Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Traite 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); Ṡevere 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 Anxiey 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 GraphpaPad website is the randomization tool. In order to allocation concealment, central randomization method is used. That is, the randomization sequence is provided to the Kolahdooz 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

kodakyar Ave., daneshjo Blvd.,Evin

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

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 of Spiel Berger's Inventory (STAI)

Timepoint

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

Method of measurement

Spiel Berger'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

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Hamidreza Khankeh
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kodakyar Ave., daneshjo Blvd.,Evin
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hamid.khankeh@ki.se
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
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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