Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of Cognitive Behavioral Therapy (CBT) on Post-Traumatic Stress, Mental Health, and Depression in Neglected and Orphaned Adolescents Living in Residential Care Centers in Shiraz

Protocol summary

Study aim

The Effectiveness of Cognitive Behavioral Therapy (CBT) on Post-Traumatic Stress, Mental Health, and Depression in Neglected and Orphaned Adolescents

Design

A controlled clinical trial with parallel, unblinded, randomized groups on 30 individuals. The rand function of Excel software was used for randomization.

Settings and conduct

The method of the present study was a quasi-experimental study with a pre-test-post-test design with a control group. The statistical population of this study included all neglected and unsupervised adolescents living in care centers in Shiraz in 1405. This population included five official care centers for adolescents, with a total of 32 eligible individuals between the ages of 12 and 18

Participants/Inclusion and exclusion criteria

Meeting diagnostic criteria for depressive disorders; age 12 to 18 years; parental consent; individual availability

Intervention groups

In the present study, the cognitive-behavioral treatment protocol for depression was used. This treatment protocol is designed based on the cognitive-behavioral approach and is presented in the form of a structured program consisting of 12 treatment sessions. The initial framework of this program was presented by Munoz and Miranda in the book "Cognitive-Behavioral Treatment of Depression" and was developed in research projects at the University of California, San Francisco and the Prevention Centers affiliated with Palo Alto University. The control group received no intervention and was placed on a waiting list for treatment.

Main outcome variables

Post-traumatic stress disorder score; Mental health score; Depression score

General information

Reason for update

Acronym

CBT

IRCT registration information

IRCT registration number: **IRCT20260509069302N1**
Registration date: **2026-05-19, 1405/02/29**
Registration timing: **prospective**

Last update: **2026-05-19, 1405/02/29**
Update count: **0**

Registration date

2026-05-19, 1405/02/29

Registrant information

Name

Seyede Tarah Hosseini Haghighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 917 312 7361

Email address

tarah.hosseini.h@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-20, 1405/02/30

Expected recruitment end date

2026-06-20, 1405/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effectiveness of Cognitive Behavioral Therapy (CBT) on Post-Traumatic Stress, Mental Health, and Depression in Neglected and Orphaned Adolescents Living in Residential Care Centers in Shiraz

Public title
Cognitive Behavioral Therapy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having diagnostic criteria for depressive disorders Age 12 to 18 years Parental consent Availability of the individual
Exclusion criteria:
Presence of severe psychiatric disorders such as psychotic disorders or bipolar disorder based on medical records or clinical assessment Cognitive or intellectual impairment that interferes with understanding or participation in cognitive behavioral therapy sessions Concurrent participation in structured psychological therapy similar to the intervention at the time of enrollment Changes in psychiatric medication within the past four weeks Presence of severe or unstable medical illness that prevents participation in therapy sessions Lack of informed consent from the legal guardian or the adolescent participant
Age
From **12 years** old to **18 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 participants will be enrolled after providing informed consent. Participants will then be randomly assigned to either the intervention group (cognitive behavioral therapy) or the control group using simple randomization based on a computer-generated random numbers table. The allocation ratio will be 1:1.
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 Firozabad Azad University
Street address
No 34, Fadak Blvd
City
shiraz
Province
Fars
Postal code
7156787498
Approval date
2024-05-30, 1403/03/10
Ethics committee reference number
IR.IAU.M.REC.1403.520

Health conditions studied

1

Description of health condition studied
Depression, post-traumatic stress
ICD-10 code
F32.8
ICD-10 code description
Other depressive episodes

Primary outcomes

1

Description
Post-traumatic stress disorder score measured by a PTSD scale at baseline and after completion of the intervention
Timepoint
Before treatment, after the end of treatment
Method of measurement
Mississippi Questionnaire

2

Description
Score of mental health measured by the General Health Questionnaire (GHQ-28) at baseline and after completion of the intervention
Timepoint
Before treatment, after the end of treatment
Method of measurement
General Health Questionnaire (GHQ-28)

3

Description
Severity of depressive Depression score measured by a depression questionnaire at baseline and after completion of the intervention
Timepoint
Before treatment, after the end of treatment

Method of measurement
Beck depression questionnaire

Secondary outcomes

1

Description
Post-traumatic stress disorder score measured by a PTSD scale at baseline and after completion of the intervention
Timepoint
After the intervention
Method of measurement
Mississippi Questionnaire

2

Description
Score of mental health measured by the General Health Questionnaire (GHQ-28) at baseline and after completion of the intervention
Timepoint
After the intervention
Method of measurement
General Health Questionnaire (GHQ-28)

3

Description
Depression score measured by a depression questionnaire at baseline and after completion of the intervention
Timepoint
After the intervention
Method of measurement
Beck depression questionnaire

Intervention groups

1

Description
Intervention group: Participants in this group will receive group-based Cognitive Behavioral Therapy (CBT). The intervention consists of eight weekly sessions lasting 60 minutes each, delivered by a trained therapist. The sessions include cognitive restructuring, identification and modification of dysfunctional thoughts, coping skills training, and emotion regulation techniques.
Category
Behavior

2

Description
Control group: Participants in this group will receive routine services provided by the residential center and will not receive the CBT intervention during the study period. After completion of the study, the intervention will be offered if desired.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz city care centers
Full name of responsible person
Seyedeh Tara Hoseinihaghighi
Street address
Fadak st.
City
Shiraz
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Fars
Postal code
7156787498
Phone
+98 71 3725 8261
Email
tarah.hosseini.h@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Behboudi Green Villa Maintenance Center
Full name of responsible person
Hadi Daneshparvar
Street address
Vilay sabz, kavar Street, Modares Blvd
City
shiraz
Province
Fars
Postal code
7166694696
Phone
+98 71 3272 5447
Email
5480112082@iau.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Behboudi Green Villa Maintenance Center
Proportion provided by this source
50
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

2

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Hadi Daneshparvar
Street address
Vilay sabz center, kavarstreet, Modars Blvd
City
shiraz
Province
Fars
Postal code
7166694696
Phone
+98 71 3273 5447
Email
ramin3677s@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Seyede Tarah
Position
Psychologist
Latest degree
Master
Other areas of specialty/work
Psychology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

No - There is not 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

Only part of the data, such as information related to the main outcome or the like, can be shared.

When the data will become available and for how long

Access period starts from March 2027

To whom data/document is available

The data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

General data is for guidance only.

From where data/document is obtainable

I am Seyyed Tara Hosseini Haghighi - Rost Psychological Counseling and Services Center - Shiraz, North Motahari Boulevard - Ibn Sina Medical Building - Second Floor, Unit 8 - 09173127361

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

The applicant must send his/her application with a complete explanation of why and how the work is being done to my email address tarah.hosseini.h@gmail.com

Comments