

# 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 Pain Coping Strategies, Severity of Pain Perception, Disaster Pain Imagery, and Pain Related Anxiety in patients with dental anxiety

#### Protocol summary

Pain Coping Strategies; Severity of Pain Perception;  
Disaster Pain Imagery; Pain Related Anxiety

#### Study aim

Determination and Comparison of the effectiveness of therapy based on acceptance and commitment and cognitive-behavioral therapy on Pain Coping Strategies, Severity of Pain Perception, Disaster Pain Imagery, and Pain Related Anxiety 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. Exclusion 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: oral health education

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190505043473N2**

Registration date: **2020-03-14, 1398/12/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-14, 1398/12/24**

Update count: **0**

##### Registration date

2020-03-14, 1398/12/24

##### Registrant information

##### Name

Elham Binandeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 5512

##### Email address

binandeh@mail.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-01, 1398/12/11

##### Expected recruitment end date

2020-04-30, 1399/02/11

##### 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 Pain Coping Strategies, Severity of Pain Perception, Disaster Pain Imagery, and Pain Related Anxiety in patients with dental anxiety

**Public title**  
Comparison of the effectiveness of "ACT" and "CBT" on pain

**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 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

**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**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical sciences, Hezarjarib street

##### City

isfahan

##### Province

Isfahan

##### Postal code

8174619461

#### Approval date

2020-02-29, 1398/12/10

#### Ethics committee reference number

IR.MUI.MED.REC.1398.626

## Health conditions studied

### 1

#### Description of health condition studied

dental anxiety

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

pain Coping Strategies score in Coping Strategies Questionnaire

#### Timepoint

Before intervention, after intervention, after 3 months

#### Method of measurement

Coping Strategies Questionnaire

### 2

#### Description

Severity of Pain Perception score by McGill Pain

Questionnaire

**Timepoint**

Before intervention, after intervention, after 3 months

**Method of measurement**

McGill Pain Questionnaire

**3**

**Description**

Disaster Pain Imagery score by Pain Catastrophe Scale

**Timepoint**

Before intervention, after intervention, after 3 months

**Method of measurement**

Pain Catastrophe Scale

**4**

**Description**

Pain Related Anxiety score by Pain Anxiety Symptoms Scale

**Timepoint**

Before intervention, after intervention, after 3 months

**Method of measurement**

Pain Anxiety Symptoms Scale

**Secondary outcomes**

empty

**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: oral health education

**Category**

Other

**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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Dental Research Center, Isfahan University of Medical Sciences, Hezar jarib street , Isfahan

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

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**Full name of responsible person**

dr shaghayegh hagh joo

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research@dnt.mui.ac.ir

**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**  
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

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## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Esfahan University of Medical Sciences  
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دکترای تخصصی غیر هیات علمی  
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Psychology  
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## Person responsible for updating data

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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**  
Not applicable  
**Data Dictionary**  
Not applicable