

# 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

Afsaneh Nouri

##### Name of organization / entity

The University of Islamic Azad Arsanjan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 4352 3908

##### Email address

afsane1@yahoo.com

##### 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

Fars

##### 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

###### **Street address**

Chamran Blvd

###### **City**

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###### **Province**

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###### **Postal code**

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###### **Phone**

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### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Arsanjan Islamic Azad University

###### **Full name of responsible person**

Dr. Ali Mohammad Rezaei

###### **Street address**

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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

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Psychiatrics

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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