

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Efficacy of Transdiagnostic Cognitive Behavior therapy on Emotion Regulation, Repetitive Negative Thought, Social Adjusting in Adolescents With Sub-clinical Diagnostic of Emotional Disorders

Protocol summary

Study aim

the effect of Transdiagnostic Cognitive Behavior therapy on Emotion Regulation, Repetitive Negative Thought, Social Adjusting in Adolescents With Sub-clinical Diagnostic of Emotional Disorders.

Design

A randomized controlled trial will use the Excel software rand function for randomization.

Settings and conduct

The intervention is individual and will be done in 12 sessions online. The length of the sessions will be 45 minutes. The evaluator and therapist of the project will be an individual who will perform the protocol modalities according to the protocol as well as the number of sessions designated for each modal.

Participants/Inclusion and exclusion criteria

Entry criteria: Presence of sub-clinical symptoms, Age range 12 to 17 years, No severe psychiatric disorders, Abstinence from drugs and alcohol in the last three months, Failure to receive cognitive-behavioral interventions, Failure to receive medication, Participants' interest in participating in the research, No chronic medical illness Exist criteria : Receiving other similar psychological interventions, Medication at the same time as the intervention

Intervention groups

12 45-minute treatment sessions will be performed for the members of the intervention group. The main focus of the sessions is on cognitive reconstruction, awareness of bodily senses, awareness of the moment, teaching the concepts of contrasting behavior, and the three components of emotion that include thoughts, bodily senses, and behavior. Members of the control group will also not receive any intervention. They will be evaluated in only three periods.

Main outcome variables

Emotion regulation, Repetitive Negative Thoughts, Social

adjustment, Preclinical symptoms of anxiety and depression.

General information

Reason for update

Add two new secondary variables to the Clinical trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20210428051113N1**

Registration date: **2021-06-14, 1400/03/24**

Registration timing: **prospective**

Last update: **2021-10-23, 1400/08/01**

Update count: **1**

Registration date

2021-06-14, 1400/03/24

Registrant information

Name

vahideh javadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3372 5349

Email address

vjavadi76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-29, 1400/04/08

Expected recruitment end date

2021-08-30, 1400/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Transdiagnostic Cognitive Behavior therapy on Emotion Regulation, Repetitive Negative Thought, Social Adjusting in Adolescents With Sub-clinical Diagnostic of Emotional Disorders

Public title

The Effect of Cognitive Behavior therapy on Emotion Control, Repetitive Annoying Thought, Adjusting in Adolescents With Mild to moderate Symptoms of Anxiety and Depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Presence of sub-clinical symptoms of anxiety and depression Age range 12 to 17 years Participants' interest in participating in the research on the provisions of written consent

Exclusion criteria:

Existence of drug or alcohol addiction Existence of chronic medical disease Having severe psychiatric disorders (psychotic spectrum, bipolar disorders) Receive medication one month before starting treatment Receive cognitive-behavioral interventions for at least 8 sessions in the last 5 years

Age

From **12 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using Excel software. halve the number of participants and enter in tow columns 1 and 2. in the second column, we generate a random number using the Rand function option; then we sort the data by their values (ascending or descending). according to the order of numbers 1 and 2, the samples are randomly assigned to two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Zanjan University of Medical Sciences

Street address

Karmandan town, Mahdavi Avenu, Zanjan university and Medical Science

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2021-05-27, 1400/03/06

Ethics committee reference number

IR.ZUMS.REC.1400.053

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

Major depressive disorder, single episode

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

2**Description of health condition studied**

Major depressive disorder, recurrent

ICD-10 code

F33

ICD-10 code description

Major depressive disorder, recurrent

3**Description of health condition studied**

Persistent mood [affective] disorders

ICD-10 code

F34

ICD-10 code description

Persistent mood [affective] disorders

4**Description of health condition studied**

Social phobias

ICD-10 code

F40.1

ICD-10 code description

Social phobias

5

Description of health condition studied

Panic disorder

ICD-10 code

F41.0

ICD-10 code description

Panic disorder [episodic paroxysmal anxiety] without agoraphobia

6

Description of health condition studied

Generalized anxiety disorder

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

7

Description of health condition studied

Other mixed anxiety disorders

ICD-10 code

F41.3

ICD-10 code description

Other mixed anxiety disorders

8

Description of health condition studied

Mixed anxiety and depressive disorder

ICD-10 code

F41.2

ICD-10 code description

Mixed anxiety and depressive disorder

Primary outcomes

1

Description

Sub-clinical symptoms of anxiety and depression mean that the necessary criteria for depressive or anxiety disorders are not met, and only symptoms of anxiety and depression that are in the mild to moderate range.

Timepoint

Measurements will be performed in three periods one period before the start of the intervention, 7 days later and 3 months later.

Method of measurement

For the anxiety and depression variable, the 21 _DASS questionnaire will be used. The subject's score in the range of 14-18 for anxiety and 10 to 20 for depression indicates the presence of sub-clinical symptoms of anxiety and depression.

2

Description

Emotion regulation, which means the ability to reduce, increase or modify emotions.

Timepoint

Measurements will be performed in three periods one period before the start of the intervention, 7 days later and 3 months later.

Method of measurement

The Cognitive Emotion Regulation Questionnaire (CERQ) will be used to measure emotion regulation. This questionnaire has 36 items.

3

Description

Repetitive negative thoughts whose main characteristic is repetitive, annoying and unwanted.

Timepoint

Measurements will be performed in three periods one period before the start of the intervention, 7 days later and 3 months later.

Method of measurement

A negative recurring thoughts questionnaire (RTQ_10) will be used to measure this variable. This questionnaire has 10 items.

4

Description

Social adjustment means the ability to adapt and compromise with oneself, the environment and others.

Timepoint

Measurements will be performed in three periods one period before the start of the intervention, 7 days later and 3 months later.

Method of measurement

The Bell Social Adjustment Questionnaire will be used to measure this variable. This questionnaire has 32 items.

Secondary outcomes

1

Description

Cognitive Flexibility

Timepoint

Before the intervention, 14 days and 3 months after the intervention

Method of measurement

Questionnaire of psychological flexibility or acceptance of action with 7 questions (AAQ) Acceptance and Action Questionnaire

2

Description

Stress Vulnerability

Timepoint

Before the intervention, 14 days and 3 months after the intervention

Method of measurement

7 Stress Questions Out of 21 questions in the Depression, Anxiety and Stress Questionnaire (DASS)

Intervention groups

1

Description

Intervention group: The intervention group will be implemented based on an integrated transdiagnostic treatment protocol for adolescents. This protocol has 8 modals that will be implemented in 12 sessions. Protocol modalities include 1) Motivating and maintaining it 2) Identifying emotions and behaviors 3) Introducing emotion-focused behavioral experiments 4) Awareness of bodily senses 5) Flexibility in thinking 6) Awareness of emotional experiences 7) Facing situational emotions 8) Review skills and progress towards goals and maintain achievements. The main focus of the protocol is on emotion and its three basic components, namely thoughts, body senses and behavior. In the thought component, the focus on teaching mental errors is cognitive reconstruction. In the component of bodily senses, techniques of awareness of bodily senses are performed. In the behavior component, the concepts of driver and contrasting behavior are taught. Finally, situational emotion coping techniques and behavioral experiments will be performed. The modals will run for 8 sessions of 45 minutes for approximately 5 weeks. Depending on the age of the client and his / her understanding of the concepts and problems related to preclinical symptoms of emotional disorder that are unique to each client, these modals will be distributed in the sessions and the participation of parents will be determined if necessary.

Category

Treatment - Other

2

Description

Control group: Members of the control group will be evaluated in three periods without receiving any intervention. During this time, they should not seek psychological treatment or medication for their symptoms. The evaluation period for the members of this group lasted four months according to the quarterly follow-up period.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Dr Mohsen Dadashi

Street address

Beheshti Hospital, Ark Town.

City

Zanjan

Province

Zanjan

Postal code

4514147814

Phone

+98 24 3354 4004

Email

beheshti@zums.ac.ir

Web page address

<https://beheshti.zums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Parviz Ghezelbash

Street address

Zanjan University of Medical Science, Mahdavi Avenue.

City

Zanjan

Province

Zanjan

Postal code

4513956184

Phone

+98 24 3301 8100

Email

zums.ac.ir@riasat

Web page address

<https://zums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Dr Mohsen Dadashi

Position

Assistant Professor, Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Ark Town, Beheshti Hospital

City

Zanjan

Province

Zanjan

Postal code

1578845136

Phone

+98 24 3354 4001

Email

psy.mohsen@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Elnaz Mousavi

Position

Assistant Professor, Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Shahid Arabi St, Yemen St, Chamran Highway.

City

Tehran

Province

Zanjan

Postal code

1985717443

Phone

+98 21 23871

Email

Elnaz48.mousavi@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Mohsen Dadashi

Position

Assistant Professor, Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Beheshti Hospital, Ark Town

City

Zanjan

Province

Zanjan

Postal code

1578845136

Phone

+98 24 3354 4001

Email

psy.mohsen@gmail.com

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available