Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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
2023-12-20, 1402/09/29

Registrant information
Name
Habibeh Kholghi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 8800 3656
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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

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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

Behavior

Academic

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

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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
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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