

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effectiveness of child-centered mindfulness on emotion regulation, cognitive flexibility, and anxiety and depression levels in children with diabetes

Protocol summary

Study aim

Determining the effectiveness of child-centered mindfulness on emotion regulation, cognitive flexibility and levels of anxiety and depression in children with diabetes

Design

The clinical trial has two control and experimental groups, which are randomly selected in the groups of this location.

Settings and conduct

The experimental groups will be treated with mindfulness; But the control group does not receive any intervention. Both the experimental group and the control group are measured twice (pre-test-post-test) separately. The statistical population will be all children with type 2 diabetes in Shiraz city. A 90-minute intervention session and an introduction session will be held weekly before the research, in person with the children and parents of the sample group.

Participants/Inclusion and exclusion criteria

All children with type 2 diabetes with a definite diagnosis from a doctor who have been prescribed insulin injections and are between 10 and 12 years old.

Intervention groups

Debra Burdick's child-centered mindfulness intervention program will be taught and performed in 10 90-minute sessions for the experimental group (15 people) and the control group will not receive any training or intervention before starting the intervention of both groups in terms of variables. Research will be evaluated by questionnaires

Main outcome variables

Child-centered mindfulness therapy: qualitative
independent Cognitive flexibility: Quantitative correlates
Emotion regulation: slightly dependent Depression: little dependent
Anxiety: slightly dependent

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221211056773N1**

Registration date: **2023-01-16, 1401/10/26**

Registration timing: **retrospective**

Last update: **2023-01-16, 1401/10/26**

Update count: **0**

Registration date

2023-01-16, 1401/10/26

Registrant information

Name

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Name of organization / entity

The University of Islamic Azad Arsanjan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-13, 1401/09/22

Expected recruitment end date

2022-12-23, 1401/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of child-centered mindfulness on emotion regulation, cognitive flexibility, and anxiety and depression levels in children with diabetes

Public title

The effectiveness of child-centered mindfulness on emotion regulation, cognitive flexibility, and anxiety and depression levels in children with diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All children with type 2 diabetes

Exclusion criteria:

Outside the age group of 10 to 12 years

Age

From **10 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 30 people are selected according to similar research, in an accessible way. Then random replacement is done by lottery method (one number will be assigned to each of the sampled people). We write down the numbers on paper, fold them and put them in a container. We mix and stir the papers completely. Then we take out the papers one by one and put one number in the first group and one number in the second group. Then random application will be done. In this way, one group is known as "control group" and the other group is known as "intervention group". The lottery will be done by putting the two groups obtained from the previous step (random replacement step) into two separate envelopes and placing them in a container. Then we randomly take one envelope out of the container and assign it to the "intervention group" and the other envelope to the "control group". Research data are analyzed using SPSS version 21 statistical package software in social sciences.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee

Street address

University blvd

City

Arsanjan

Province

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Postal code

7133864396

Approval date

2022-10-10, 1401/07/18

Ethics committee reference number

IR.IAU.A.REC.1401.015

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

بیماریهای

ICD-10 code description

بیماریهای طبی

Primary outcomes

1

Description

"Determining the effectiveness of child-centered mindfulness on anxiety" anxiety score in the Spence anxiety questionnaire and obtaining a score higher than 60 in this questionnaire

Timepoint

Evaluation of the anxiety score before the intervention and after 10 sessions of mindfulness training

Method of measurement

The way to measure the outcome variable is through the Spence Anxiety Questionnaire.

2

Description

"Determining the effectiveness of child-centered mindfulness on depression" depression score in Maria's children's depression questionnaire and obtaining a score higher than 27 in this questionnaire

Timepoint

Assessment of depression score before the intervention and after 10 sessions of mindfulness training

Method of measurement

The method of measuring the outcome variable is through the Maria Kovacs Children's Depression Questionnaire.

3

Description

"Determining the effectiveness of child-centered mindfulness on emotion regulation" The emotion regulation score in the cognitive regulation of emotion questionnaire by Garnofsky and obtaining a score higher than 50 in this questionnaire

Timepoint

Evaluation of the emotion regulation score before the intervention and after 10 sessions of mindfulness training

Method of measurement

The way to measure the outcome variable is through the Garnofsky emotion regulation questionnaire.

4

Description

"Determining the effectiveness of child-centered mindfulness on cognitive flexibility" cognitive flexibility score in Dennis and Vanderwaal's cognitive flexibility questionnaire and obtaining a score of less than 20 in this questionnaire

Timepoint

Evaluation of the cognitive flexibility score before the intervention and after 10 sessions of mindfulness training

Method of measurement

The method of measuring the outcome variable is through Dennis and Vanderwaal's cognitive flexibility questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will undergo child-centered mindfulness therapy for 10 sessions of 45 minutes based on a certain schedule in the sessions determined according to the headings of the educational package taken from Debra Burdick's method of child and adolescent mindfulness.

Category

Rehabilitation

2

Description

Control group: This group will not receive any intervention and will only be evaluated based on research variables before the intervention and after the intervention for the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Shiraz Hospital

Full name of responsible person

Dr. Sara Deh Gorgi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arsanjan 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?

Yes

Title of funding source

Arsanjan Islamic Azad University

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
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Sara Deh Gorgi

Position
Child and adolescent psychiatrist

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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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