Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effectiveness of Mentalization-Based Treatment (MBT) on Emotion Regulation, Psychological Distress, and Resilience in Adolescents with Childhood Trauma and Externalizing Symptoms

Protocol summary

Study aim

Overall Objective 1. The effectiveness of mentalization-based therapy on emotion regulation, psychological distress, and resilience in adolescents with childhood trauma Sub-objectives 1. Determining the effectiveness of mentalization-based therapy on emotion regulation in adolescents with childhood trauma and externalizing symptoms 2. Determining the effectiveness of mentalization-based therapy on psychological distress in adolescents with childhood trauma and externalizing symptoms 3. Determining the effectiveness of mentalization-based therapy on resilience in adolescents with childhood trauma and externalizing symptoms

Design

This trial was conducted with a quasi-experimental design with a pretest-posttest design with a control group and random assignment in one phase on 40 subjects in the experimental group.

Settings and conduct

This study was conducted over two months, with two 90-minute sessions per week, at the Comprehensive Health Clinic of the Vice Chancellor for Medical Sciences, Shiraz Azad University, without blinding.

Participants/Inclusion and exclusion criteria

Adolescents in the age range (12 to 18 years) Having externalizing symptoms based on the Achenbach Child Behavior Questionnaire Willingness to participate in the research (informed consent)

Intervention groups

This study included two intervention groups (experimental and control groups). The experimental group received an 8-session mindfulness-based intervention, two sessions per week, for two months. The control group was free during this period and did not receive any intervention.

Main outcome variables

Emotional, regulation Psychological and distress Resilience

General information

Reason for update

Acronym

MBT

IRCT registration information

IRCT registration number: **IRCT20260513069386N1**
Registration date: **2026-05-21, 1405/02/31**
Registration timing: **prospective**

Last update: **2026-05-21, 1405/02/31**
Update count: **0**

Registration date

2026-05-21, 1405/02/31

Registrant information

Name

Ailar Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 9125

Email address

ailar.akbari@iau.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-20, 1405/04/29

Expected recruitment end date

2026-09-20, 1405/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Mentalization-Based Treatment (MBT) on Emotion Regulation, Psychological Distress, and Resilience in Adolescents with Childhood Trauma and Externalizing Symptoms

Public title

The Effec of Mentalization Treatment on Emotion Regulation, Psychological Distress, and Resilience

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having externalizing symptoms based on the Achenbach Child Behavioral Inventory Power to participate in the research (informed consent) Adolescents in the age range (12 to 18 years)

Exclusion criteria:

Cancellation of further cooperation Absence of more than two sessions of concurrent participation in similar psychotherapy programs or emotion-based interventions, which could affect the results of the study. History of receiving psychological interventions and taking psychiatric medications within the past 6 months Diagnosis of chronic and severe psychological disorders (major depression, bipolar disorders, conduct disorder, psychotic disorders, and personality disorders)

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, based on the entry criteria, 40 subjects will be selected purposively and then, using a simple random method, the subjects will be assigned to two groups of 20, the experimental and control groups. Regarding the method of drawing lots, one name from each name bag will be placed in the experimental group and the next name will be placed in the control group.

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 Islamic Azad University of Shiraz

Street address

Faculty of Dentistry, Alley 14, South Ghaani Street

City

Shiraz

Province

Fars

Postal code

۷۱۹۵۶۱۵۸۷۸

Approval date

2026-05-13, 1405/02/23

Ethics committee reference number

IR.IAU.SHIRAZ.REC.1405.028

Health conditions studied

1

Description of health condition studied

Emotion Regulation

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Psychological Distress

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Resilience

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Emotion Regulation

Timepoint

Emotional regulation was measured before the intervention began and a second time, two months after the intervention period, was measured at the post-test.

Method of measurement

Gross and John's Emotion Regulation Questionnaire (2003)

2

Description
Psychological Distress
Timepoint
psychological distress was measured before the intervention began and a second time, two months after the intervention period, was measured at the post-test.
Method of measurement
Kessler et al.'s Psychological Distress Questionnaire (2003)

3

Description
Resilience
Timepoint
resilience was measured before the intervention began and a second time, two months after the intervention period, was measured at the post-test.
Method of measurement
Connor and Davidson's Resilience Questionnaire (2003)

Secondary outcomes

1

Description
Childhood trauma
Timepoint
Childhood trauma was measured before the intervention began and a second time, two months after the intervention period, was measured at the post-test.
Method of measurement
Achenbach's Child Behavioral Inventory (CBCL) (1991)

2

Description
externalizing symptoms
Timepoint
externalizing symptoms was measured before the intervention began and a second time, two months after the intervention period, was measured at the post-test.
Method of measurement
Bernstein et al.'s Childhood Trauma Questionnaire (CTQ) (2003)

Intervention groups

1

Description
Intervention group: Intervention group: Based on the mentalization-based therapy intervention approach derived from the Malberg protocol (2021), they will receive 8 intensive sessions (2 hours) over a period of two months (one session per week).
Category
Behavior

2

Description
Control group: After the pre-test, this group was left free for two months and then re-tested.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Rahavard Mokashefe Vojod Clinic
Full name of responsible person
Dr. Hamideh Beik
Street address
Unit 5, 3rd Floor, Hakimi Medical Complex, West Hakimi Street, Molla Sadra
City
Shiraz
Province
Fars
Postal code
7134614151
Phone
+98 917 208 0748
Email
Hamideh.beik59@gmail0com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mohammad Amin Shaygan
Street address
Shiraz Islamic Azad University, 5th km of Sadra Road
City
Shiraz
Province
Fars
Postal code
۷۱۹۶۴۸۴۴۷۱
Phone
+98 71 3641 0041
Email
info@iaushiraz.ac.ir
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

Ailar Akbari

Position

Postgraduate student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

No. 21, Sub-section 16/1, Alley 16, Abavardi Ave, Chamran Blvd.

City

Shiraz

Province

Fars

Postal code

7194744759

Phone

+98 71 3627 9125

Fax

Email

ailar.akbari@iau.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Fatemeh Ghanbari

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Unit 9, 2nd floor, Shiraz Mehr Medical Complex, Alley 6, Shahid Jamali St., Molla Sadra St.

City

Shiraz

Province

Fars

Postal code

۷۱۹۳۶۱۶۱۳۸

Phone

+98 71 9361 6138

Email

ghanbari.f@iau.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ailar Akbari

Position

Postgraduate student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

Street address

No. 21, Sub-section 16/1, Alley 16, Abavardi Ave, Chamran Blvd.

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Fars

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7194744759

Phone

+98 71 3627 9125

Fax

Email

ailar.akbari@iau.ir

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

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All information and data collected, after being de-identified, will be shared to assist in relevant studies and future research.

When the data will become available and for how long

Data access will begin 6 months after the results are published.

To whom data/document is available

Psychology professors, researchers, and students are allowed to request data and other documentation.

Under which criteria data/document could be used

The data will be used to develop future research results

and meta-analyses.

From where data/document is obtainable

Applicants can contact the corresponding author's academic email address to receive the data. ailar.akbari@iau.ir

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

After submitting their application, applicants will be able to receive the data within one month by attaching research documentation demonstrating the necessity of the data to achieve the research goals.

Comments