Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

The effectiveness of online Mindfulness-Based Stress Reduction (MBSR) intervention on physical, psychological and cognitive health indicators in adolescents with type 1diabetes in Isfahan

Protocol summary

Study aim
Investigating the effect of online mindfulness-based stress reduction intervention on hemoglobin A1C, diabetes distress, psychological well-being and attention bias in adolescents with type 1 diabetes.

Design
Clinical trial has two experimental and control groups, with parallel groups, randomized with Excel software

Settings and conduct
The sample group will be 50 adolescents with type 1 diabetes who have a file in the Endocrine and Metabolism Research Center of Isfahan, located in the Hazrat Sedigheh Tahereh Research and Training Center. And will be randomly assigned to the experimental and control groups. After the pre-test, all members of the experimental group will receive the online intervention in eight sessions (one session per week for two hours) by the Mindfulness-Based Stress Reduction intervention (MBSR) instructor. At the end of the intervention sessions, the post-test will be performed on the experimental and control groups. Also, in order to observe ethical considerations, after the post-test, the MBSR intervention will be performed on the control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adolescents 15 to 25 years old with type 1 diabetes who have had diabetes for at least a year and have a hemoglobin A1C level above 7%. exclusion criteria: having severe psychiatric illnesses; Use of drugs or psychotropic drugs; Physical and mental disabilities; Being pregnant; Having other autoimmune diseases in addition to diabetes.

Intervention groups
Intervention group: mindfulness-based stress reduction intervention will be conducted online in 8 weekly sessions (two hours each session). Homework will also be provided daily. Control group: The control group will not receive any intervention.

Main outcome variables
HemoglobinA1C; Diabetes distress; Psychological well-being; Attention bias

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210104049937N1**
Registration date: **2021-04-21, 1400/02/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-21, 1400/02/01**
Update count: **0**

Registration date
2021-04-21, 1400/02/01

Registrant information

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Name of organization / entity
University of Esfahan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-19, 1400/01/30

Expected recruitment end date
2021-05-05, 1400/02/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of online Mindfulness-Based Stress Reduction (MBSR) intervention on physical, psychological and cognitive health indicators in adolescents with type 1diabetes in Isfahan

Public title
The effect of mindfulness on diabetes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Adolescents with type 1 diabetes who have had diabetes for more than a year. Adolescents with type 1 diabetes who have a hemoglobin A1C above 7%. Adolescents with type 1 diabetes who have the ability to work with e-learning software and access the Internet. Adolescents with type 1 diabetes who live in Isfahan province.
Exclusion criteria:
People with severe psychiatric illnesses. People with other autoimmune diseases in addition to diabetes. Those who use psychotropic drugs or substance abuse. Those with physical and mental disabilities. Those who are pregnant.
Age
From **15 years** old to **25 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the restricted randomization method of the type of "random allocation law" will be implemented by a person separate from other researchers. In this way, in the first stage, the required number of specified samples (50 people) will be selected from the people who meet the inclusion criteria. And in the second step, we assign a number from 1 to 50 to each of these people, respectively. In the third step, we produce 50 random numbers without repetition between 1 and 50 by Excel software and this is the random sequence we want. Each of these numbers corresponds to the number assigned to each of the people we have specified in the initial list of 50 selected. In this study, we consider even numbers for the intervention group and odd numbers for the control group, and of course this is not obvious to the participant before performing random allocation.
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
Ethics Committee of Isfahan University
Street address
Room 325, 3rd Floor, Central Building, University of Isfahan, Hezar Jerib St.
City
Isfahan
Province
Isfehan
Postal code
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Approval date
2020-11-18, 1399/08/28
Ethics committee reference number
IR.UI.REC.1399.061

Health conditions studied

1

Description of health condition studied
Type one diabetes
ICD-10 code
E10
ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
Diabetes distress
Timepoint
Before and after the intervention
Method of measurement
Problem Areas in Diabetes Questionnaire; Iranian version

2

Description
Blood sugar control
Timepoint
Before and after the intervention
Method of measurement
Blood test for hemoglobinA1C

3

Description
Psychological well-being
Timepoint
Before and after the intervention
Method of measurement
Ryff's Scales of Psychological Well-being; Short Form

4

Description
Attentional bias
Timepoint
Before and after the intervention
Method of measurement
Modified Stroop Test (emotional)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Mindfulness-based stress reduction is an 8-week training program that uses formal and informal mindfulness exercises. The regular agenda of each session will include reviewing the homework of the previous session, feedback, troubleshooting questions, teaching content and techniques, meditation skills, discussing stress, coping method and homework. The material presented during the 8 sessions includes the following: Introduction of mindfulness training, training and exercises related to the state of mindfulness exercises, attention to breathing, body scanning exercises, doing sitting care, doing yoga movements, doing mind eating exercises Consciously, taking care of conscious mind walking, preparing a personal mindfulness program. Participants are asked to do mindfulness exercises for 45 minutes on a daily basis as homework.
Category
Behavior

2

Description
Control group: The control group is under routine care and no intervention is performed on them.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Sedigheh Tahereh Endocrine and Metabolism Training, Treatment and Research Center
Full name of responsible person
Dr. Maryam Esmaili
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First Floor, Faculty of Educational Sciences and Psychology, University of Isfahan, Azadi Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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Vice Chancellor for Research and Technology, Hezar Jerib St. Isfahan University of Medical Sciences and Health Services, Building No. 4, No. 4,
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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
Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person
Zahra Nouri Sari

Position
student

Latest degree
Master

Other areas of specialty/work
Psychology

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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
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

Title and more details about the data/document
Part of the patients' demographic information and the main outcome can be shared.

When the data will become available and for how long
One year after printing the results

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Scientific uses

From where data/document is obtainable
Zahra Nouri Sari z.noooori1994@gmail.com

What processes are involved for a request to access data/document
The data is sent by official request and by email

Comments