

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

The Efficacy of TARGET Model in Reducing Anxiety Symptoms and Correlates of Trauma among Women with Anxiety Disorders who had histories of Childhood Trauma

Protocol summary

Study aim

Determining the efficacy of TARGET on reducing anxiety symptoms and trauma correlates in people with anxiety disorders with a history of childhood trauma

Design

A randomized clinical trial with one experimental group and a control group; semi-experimental; with 40 participants, each group including 20 patients. Online randomization will be done via www.graphpad.com/quickcals

Settings and conduct

Among those who visit two Psychiatric Offices from Aug 22, 2020, to Dec 20, 2020, patients with anxiety disorders fill out the Childhood Trauma screening tool. The researcher does not distribute the forms (but the office secretary). People enter the study if they have the necessary criteria. The 10-session intervention phase is performed then. The posttest phase is within 2 weeks later and there is a 2-month follow-up.

Participants/Inclusion and exclusion criteria

The inclusion criteria: Female gender; Diagnosed with an anxiety disorder, moderate to severe, based on the Spielberger Anxiety Questionnaire scores on State or Trait anxiety (score 20-53); History of childhood trauma based on the Childhood Trauma Questionnaire; The exclusion criteria: Evidence of cognitive impairments (orientation, attention, and impaired memory in Mini-mental state examination); Severe mental disorders, such as schizophrenia and bipolar disorder, according to the psychiatrist's diagnosis

Intervention groups

The experimental group is the patients who are undergoing medications and TARGET group psychotherapy at the same time; and the control group is patients who are treated only by medications as Treatment As Usual.

Main outcome variables

Anxiety; Depression; Post-traumatic cognitions; Coping strategies; Difficulties in Emotion Regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191230045947N1**

Registration date: **2020-07-19, 1399/04/29**

Registration timing: **prospective**

Last update: **2020-07-19, 1399/04/29**

Update count: **0**

Registration date

2020-07-19, 1399/04/29

Registrant information

Name

Narges Barzgar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 0045

Email address

narkises73@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Efficacy of TARGET Model in Reducing Anxiety Symptoms and Correlates of Trauma among Women with Anxiety Disorders who had histories of Childhood Trauma

Public title
TARGET Efficacy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
History of childhood trauma suffering from an anxiety disorder
Severity of anxiety ranging from 20 to 53 in Spielberger Anxiety Questionnaire
Informed Consent
Female gender ages 18 to 65
Exclusion criteria:
Having severe mental disorders including Schizophrenia spectrum and Bipolar; Antisocial, Borderline, Paranoid, and Schizotypal Personality Disorders
Having severe personality disorders including antisocial, borderline, paranoid, and schizotypal personality disorders
Evidence of cognitive impairments (orientation, attention, and impaired memory in Mini-mental state examination-MMSE)
Hospitalization in a psychiatric hospital in the last month
Participate in another psychological treatment at the same time

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple. After the initial screening, 40 people who meet the inclusion criteria and gave informed consent to participate in the study are selected. The Online randomization method is used to create randomization sequences. The randomization unit is an individual, and the Graphpad website is the randomization tool. In order to allocation concealment, central randomization method is used. That is, the randomization sequence is provided to the Kolehdoz center, and the researcher, based on the order in which the participants enter the study, communicates with the relevant center and, in the case of the random allocation of the participant, is assigned to the participant.
Communication methods include the use of phone or text messages.

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 University of Social Welfare and Rehabilitation Sciences

Street address

Kodakyan Ave., Daneshjoo Blvd., Evin

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Tehran

Postal code

1985713834

Approval date

2020-02-25, 1398/12/06

Ethics committee reference number

IR.USWR.REC.1399.015

Health conditions studied

1

Description of health condition studied

Anxiety Disorders

ICD-10 code

F40

ICD-10 code description

Phobic anxiety disorders

2

Description of health condition studied

Childhood Trauma

ICD-10 code

F93.9

ICD-10 code description

Childhood emotional disorder, unspecified

Primary outcomes

1

Description

Anxiety level based on Spielberger's Inventory (STAI)

Timepoint

Before the intervention, 2 weeks after the intervention, 2 months later in the follow-up

Method of measurement

Spielberger's Anxiety Questionnaire (STAI)

Secondary outcomes

1

Description

Depression score

Timepoint

Before the intervention, 2 weeks after the intervention, and 2-month follow-up

Method of measurement

Beck Depression Inventory-II (BDI-II)

2

Description

Posttraumatic Cognitions

Timepoint

Before the intervention, 2 weeks after the intervention, and 2-month follow-up

Method of measurement

Posttraumatic Cognitions Inventory- 9 item (PTCI-9)

3

Description

Coping Strategies

Timepoint

Before the intervention, 2 weeks after the intervention, and 2-month follow-up

Method of measurement

COPE-brief

4

Description

Emotion Dysregulation

Timepoint

Before the intervention, 2 weeks after the intervention, and 2-month follow-up

Method of measurement

Difficulties in Emotion Regulation Scale (DERS-16)

Intervention groups

1

Description

Intervention group: TARGET Group Therapy. TARGET (Trauma Affect Regulation: Guide for Education and Therapy) is one of the new methods of cognitive-behavioral therapy, useful for traumatic disorders. This method trains emotional self-regulation skills for survivors of trauma. This program includes 7 skills, called 7 steps towards FREEDOM, and each of the FREEDOM letters is representative of one skill. According to the group's Manual, the patients participate in 10 sessions (90-minute each session) of emotional self-regulation skills and stress management. These sessions hold once per week.

Category

Treatment - Other

2

Description

Control group: Psychiatric medications. Patients with anxiety disorders who visit a psychiatrist receive their medications depending on the type and severity of the disorder. The most common prescriptions for these patients are Citalopram 20, once per night; Chlorodiazepoxide 10, once per night; S Citalopram 10, once per night; Clonazepam 1, once per night; Gabapentin 100 capsules, consuming in the morning, noon, and at night. The duration of usage, depending on the severity of the disorder and after the control of symptoms, lasts for six months to one year in for stabilization.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Dr. Manteghi

Full name of responsible person

Ali akhoundpour Manteghi

Street address

First Floor, Nikan building, Koohsangi 6, Kouhsangi

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Khankeh

Street address

kodakyar Ave., daneshjo Blvd.,Evin

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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

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

Full name of responsible person

Narges Barzgar

Position

Msc Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The sensitivity of trauma and confidentiality of patients' information

Study Protocol

No - There is not 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable