

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, alexythymia, 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 alexythymia

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)

Phone

+98 31 3630 3789

Email address

zsoltani@edu.ui.ac.ir

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 alexythymia 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

Isfahan

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
Zivar soltani ghahfarokhi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Isfahan
Full name of responsible person
Rasoul Rokni zade
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rokni@sci.ui.ac.ir
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

Full name of responsible person

Zivar soltani ghahfarokhi

Position

PhD student in psychology

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

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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 FormUndecided - 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/documentThe 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 obtainableTheses 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