Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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 by Ost,Öst & Skaret 2013. control group:oral health education

Main outcome variables
Pain Coping Strategies; Severity of Pain Perception; Disaster Pain Imagery; Pain Related Anxiety

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

Isfehan

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

Street address

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

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 5512

Fax

+98 31 3792 5569

Email

binandeh@mail.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

dr shaghayegh hagh joo

Street address

Isfahan University of Medical Sciences, Hezar jarib street , Isfahan

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 5512

Fax

+98 31 3792 5569

Email

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

Person responsible for general inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Elham sadat Binandeh
Position
دکترای تخصصی غیر هیات علمی
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Dental research Center of Isfahan University of Medical sciences, Hezarjarib street
City
isfahan
Province
Isfehan
Postal code
8174619461
Phone
+98 31 3792 5512
Fax
+98 31 3792 5569
Email
binandeh@mail.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Elham sadat binandeh
Position
دکتری تخصصی
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Dental research Center of Isfahan University of Medical sciences, Hezarjarib street
City
isfahan
Province
Isfehan
Postal code
8174619461
Phone
+98 31 3792 5512
Fax
+98 31 3792 5569
Email
binandeh@mail.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
elham sadat binandeh
Position
دکتری تخصصی
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Dental research Center of Isfahan University of Medical sciences, Hezarjarib street
City
Isfahan
Province
Isfehan
Postal code
8174619461
Phone
+98 31 3792 5512
Fax
+98 31 3792 5569
Email
binandeh@mail.mui.ac.ir

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