Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of trauma-focused cognitive-behavioral therapy(TF-CBT) on adolescents' psychological and cognitive structures with complex post-traumatic stress disorder(CPTSD).

Protocol summary

Study aim

The effectiveness of trauma-focused cognitive-behavioral therapy on body image, trauma-related memory quality, self-harm, emotion regulation, and Dissociative experiences in adolescents with complex post-traumatic stress disorder.

Design

A clinical trial study with a control group of Parallel groups, one-blind, randomized groups was performed on 32 people, and random generator software was used for randomization.

Settings and conduct

The present study is applied in terms of purpose and available sampling method in the data collection method. This study is a single-blind clinical trial with a control and experimental group. First, the International Trauma Questionnaire for adolescents with trauma is standardized to obtain valid data, and then to conduct research, preferably a psychologist By referring to the forensic medicine center and psychology clinic of Taleghani hospital in Tehran, examines the patients' files. By determining the admission criteria and considering the International Trauma Questionnaire and clinical interview score, people diagnosed with post-traumatic stress disorder are complicated. , Are selected using the available sampling method in 1401 and are randomly divided into experimental and control groups.

Participants/Inclusion and exclusion criteria

Willingness to participate in research. Do not take psychiatric drugs. Do not have mental disorders. Do not have suicidal thoughts. Simultaneous participation in psychological intervention. 2 consecutive absences.

Intervention groups

The experimental group receives trauma-focused cognitive therapy according to a 12-session protocol.

Main outcome variables

Self-harm- emotion regulation-Body image-Trauma-related memory quality-Dissociative experiences.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201009048974N4**
Registration date: **2022-05-07, 1401/02/17**
Registration timing: **prospective**

Last update: **2022-05-07, 1401/02/17**
Update count: **0**

Registration date

2022-05-07, 1401/02/17

Registrant information

Name
Maryam Bakhtiari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effectiveness of trauma-focused cognitive-behavioral therapy(TF-CBT) on adolescents' psychological and cognitive structures with complex post-traumatic stress disorder(CPTSD).

Public title
The effectiveness of trauma-focused cognitive-behavioral therapy in adolescents with complex post-traumatic stress disorder.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Minimum age 12 and maximum 18 years. To obtain the desired score in the International Trauma Questionnaire (to diagnose CPTSD, in addition to getting the required score in PTSD clusters, the person must have a score equal to or higher than 10 in the DSO cluster for items AD5-AD1 or a score similar to AD6-AD9 or Above 10, score NSC equal to or higher than eight and score DR points equal to or higher than 6). Not having adolescents with mental disorders requiring immediate treatment such as substance abuse and psychotic disorders based on clinical interview. Lack of intense thinking about self-harm or suicide. Not participating in psychological interventions during the last year (not participating in at least five psychotherapy sessions). Willingness to participate in research. Do not use psychiatric drugs.
Exclusion criteria:
Two consecutive absences in the process of meetings. Thinking about suicide during the research Adolescents suffer from mental disorders requiring immediate treatment, such as substance and alcohol use disorders and psychotic disorders during the study Simultaneous participation in another psychotherapy program.

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be a simple Randomization method. The random unit is individuals.32 Adolescents with complex post-traumatic stress disorder will be divided into intervention and control groups by the software Exel software using Rand. in this way, a table of random numbers is prepared, and the Randbetween function is created. The adolescents are divided into two groups of 16 people, respectively.

Blinding (investigator's opinion)
Single blinded

Blinding description
The outcome assessor in data collection after the intervention and the analysts will be unaware of the study's objectives.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Iran - Tehran - Shahid Chamran Highway Yemen Street - Shahid Arabi Street - next to Ayatollah Taleghani Hospital - Shahid Beheshti School of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2022-03-08, 1400/12/17

Ethics committee reference number
IR.SBMU.MSP.REC.1400.830

Health conditions studied

1

Description of health condition studied
Complex post-traumatic stress disorder

ICD-10 code
F43.1

ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
self-harm

Timepoint
Beginning of the study (before the intervention) -6 months after the intervention.

Method of measurement
Sanson et al. Self -harm Questionnaire (SHI).

2

Description
Difficulty regulating excitement
Timepoint
Beginning of the study (before the intervention) -6 months after the intervention.
Method of measurement
Gretz and Roemer Emotion Difficulty Questionnaire (DERS).

3

Description
Bode Image
Timepoint
Beginning of the study (before the intervention) -6 months after the intervention.
Method of measurement
Littleton.Body Image Fear Questionnaire (BICI)

4

Description
Trauma-related memory quality
Timepoint
Beginning of the study (before the intervention) -6 months after the intervention.
Method of measurement
Meiser-Stedman. Trauma Memory Quality Questionnaire (TMQQ).

5

Description
Dissociative experiences
Timepoint
Beginning of the study (before the intervention) -6 months after the intervention.
Method of measurement
Bernstein and Carlson. Dissociative Experiences Scale (DES-II)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the experimental group, trauma-focused cognitive therapy is conducted according to the protocol of Cohen et al. Their treatment routine is 12 sessions of 45 minutes, once a week as an individual, which will be performed by a psychologist who is a doctoral student in clinical psychology under the supervision of a tutor. This method has been developed as a step-by-step approach that includes the following components: 1- psychoeducation and parenting skills, 2- Relaxation skills, 3- Emotional adjustment and expression, 4- Cognitive processing and coping and trauma narration, 6- Trauma reminders in Body, 7- Joint parent-child therapy sessions, 8- Strengthening security and 9- Future growth.
Category
Treatment - Other

2

Description
Control group: Initially, the control group did not receive any intervention, and only the results of their assessments performed by the questionnaire will be compared with the intervention group. At the end of the study, the trauma-focused cognitive-behavioral intervention will be completed in 12 individual 45-minute sessions according to the Cohen protocol.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Homa Shahkaram
Street address
Psychology Group, Floor4, Taleghani hospital, Erabi Ave., Yaman Ave., Chamran highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afsin Zarghi
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Vice-Chancellor of Research Affairs,Shahid Beheshti University of Medical Sciences, Next to Taleghani hospital, Erabi Ave., Chamran highway
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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Bakhtiari

Position

Professor

Latest degree

Ph.D.

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

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