

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### The efficacy of Trauma-focused cognitive behavioral therapy on reducing trauma symptoms and improving cognitive function in children with posttraumatic stress symptoms

#### Protocol summary

##### Study aim

The efficacy of Trauma-focused cognitive behavioral therapy on reducing trauma symptoms and improving cognitive function in children with posttraumatic stress symptoms

##### Design

Clinical trial with a control group (n = 17) and an intervention group (n = 17), sample size including 34 subjects, randomized through rolling the dice(Eligible individuals are divided into control and intervention groups by rolling the dice).

##### Settings and conduct

Due to the prevalence of Covid-19 disease, sampling Sampling will be done in absentia and through virtual pages(Rubika, Instagram, WhatsApp). Sampling is done among the people who contact the researcher and want to participate in the research according to the entry and exit criteria.

##### Participants/Inclusion and exclusion criteria

Entry criteria:1-Trauma history (grief,sexual abuse,natural disasters,accidents); 2-Having symptoms associated with trauma and post traumatic stress; 3- Being in the range of 7 to 13 years; 4-Not attending psychotherapy courses for at least one year ago Exit criteria: 1-Simultaneous diagnosis of autism spectrum disorder, intellectual disorder, childhood psychosis, major depressive disorder in childhood, severe childhood mania, conduct disorder, severe bipolar disorder; 2-Acute psychiatric disorder of parents participating in treatment; 3-Use any psychotropic drugs; 4-Need psychiatric emergencies.

##### Intervention groups

Intervention group: Individuals in this group receive 16 sessions of 90 minutes, three sessions per week, for trauma-based cognitive-behavioral therapy. In this study, a 16-session protocol of this treatment was used. Control group: During the study, members of this group are on

the waiting list and after completion, they receive the same treatment as the intervention group.

##### Main outcome variables

Trauma symptoms; attention; inhibition

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190701044063N1**

Registration date: **2021-02-11, 1399/11/23**

Registration timing: **retrospective**

Last update: **2021-02-11, 1399/11/23**

Update count: **0**

##### Registration date

2021-02-11, 1399/11/23

##### Registrant information

##### Name

Negar Bagher

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3631 4479

##### Email address

negar7178@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2020-07-20, 1399/04/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The efficacy of Trauma-focused cognitive behavioral therapy on reducing trauma symptoms and improving cognitive function in children with posttraumatic stress symptoms

**Public title**  
Childhood trauma treatment

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Trauma history (grief,sexual abuse,natural disasters,accidents) Having symptoms associated with trauma and post traumatic stress Being in the range of 7 to 13 years Not attending psychotherapy courses for at least one year ago  
**Exclusion criteria:**  
Simultaneous diagnosis of autism spectrum disorder, intellectual disorder, childhood psychosis, major depressive disorder in childhood, severe childhood mania, conduct disorder, severe bipolar disorder Acute psychiatric disorder of parents participating in treatment Use any psychotropic drugs Need psychiatric emergencies

**Age**  
From **7 years** old to **13 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Eligible individuals are divided into control and intervention groups by rolling the dice.

**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**  
Ethics Committee in Research, University of Social Welfare and Rehabilitation Sciences  
**Street address**  
Koodak Yar Deadlock, Daneshjoo Blvd, Evin, Tehran, University of Social Welfare and Rehabilitation Sciences  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
۱۹۸۵۷۱۳۸۳۴  
**Approval date**  
2020-02-25, 1398/12/06  
**Ethics committee reference number**  
IR.USWR.REC.1399.019

## Health conditions studied

1

**Description of health condition studied**  
Post-traumatic stress disorder  
**ICD-10 code**  
F43.1  
**ICD-10 code description**  
Post-traumatic stress disorder

## Primary outcomes

1

**Description**  
Post-traumatic Stress Symptoms  
**Timepoint**  
Before intervention, 3 to 7 days after intervention  
**Method of measurement**  
Parent Report of Post-traumatic Stress Symptoms, Child Report of Post-traumatic Symptoms

2

**Description**  
Cognitive function  
**Timepoint**  
Before intervention, 3 to 7 days after intervention  
**Method of measurement**  
Emotional stroop

## Secondary outcomes

empty

## Intervention groups

1

**Description**

Intervention group: Individuals in this group receive 16 sessions of 90 minutes, three sessions per week, for trauma-based cognitive-behavioral therapy. In this study, a 16-session protocol of this treatment was used. Session 1: Psychological education. Session 2: Parenting. Session 3: Relaxation. Session 4: Affect Identification & Regulation. Sessions 5 and 6: Cognitive Coping. Sessions 7 and 8: Trauma Processing and Narration Part I. Sessions 9, 10, and 11: Trauma Processing and Narration Part II. Sessions 12, 13, and 14: in vivo mastery. Session 15: Conjoint Parent-Child Sessions. Session 16: Enhancing Safety & Future Development

**Category**

Treatment - Other

**2****Description**

Control group: During the study, members of this group are on the waiting list and after completion, they receive the same treatment as the intervention group.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Nezam Mafi Rehabilitation Medical Center

**Full name of responsible person**

Negar Bagher

**Street address**

1st W, W, South Jannat Abad, Tehran, Tehran Province

**City**

Karaj

**Province**

Tehran

**Postal code**

1969615533

**Phone**

+98 21 4403 8755

**Email**

negar7178@yahoo.com

**2****Recruitment center****Name of recruitment center**

social media

**Full name of responsible person**

Negar Bagher

**Street address**

Alborz, Mohammadshahr, Homayoun Villa, Alavi St., Daneshvar Alley, Naghsh Jahan Building 3, Unit 25

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318461211

**Phone**

+98 26 3631 4479

**Email**

negar7178@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Hamid Reza Khankeh

**Street address**

Alborz, Mohammadshahr, Homayoun Villa, Alavi St., Daneshvar Alley, Naghsh Jahan Building 3, Unit 25

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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**

Negar Bagher

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Negar Bagher

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

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University of social welfare and rehabilitation sciences

**Full name of responsible person**

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**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Psychology

**Street address**

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**Email**

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

release schedule is not yet known.

**When the data will become available and for how long**

After completing the research

**To whom data/document is available**

Researchers and scientific centers

**Under which criteria data/document could be used**

Trauma and treatment centers

**From where data/document is obtainable**

negar7178@yahoo.com

**What processes are involved for a request to access data/document**

The request will be checked by email and sent if necessary.

**Comments**