Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Assessing the impact of two selected exercise training on the alterations in the expression of miRNA-25, miRNA-93, and some physiological parameters in children diagnosed with type 1 diabetes.

Protocol summary

Study aim

The primary objective of this study is to assess the impact of two chosen resistance and aerobic training techniques on the expression levels of miRNA-25, miRNA-93, and various physiological parameters in children diagnosed with type 1 diabetes.

Design

This clinical trial will be carried out with parallel groups and will utilize randomization through a random number table involving 30 adolescents diagnosed with type 1 diabetes. This study will not implement blinding, and participants will be assigned to two groups—resistance and aerobic exercise—based on the odd and even values of the table, with 15 individuals allocated to each group.

Settings and conduct

This research will take place at the University of Isfahan, where participants will be allocated to the intervention groups at random, and no blinding will be implemented. The exercise regimen will consist of three sessions each week, lasting between 30 to 90 minutes per session, over a duration of eight weeks in the gym.

Participants/Inclusion and exclusion criteria

The inclusion criteria: participants must not have participated in regular physical activities during the preceding year and must have a diagnosis of type 1 diabetes. The exclusion criteria for the study encompassed voluntary withdrawal by participants, physical injuries, the existence of other particular medical conditions, and the absence from more than three sessions of exercise interventions.

Intervention groups

The intervention groups comprised individuals engaging in aerobic exercises and another group involved in resistance exercises over a duration of 8 weeks, with 3 sessions each week.

Main outcome variables

Lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250908067184N1**
Registration date: **2025-11-10, 1404/08/19**
Registration timing: **prospective**

Last update: **2025-11-10, 1404/08/19**
Update count: **0**

Registration date

2025-11-10, 1404/08/19

Registrant information

Name

Niyayesh Gheisari

Name of organization / entity

The University of Isfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-06, 1404/09/15

Expected recruitment end date

2026-03-11, 1404/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessing the impact of two selected exercise training on the alterations in the expression of miRNA-25, miRNA-93, and some physiological parameters in children diagnosed with type 1 diabetes.

Public title
Assessing the impact of two chosen exercise techniques on alterations in specific biomarkers and physiological indicators in children diagnosed with type 1 diabetes.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
An absence of participation in routine physical activities during the preceding year Type 1 diabetes identified by a medical expert Being within the age range of 12 to 15 years
Exclusion criteria:
Participants' free withdrawal from further interventions Physical injury during interventions Having other specific diseases Absence of more than 3 sessions in designated exercise interventions

Age
From **12 years** old to **15 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be allocated randomly into two experimental groups by utilizing a random number table. A total of 15 individuals will be chosen for the resistance training group, while another 15 individuals will be selected for the aerobic training group.

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
University of Isfahan Research Ethics Committee
Street address
University St., University of Isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73441

Approval date
2025-09-13, 1404/06/22

Ethics committee reference number
IR.UI.REC.1404.149

Health conditions studied

1

Description of health condition studied
Type 1 Diabetes

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Lipid Profile

Timepoint
Prior to the intervention and following 8 weeks of exercise interventions

Method of measurement
Measurements are conducted utilizing specialized kits.

2

Description
Insulin

Timepoint
Prior to the intervention and following 8 weeks of exercise interventions

Method of measurement
The assessment of insulin levels is conducted through the utilization of immunoassay-based insulin analysis kits.

3

Description
Blood sugar

Timepoint
Prior to the intervention and following 8 weeks of exercise interventions

Method of measurement
Blood glucose levels are assessed through the use of blood glucose kits and the photometric technique.

4

Description
miRNA-25
Timepoint
Prior to the intervention and following 8 weeks of exercise interventions
Method of measurement
The levels of miRNA-25 are extracted from blood serum using special kits and a real-time PCR device.

5

Description
miRNA-93
Timepoint
Prior to the intervention and following 8 weeks of exercise interventions
Method of measurement
The levels of miRNA-93 are extracted from blood serum using special kits and a real-time PCR device.

6

Description
Cardiorespiratory endurance
Timepoint
Prior to the intervention and following 8 weeks of exercise interventions
Method of measurement
The participants' cardiorespiratory endurance will be determined using a 20-meter shuttle run test.

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group 1: Participants in this group will perform a selected aerobic exercises for 8 weeks.
Category
Lifestyle

2

Description
Intervention Group 2: Participants in this group will partake in a resistance training regimen utilizing bodyweight exercises for a period of 8 weeks.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
University of Isfahan
Full name of responsible person
Vazgen Minasian
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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?
Yes
Title of funding source
The University of Isfahan
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
The University of Isfahan
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Niyayesh Gheisari

Position
MSc Student
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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
Not applicable
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The data file will only be made available to academic researchers after obtaining permission from the university's research director.
When the data will become available and for how long
Access to data will commence three months following the publication of the results in an article format.
To whom data/document is available
Only researchers working at universities and scientific centers will have access to the data.
Under which criteria data/document could be used
The data will be accessible to researchers exclusively for the purposes of research studies and statistical analyses.
From where data/document is obtainable
To acquire data, kindly reach out to or corresponding author of published article, following the receipt of authorization from the university's research director.
What processes are involved for a request to access data/document
To receive data, permission from the university's research director is required, and the author responsible for the article will provide the data within 2 weeks.
Comments