Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) on Emotional Security, Loneliness, Alexithymia, and Well-Being in Adolescents with Divorced Parents Living in Kashan

Protocol summary

Study aim

Determining the Effectiveness of Trauma-Focused Cognitive-Behavioral Therapy (TF-CBT) on Emotional Security, Loneliness, Alexithymia, and Psychological Well-Being in Adolescents of Divorce in Kashan City

Design

This is a non-randomized, no blinding, parallel-group controlled clinical trial with an experimental group and a control group, comprising 32 participants in each group

Settings and conduct

This study is conducted at the School of Medicine, Kashan University of Medical Sciences. . Participants are non-randomly assigned to either an experimental group or a control group. The experimental group receives 12 weekly 45-minute sessions of trauma-focused cognitive-behavioral therapy, while the control group receives no intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1. Adolescents between 12 and 18 years of age 2. At least 6 months and at most 5 years have passed since the parents' divorce3. A score below 27 on the Emotional Security Scale (from the Emotional Security Questionnaire)4. Reporting parental divorce as a traumatic event during the initial interview Exclusion Criteria 1. Non-cooperation or failure to complete assigned therapeutic tasks.2. Lack of commitment to attend sessions or more than two consecutive/overall absences.3. Emergence of suicidal ideation reported by the participant during the study.

Intervention groups

Adolescents (12–18) from divorced families were selected via purposive sampling. The experimental group received 12 TF-CBT sessions while controls received no intervention. Post-study, treatment was offered to the control group to maintain therapeutic equity.

Main outcome variables

alexithymia, loneliness, emotional security, and psychological well-being,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260616069840N1**
Registration date: **2026-07-19, 1405/04/28**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-19, 1405/04/28**
Update count: **0**

Registration date

2026-07-19, 1405/04/28

Registrant information

Name

Reyhaneh Alsadat Sherafat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4409 3573

Email address

sherafat-r@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-11, 1405/04/20

Expected recruitment end date

2026-09-23, 1405/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effectiveness of Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) on Emotional Security, Loneliness, Alexithymia, and Well-Being in Adolescents with Divorced Parents Living in Kashan

Public title
The Effectiveness of Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) on Emotional Security, Loneliness, Alexithymia, and Well-Being in Adolescents with Divorced Parents Living in Kashan

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Adolescents between 12 and 18 years of age At least 6 months and at most 5 years have passed since the parents' divorce A score below 27 on the Emotional Security Scale (from the Emotional Security Questionnaire) Reporting parental divorce as a traumatic event during the initial interview Absence of severe psychiatric disorders requiring medication or hospitalization (e.g., severe psychotic disorders) Informed consent from both the adolescent and their legal guardian, along with a willingness to participate in the study Basic literacy skills to complete questionnaires or participate in exercises Basic literacy skills to complete questionnaires or participate in exercises Not receiving concurrent psychological intervention

Exclusion criteria:
Development of an acute psychiatric condition that prevents continuation of treatment Occurrence of suicidal ideation reported by the participant Occurrence of an incident that prevents or disrupts attendance at sessions

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: **64**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 Kashan University of Medical Sciences

Street address
Kashan - Qotb-e Ravandi Boulevard - Pezeshk Boulevard (University Campus)

City
kashan

Province
Isfehan

Postal code
8713783976

Approval date
2026-05-24, 1405/03/03

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1405.037

Health conditions studied

1

Description of health condition studied
children of divorce

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Emotional Security

Timepoint
Emotional security will be measured at the beginning of the study (before the intervention) and at the end of the study, after receiving 12 sessions of treatment.

Method of measurement
Security in the Family System (SIFS)

Secondary outcomes

1

Description
Loneliness

Timepoint
Loneliness will be measured at the beginning of the study (before the intervention) and at the end of the study, after receiving 12 sessions of treatment

Method of measurement
UCLA Loneliness Scale

2

Description
Alexithymia
Timepoint
Alexithymia will be measured at the beginning of the study (before the intervention) and at the end of the study, after receiving 12 sessions of treatment.
Method of measurement
Toronto Alexithymia Scale (TAS-20)

3

Description
Well being
Timepoint
Psychological well-being will be measured at the beginning of the study (before the intervention) and at the end of the study, after receiving 12 sessions of treatment
Method of measurement
Multidimensional Well being in Youth Scale (MWYS)

Intervention groups

1

Description
Intervention group: Adolescents aged 12 to 18 years who are children of divorce.In this group, Trauma-Focused Cognitive Behavioral Therapy (TF-CBT) will be delivered in 12 sessions of 45 to 60 minutes for the adolescents. Additionally, several sessions will be conducted for their guardians or parents.
Category
Treatment - Other

2

Description
Control group: Adolescents aged 12 to 18 years who are children of divorce will not receive any treatment and will remain on a waitlist
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashan University of Medical Sciences
Full name of responsible person
Reyhaneh Sadat Sherafat
Street address
Kashan - Qotb-e Ravandi Boulevard - Pezeshk Boulevard (University Campus)
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Maryam Hashemi Moghaddam
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Kashan - Qotb-e Ravandi Boulevard - Pezeshk Boulevard (University Campus)
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Reyhaneh Sadat Sherafat
Position
Master's Student in Clinical Psychology
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 11, 5th Unit, East Banafsheh Alley, South Salimi

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1481746851

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Person responsible for scientific inquiries

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Full name of responsible person
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Latest degree
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Web page address

Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Master Student in Clinical Psychology

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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Postal code
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Email
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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
Yes - There is 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
Individual participant data from this study will be shared after the trial's completion in a de-identified manner, without any identifiable information. Access to raw data related to the primary outcome variables, including loneliness scores, alexithymia, emotional security, and psychological well-being, will be made available upon request to qualified researchers. Under no circumstances will participants' identifiable information be accessible to individuals outside the research team at any stage.

When the data will become available and for how long
The access period begins 6 months and 2 yeras after the results are published

To whom data/document is available
De-identified individual participant data will be made available to qualified researchers. Requests will be accepted only from investigators affiliated with recognized academic institutions, research centers, or scientific organizations with a clear and relevant research purpose. Requests will be reviewed and approved by the study investigators.

Under which criteria data/document could be used
De-identified individual participant data will be used solely for scientific and non-commercial research purposes. Data use is limited to statistical analyses consistent with or complementary to the objectives of the original study. Commercial use, marketing purposes, or any non-scientific applications are strictly prohibited. Data recipients must maintain confidentiality, avoid any attempt to re-identify participants, and are not permitted to share the data with third parties without written permission from the study investigators. Access will be granted only after approval by the principal investigators and in accordance with ethical research principles.

From where data/document is obtainable
Qualified applicants seeking access to the de-identified data from this study may submit their requests to the

principal investigator, Reyhaneh Sadat Sherafat, or to the supervising professor, Dr. Zahra Zanjanizadeh (Zanjani). Requests will be reviewed on a priority basis via email. If necessary, further correspondence will be conducted through the university where the study was conducted. · Reyhaneh Sadat Sherafat (Principal Investigator): reyhanesadatsherafat1381@gmail.com

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

Upon receipt of a request for access to de-identified individual participant data, the request will be reviewed by the principal investigator and the research team. The first step involves assessing the scientific merit and eligibility of the applicant. If preliminarily approved, the requester will be required to sign a data use agreement, including confidentiality and non-reidentification commitments. After completion of the required documentation, the requested data will be prepared and shared electronically with the applicant. Additional clarifications, if needed, will be handled via email correspondence. The entire process typically takes between 2 to 4 weeks.

Comments