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 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 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

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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 byVAS (score higher than1) 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
City
Ahvaz
Province
Khouzestan
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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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
Islamic Azad University
Full name of responsible person
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http://pajohesh.iaupg.ac.ir
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

Dr Omid Savabi

Street address

Dental research Center of Isfahan University of Medical sciences, Hezarjarib street

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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

Full name of responsible person

Elham sadat Binandeh

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Psychology

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Position

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Latest degree

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Latest degree

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Other areas of specialty/work

Psychology

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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