1****Description of health condition studied**

Dental anxiety

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Dental anxiety score in Stouthard dental anxiety Inventory

Timepoint

Before intervention, after intervention, after 3 months

Method of measurement

Stouthard dental anxiety Inventory

Secondary outcomes

1

Description

cognitive emotion regulation

Timepoint

Before intervention, after intervention, after 3 months

Method of measurement

Cognitive Emotion Regulation Questionnaire by Spinhoven with 36 questions

2

Description

Oral Health-related Quality of Life

Timepoint

Before intervention, after intervention, after 3 months

Method of measurement

Oral Health-related Quality of Life (OHIP-14)

Intervention groups

1

Description

Intervention group: Therapy based on acceptance and commitment: This treatment approach has six central processes that ultimately lead to psychological flexibility. These processes include acceptance, cognitive discontinuity, self as the background, relationship with the present time, values, and committed action . In this research, therapy based on acceptance and commitment will be implemented in 10 sessions (90 minutes each) using a treatment package (Haze, 2016).

Category

Other

2

Description

Intervention group: Cognitive-Behavioral Therapy: A kind of psychotherapy that helps patients to reach thoughts and feelings that affect their behavior. The cognitive-behavioral training and therapeutic sessions refer to sessions that will be conducted for at least 10 sessions (90 minutes each), during which cognitive-behavioral techniques will be taught using cognitive-behavioral therapy for anxiety and dental phobias package(Ost, Öst, & Skaret, 2013).

Category

Other

3

Description

Control group: Control group will not receive any treatment during the study period , However, after the end of the research, the intervention will be done for them, free of charge.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Research Center of Isfahan University of Medical Sciences

Full name of responsible person

Elham Sadat Binandeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Islamic Azad University

Proportion provided by this source

80

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

2

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
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
Esfahan University of Medical Sciences
Proportion provided by this source
20
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
Islamic Azad University
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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

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

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

Data Dictionary

Not applicable