

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the mindfulness-based cognitive therapy (MBCT) and cognitive- behavioral play therapy (CBPT) on anxiety, attention control and emotional regulation

Protocol summary

2023-12-20, 1402/09/29

Study aim

Comparison of the mindfulness-based cognitive therapy (MBCT) and cognitive- behavioral play therapy (CBPT) on anxiety, attention control and emotional regulation

Design

Multivariate analysis of covariance (MANCOVA) with SPSS software will be used to analyze the data obtained from the research.

Settings and conduct

The intervention is done in the school and as a group control and intervention

Participants/Inclusion and exclusion criteria

- Children 8-12 years old - Not having a physical or mental illness (through the initial screening that will be done by the counselor and school teacher) - A resident of Tehran - Not taking medicine - Not using psychological and psychotherapy services while participating in the program

Intervention groups

(CBPT) Comparison of cognitive therapy based on mindfulness

Main outcome variables

Examining anxiety, controlled attention and emotional regulation of children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230922059488N1**

Registration date: **2023-12-20, 1402/09/29**

Registration timing: **retrospective**

Last update: **2023-12-20, 1402/09/29**

Update count: **0**

Registration date

Registrant information

Name

Habibeh Kholghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 3656

Email address

habibehkholghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the mindfulness-based cognitive therapy (MBCT) and cognitive- behavioral play therapy (CBPT) on anxiety, attention control and emotional regulation

Public title

indfulness-based cognitive therapy (MBCT) and cognitive- behavioral play therapy (CBPT)

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

child
Exclusion criteria:
Having physical and mental illness
Age
From **34 years** old to **34 years** old
Gender
Female
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **42**
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
Environmental research
Street address
Tehran Ave Golha
City
Tehran
Province
Tehran
Postal code
1413874415
Approval date
2023-09-17, 1402/06/26
Ethics committee reference number
IR.IAU.TNB.REC.1402.067

Health conditions studied

1

Description of health condition studied
Disorders of psychological development
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Children's score in anxiety test, cognitive regulation test and controlled attention
Timepoint
he effect of therapeutic intervention after 12 sessions
Method of measurement
questionnaire

Secondary outcomes

1

Description
Children's mental health score
Timepoint
After 12 sessions of therapeutic intervention
Method of measurement
questionnaire

2

Description
Children's attention control score
Timepoint
After 12 sessions of therapeutic intervention
Method of measurement
Attention control questionnaire

3

Description
Emotional regulation score
Timepoint
After 12 sessions of therapeutic intervention
Method of measurement
Emotional regulation questionnaire

4

Description
Anxiety score
Timepoint
After 12 sessions of therapeutic intervention
Method of measurement
Anxiety questionnaire

Intervention groups

1

Description
Intervention group: mindfulness-based cognitive therapy (MBCT)
Category
Behavior

2

Description
Control group: Cognitive and behavioral play therapy
Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences

Full name of responsible person

dr mojtaba habibi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Islamic Azad university

Proportion provided by this source

10

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

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mojtaba Habibi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Statistical information of children's scores in psychological tests

When the data will become available and for how long

one year

To whom data/document is available

Judges and researchers

Under which criteria data/document could be used

Future research

From where data/document is obtainable

Author

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

organizational process

Comments