Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Integrating Trauma-Focused Cognitive Behavioral Therapy with Foster Care Children's Lived Experience of Complex Trauma, and Comparing its Effectiveness with Trauma-Focused Cognitive Behavioral Therapy on Complex Posttraumatic Stress Disorder, Behavioral Disorder, Alexithymia, and Resilience

Protocol summary

Study aim

The aim of the present trial is to investigate the effectiveness of the integrated intervention of trauma-focused cognitive behavioral therapy with the lived experience of complex trauma in foster care children compared to trauma- focused cognitive behavioral therapy on complex post-traumatic stress, behavioral disorder, alexythimia, resilient

Design

The clinical trial has a control group, one-sided blind, is randomized, and a table of random numbers is used for randomization.

Settings and conduct

Children from quasi-families with complex trauma experience will be selected by purposive sampling method and screened for eligibility in the research. Then they will be randomly assigned to groups. Participants will be evaluated before and after the intervention. The study is one-sided blind and only the participants are unaware of the allocation of the study groups

Participants/Inclusion and exclusion criteria

1. Living in foster care 2. Complex trauma experience 3. 9 to 11 years old 4. Not receiving psychological treatment and drug treatments at the same time as the research is being conducted 5. Desire to participate in research 6. Obtaining a clinical score in questionnaires of complex post-traumatic stress, behavioral disorder and alexythimia

Intervention groups

This trial is divided into three groups: intervention of trauma- focused cognitive behavioral therapy, integrated intervention and control group. The treatment is done on the intervention groups and the control group does not receive treatment, but due to the preservation of ethics in the research, this group is placed on the waiting list and after the end of the research, they receive the necessary treatment.

Main outcome variables

on Complex Posttraumatic Stress Disorder, Behavioral Disorder, Alexithymia, and Resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211213053378N1**
Registration date: **2023-07-11, 1402/04/20**
Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**
Update count: **0**

Registration date

2023-07-11, 1402/04/20

Registrant information

Name

Zivar Soltani Ghahfarokhi

Name of organization / entity

University of isfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01
Expected recruitment end date
2023-11-06, 1402/08/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Integrating Trauma-Focused Cognitive Behavioral Therapy with Foster Care Children's Lived Experience of Complex Trauma, and Comparing its Effectiveness with Trauma-Focused Cognitive Behavioral Therapy on Complex Posttraumatic Stress Disorder, Behavioral Disorder, Alexithymia, and Resilience

Public title
Therapy of Foster Care Children's Lived Experience of Complex Trauma
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Complex trauma experience Age 9-11 Living in Foster Care
Exclusion criteria:
Receive any psychological treatment and medication at the same time as conducting research Not have Clinical score in complex post-traumatic stress, behavioral disorders and alexythimia questionnaires Dissatisfaction to participate in research
Age
From **9 years** old to **11 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
In this trial, simple individual randomization method will be used. Randomization will be done using a table of random numbers and by someone other than the researchers, and therefore, allocation concealment will be done. For each participant, a number will be selected from the random table. With his eyes closed, this person will put his finger randomly on a part of the table and choose the corresponding number. If the 1st digit of this number is 1, 2 or 3, that participant will be assigned to the combined intervention group. If the 1st digit of this number was 4, 5, or 6, that participant would be assigned to the trauma-focused cognitive-behavioral therapy group. Finally, if the 1st digit of this number was 7, 8 or 9, that participant will be assigned to the control group. It should be noted that if the target number was zero, or if the group corresponding to a number was already filled, another number will be extracted from the table.
Blinding (investigator's opinion)
Single blinded
Blinding description
The participants and officials of quasi-family centers do not know which groups are the intervention group and which group is the control group, but they are aware that they are participating in a clinical trial and participate in this research with full consent.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Isfahan
Street address
Department of Psychology, University of Isfahan, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673441
Approval date
2021-11-24, 1400/09/03
Ethics committee reference number
IR.UI.REC.1400.087

Health conditions studied

1

Description of health condition studied
Posttraumatic Stress Disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
Complex Posttraumatic Stress Disorder
Timepoint

Before and after the intervention

Method of measurement

International Trauma Questionnaire

2

Description

Behavioral Disorder

Timepoint

Before and after the intervention

Method of measurement

Child Behavior Checklist (CBCL)

3

Description

Alexithymia

Timepoint

Before and after the intervention

Method of measurement

Alexithymia questionnaire for children

4

Description

Resilience

Timepoint

Before and after the intervention

Method of measurement

Resiliency scales of children and adolescents (RSCA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1- Integrating Trauma-Focused Cognitive Behavioral Therapy with Foster Care Children's Lived Experience of Complex Trauma, which was prepared based on the achievements of the qualitative part of the doctoral dissertation in psychology, and its validity was approved by a group of psychological experts in the field of psychological trauma. This intervention will be held in the form of 12 two-hour sessions per week.

Category

Behavior

2

Description

Intervention group: 2- Trauma-Focused Cognitive Behavioral Therapy(TF-CBT; Cohen et al., 2006) and will be held as 12 two-hour sessions per week.

Category

Behavior

3

Description

Control group: They do not receive any intervention during the research, but they are on the waiting list and after the research is completed, they receive the appropriate intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

State Welfare Organization of Isfahan province

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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 Isfahan

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 Isfahan
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Zivar soltani ghahfarokhi
Position
PhD student in 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
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The treatment protocol and study results will be available to other in the dissertation and article.
When the data will become available and for how long
After the publication of the results, it will be available forever in the form of a thesis.
To whom data/document is available
For researchers and clinicians
Under which criteria data/document could be used
Scientific and non-commercial use
From where data/document is obtainable
Theses of Isfahan University and sending email to the following address: zsoltani1516@gmail.com

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

After the email to the researcher and if the person is a researcher and ballinger.

Comments