

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**Street address**

Iran University of Medical Sciences

**City**

Tehran

**Province**

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**Postal code**

1413874414

**Phone**

+98 21 8800 3656

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habibi.m@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Mojtaba Habibi

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Iran University of Medical Sciences

**City**

Tehran

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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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Position**

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## Person responsible for updating data

### Contact

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**Latest degree**

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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**