Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

"The effect of mindfulness based cognitive behavioral therapy for children (MBCT-C) on cognitive inhibition, emotional self-regulation, and behavioral problems of children with learning disabilities"

Protocol summary

Study aim
A) General purpose: Determining The effect of mindfulness based cognitive behavioral therapy for children on cognitive inhibition, emotional self-regulation, and behavioral problems of children with learning disabilities. B) Specific goals: 1) Determination and comparison of cognitive inhibition of children with learning disabilities before and after intervention in two groups 2) Determination and comparison of emotion regulation of children with learning disabilities before and after the intervention in two groups 3) Determination and comparison of behavioral problems in children with learning disabilities before and after the intervention in two groups

Design
A clinical trial with a control group, purpose-based sampling, assigning participants to two groups randomly (table of random numbers), sample number 36 people.

Settings and conduct
Kashan learning disorder centers

Participants/Inclusion and exclusion criteria
Entry criteria: 1) Having a learning disorder based on the diagnosis of the child's psychiatrist/clinical psychologist 2) Having informed consent to participate in the research 3) Age 9 to 12 years 4) At least one of the nine diagnostic items in the learning disorder questionnaire received a positive score Non-entry criteria: 1) Suffering from an acute physical and mental illness such as diabetes, cancer, bereavement, etc. 2) Receiving other types of psychotherapy

Intervention groups
Children in both intervention and control groups will continue their usual treatment, with the difference that the experimental group will undergo MBCT-C, which is in the form of 12 sessions of 90 minutes held once a week. Also, the evidence group will be assured that they will also receive these interventions if they wish after completing the research process.

Main outcome variables
cognitive inhibition; emotional self-regulation; behavioral problems

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240827062877N1**
Registration date: **2024-10-09, 1403/07/18**
Registration timing: **prospective**

Last update: **2024-10-09, 1403/07/18**
Update count: **0**

Registration date
2024-10-09, 1403/07/18

Registrant information

Name
Fatemeh Movahedian

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-10, 1403/07/19

Expected recruitment end date
2025-02-07, 1403/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

"The effect of mindfulness based cognitive behavioral therapy for children (MBCT-C) on cognitive inhibition, emotional self-regulation, and behavioral problems of children with learning disabilities"

Public title

"The effect of mindfulness based cognitive behavioral therapy for children on learning disorders"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having a learning disorder based on the diagnosis of the child's psychiatrist or clinical psychologist Having informed consent to participate in the research Age 9 to 12 years At least one of the 9 diagnostic items in the learning disorder questionnaire received a positive score

Exclusion criteria:

Suffering from acute physical and mental illness such as diabetes, cancer, bereavement and .. Receiving various types of psychotherapy

Age

From **9 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Assigning participants to intervention and control groups is done by simple random (based on the table of random numbers), In this way, each participant will be assigned a number and with the help of "random.org/lists" they will be randomly assigned to two groups based on their number.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study has two experimental and control groups, children in both groups will continue their common treatment and after completing the treatment process (MBCT-C), the control group will also receive this intervention if they wish.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Kashan University Of Medical Sciences

Street address

Kashan University Of Medical Sciences., Pezashk Blvd., Qutb Rawandi Blvd., Kashan

City

Kashan

Province

Isfehan

Postal code

8715973474

Approval date

2024-06-29, 1403/04/09

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1403.081

Health conditions studied

1

Description of health condition studied

learning disorder

ICD-10 code

F81.9

ICD-10 code description

Developmental disorder of scholastic skills, unspecified

Primary outcomes

1

Description

Cognitive inhibition score in the Boshra Test

Timepoint

Before and after the intervention

Method of measurement

Boshra Test

2

Description

Emotion regulation score in child and adolescent emotion regulation questionnaire (ERQ-CA)

Timepoint

Before and after the intervention

Method of measurement

child and adolescent emotion regulation questionnaire (ERQ-CA)

3

Description

The score of behavioral problems in Child Behavior Checklist (CBCL), parent version

Timepoint
Before and after the intervention

Method of measurement
Child Behavior Checklist (CBCL), parent version

4

Description
The child's score in the learning disorder questionnaire(teacher form)

Timepoint
Before and after the intervention

Method of measurement
learning disorder questionnaire(teacher form)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this research, there is an intervention group with 18 children aged 9 to 12 years, and the children in this group will be treated with MBCT_C in addition to their usual treatment. mindfulness based cognitive behavioral therapy for children in the form of 12 90-minute sessions that are performed once a week.

Category
Rehabilitation

2

Description
Control group: In this research, there is a control group with 18 children aged 9 to 12 years, and the children in this group will continue their usual treatment, and they will also be assured that after completing the research process, if Will receive mindfulness based cognitive behavioral therapy for children.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Center for Counseling and Psychological Services of Education and Training in Kashan

Full name of responsible person
Fateme Movahedian

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Iqbal Lahori Alley., Shahid Rajaei St., Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Gholam Ali Hamidi

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Kashan University of Medical Sciences., Pezeshk Blvd., Qutb Rawandi Blvd., Kashan

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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
Fateme Movahedian

Position
Master's Student In Clinical Psychology

Latest degree
Bachelor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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