Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 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

City

Karaj

Province

Alborz

Postal code

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

City

Tehran

Province

Tehran

Postal code

318461211

Phone

+98 26 3631 4479

Email

negar7178@yahoo.com

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

Alborz, Mohammadshahr, Homayoun Villa, Alavi St.,

Daneshvar Alley, Naghsh Jahan Building 3, Unit 25

City
Karaj

Province
Alborz

Postal code
318461211

Phone
+98 26 3631 4479

Email
negar7178@yahoo.com

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
Psychology

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

City
Karaj

Province
Alborz

Postal code
318461211

Phone
+98 26 3136 4479

Email
negar7178@yahoo.com

Person responsible for updating data

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

City
Karaj

Province
Alborz

Postal code
318461211

Phone
+98 26 3631 4479

Email
negar7178@yahoo.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
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