

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparing of effectiveness of Emotional Self-Regulation Strategies and Systematic Desensitization on Fear and Anxiety of Adults referred to Dentistry

Protocol summary

Study aim

The purpos of this study is comparing the effects of the Emotional regulation strategies and Systematic desensitization on fear and anxiety ' dentistry of adults referred to dentistry

Design

Clinical trial with one control group and two intervention groups. Participants were selected using randomly sampling method (n=60) form individuals referred to dentistry.

Settings and conduct

This study was conducted in Dr. Parivar dental clinic. Participants were selected using convenient sampling method and from individuals who refereed to dental clinic. Therefore, 60 participants who their scores were 1 SD higher than Mean value were selected as sample size and classified into three groups including Experimental group 1 and experimental group 2 and control group. They were delivered needed instructions.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having the dental problems who needing interventions in dentistry and they could not refer to dentistry because of fear and anxiety Exclusion criteria: Patients that participate in other clinical trial

Intervention groups

Group1:Recieving emotional self-regulation-Group 2:Recieving Systematic desensitization-Group3:Control group no method recieving

Main outcome variables

Main' implication is fear and anxiety that is influenced by research two intervention methods.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220717055481N2**

Registration date: **2022-10-13, 1401/07/21**

Registration timing: **retrospective**

Last update: **2022-10-13, 1401/07/21**

Update count: **0**

Registration date

2022-10-13, 1401/07/21

Registrant information

Name

Masumeh Parivar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3310 7209

Email address

parivar90@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-17, 1401/05/26

Expected recruitment end date

2022-08-17, 1401/05/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of effectiveness of Emotional Self-Regulation Strategies and Systematic Desensitization on Fear and Anxiety of Adults referred to Dentistry

Public title

Compare of two ways of Emotional Self-Regulation Strategies and Systematic Desensitization for fear and anxiety reduction

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having dental problems Need to perform dental intervention Satisfaction to participate in the research

Exclusion criteria:

Individuals above 20 years old Individuals who have dental fear and anxiety and we study such individuals to be able to help them to decrease their fear and anxiety.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization, block is used to balance the number of samples allocated for one of studying' groups to be equal the size of all blocks in groups. In this study, size of all 20 blocks (20 participants in group 1, 20 participants in group 2 and 20 participants in control group). Unit of individual randomization: individuals with stress specified by dentist and individuals who tend to participate in pretest. We made use of randomization statistical software, random allocation using Random' software and also allocation concealment way to prevent of its clearing. We could not determine the allocated group before individual's allocation due to prevention of weak randomization process. We used opaque sealed envelopes with a random sequence, in which each of the generated random sequences is recorded on a card and the cards are placed in the letter envelopes in order. In order to maintain a random sequence, numbering is done on the outer surface of the envelopes in the same order. Finally, the lids of the envelopes are glued and placed in a box in order. At the time of registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.

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 Tabriz Islamic Azad university

Street address

Saye2,kaje 12 Ave.,South Sarvestan Street,Roshdiyeh,Tabriz

City

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Province

East Azarbaijan

Postal code

5173865955

Approval date

2022-08-17, 1401/05/26

Ethics committee reference number

IR.IAU.TABRIZ.REC.1401.044

Health conditions studied

1

Description of health condition studied

Effects of systematic desensitization and emotional regulation strategies upon fear and anxiety's reduction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The primary outcome variable is dental fear and anxiety.

Timepoint

Investigating the effect of two methods on fear and anxiety before the start of the study (before the intervention) and 60 days after the intervention

Method of measurement

Questionnaire of dentistry'anxiety by Staterd and Melberg &Hogstraten, Questionnaire of dentistry'fear by Cutbert & Melamed

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Emotional Self-regulation. The emotional self-regulation method that was taught for 8 sessions of 1.5 hours is based on Gross's theoretical

model, which includes five stages (situation selection, situation modification, attention expansion, cognitive expansion, and response adjustment), each of which is a set of strategies includes an adjustment. Participants were taught to identify and correct negative emotion regulation strategies and replace them with positive strategies.

Category

Behavior

2

Description

Control Group: Pre and posttest were conducted on control group, however, they were not delivered any instruction. The research method were introduced in detail.

Category

Behavior

3

Description

Intervention group 2: Systematic Desensitization. The systematic desensitization method that was taught for 8 sessions of 1.5 hours is based on relaxation, hierarchy of anxiety, desensitization. Participants were taught to confront situational anxiety and state of relaxation.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic'Doctor Zahra Parivar

Full name of responsible person

Doctor Zahra Parivar

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Emam Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Doctor Hassan Rasuli

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Islamic Azad University

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

PayameNoor

Full name of responsible person

Akbar Rezaie

Position

University professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

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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