

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of traumatic cognitive-behavioral therapy on the reduction of posttraumatic stress syndrome and behavioral problems in surviving children from the earthquake in Kermanshah

Protocol summary

Study aim

Assessing the effect of early trauma-focused cognitive behavioral method on post-traumatic stress disorder and behavioral problems in children who survived of the earthquake in Kermanshah city

Design

This study is an open label clinical trial. 60 persons will be selected in available method and randomly will be divided into two groups (30 patients experimental group and 30 patients in control group).

Settings and conduct

The study population will consist of all earthquake children in Kermanshah city that 60 persons will be selected in available method and randomly will be divided into two groups (30 patients experimental group and 30 patients in control group). The experimental and control group will complete the Post traumatic stress disorder and children's behavioral problems questionnaires. The experimental group will receive group training trauma-focused cognitive behavioral therapy 8 sessions and the control group will not receive any tests. Both groups will be compared in terms of Post traumatic stress disorder and behavioral problems. After the end of the study in order to maintain ethics and the rights of research participants, the control group also will receive group early trauma-focused cognitive behavioral method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: lack of serious psychiatric disorders.
Exclusion criteria: The absence of comorbid psychiatric disorders symptoms.

Intervention groups

The experimental group will undergo trauma-focused cognitive behavioral therapy in 8 sessions per hour

Main outcome variables

Post traumatic stress disorder and behavioral problems

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160717028967N6**

Registration date: **2018-05-17, 1397/02/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-17, 1397/02/27**

Update count: **0**

Registration date

2018-05-17, 1397/02/27

Registrant information

Name

Safora Salemi

Name of organization / entity

Shahid Chamran University of Ahvaz

Country

Iran (Islamic Republic of)

Phone

+98 83 3821 1001

Email address

e.mahmoudi@cobeldarou.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of traumatic cognitive-behavioral therapy on the reduction of posttraumatic stress syndrome and behavioral problems in surviving children from the earthquake in Kermanshah

Public title
Treatment for surviving children from the earthquake

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
lack of serious psychiatric disorders
Exclusion criteria:
The absence of comorbid psychiatric disorders symptoms

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

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 Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medic Building No.2, Shahid Beheshti Blvd, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Approval date

2017-12-13, 1396/09/22

Ethics committee reference number

kums.rec.1396.509

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 disorder

Timepoint

Baseline and two months after intervention

Method of measurement

Post traumatic stress disorder questionnaire

2

Description

behavioral problems

Timepoint

Baseline and two months after intervention

Method of measurement

behavioral problems questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will receive trauma-focused cognitive-behavioral intervention in 8sessions.

Category

Behavior

2

Description

Control group: The control group will not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Schools

Full name of responsible person

Sahnaz Mahmoudi

Street address

Noor School, Resalat Town, Kermanshah

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6610785471

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

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Building No.2, Shahid Beheshti Blvd, Vice Chancellor
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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Vahid Farnia

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Safora Salemi

Position

teacher

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Faculty of Social Science, Opp to Ayatollah Taleghani
Hospital, Shahid Beheshti Blvd, Kermanshah

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

I have no plans at this time

When the data will become available and for how long

I have no plans at this time

To whom data/document is available

I have no plans at this time

Under which criteria data/document could be used

I have no plans at this time

From where data/document is obtainable

I have no plans at this time

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

I have no plans at this time

Comments