Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 lable clinical trial. 60 persons will 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 consisted of all earthquake children in Kermanshah city that 60 persons will 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 completed the Post traumatic stress disorder and children's behavioral problems questionnaires. The experimental group will received group training trauma-focused cognitive behavioral therapy 8 sessions and the control group will not receive any tests. both groups will 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,Control group also will received 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
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Iran (Islamic Republic of)
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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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teacher

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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