

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison the effectiveness of a 6 months home-based aerobic High-intensity interval training (HIIT) and resistance exercises on glycemic and metabolic control of adolescents with type 1 diabetes mellitus and identification of disease related microRNAs

Protocol summary

Study aim

-To evaluate glycemic and metabolic control after 6 months home-based aerobic High-intensity interval training(HIIT) and resistance exercises in diabetic adolescents with Type 1Diabetes Mellitus in Isfahan

Design

Double-blind randomized controlled trial,with two arm parallel groups,phase 3 of 90 patients .Simple randomization with computer software

Settings and conduct

This study will be a double-blind randomized controlled trial, where equal numbers of participants will be assigned to either (i) High-intensity interval training (HIIT) group , (ii) Resistance exercise and (iii) control (CON) group. Participants in exercise intervention groups will complete two home-based resistance and high intensity aerobic exercise program for 26 weeks. The control group will be asked to maintain their current activity and dietary behaviors. Physiological and clinical measurements of cardiorespiratory fitness, body composition and cardiometabolic health will be done at baseline and on completion of the intervention at the 26th week.

Participants/Inclusion and exclusion criteria

Inclusion criteria; adolescents aged 14-18 years old with type 1 diabetes Non inclusion criteria;Having movement restriction or movement disorder Having limb or body injuries Chronic cardiac or respiratory diseases, blood pressure Any chronic disease that causes the child's inability to perform physical activity Family history of sudden death, uncontrolled hypertension, type II diabetes and cardiovascular disease

Intervention groups

Control group Intervention group1;High-intensity interval training Intervention group 2; Resistance exercises

Main outcome variables

Glycemic control(glycosylated hemoglobin); Metabolic control(Lipid profile, Fasting Blood Sugar)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221026056299N1**

Registration date: **2023-07-12, 1402/04/21**

Registration timing: **retrospective**

Last update: **2023-07-12, 1402/04/21**

Update count: **0**

Registration date

2023-07-12, 1402/04/21

Registrant information

Name

Silva Hovsepian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5257

Email address

s.hovsepian@res.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness of a 6 months home-based aerobic High-intensity interval training (HIIT) and resistance exercises on glycemic and metabolic control of adolescents with type 1 diabetes mellitus and identification of disease related microRNAs

Public title

Comparison the effectiveness of a 6 months home-based aerobic High-intensity interval training and resistance exercises on glycemic of adolescents with type 1 diabetes mellitus

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Adolescents with Type 1 diabetes 14-18 years old

Exclusion criteria:

Having movement restriction or movement disorder
Having limb or body injuries Chronic cardiac or respiratory diseases, blood pressure Any chronic disease that causes the child's inability to perform physical activity Family history of sudden death, uncontrolled hypertension, type II diabetes and cardiovascular disease

Age

From **14 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, table of random number In this study, first the subjects (90 people) are selected and a two-digit code is assigned to each of them, and the researcher randomly starts from a point of the table in the direction of the row or column to select the sample people from the table considering the last two digits of the numbers in the table as follows; the first 30 as the control group, the second 30 as the intervention group 1, and the third 30 as the intervention group 2.

Blinding (investigator's opinion)

Double blinded

Blinding description

The adolescents with Type 1 diabetes and the investigator who collect the data and assess the outcomes will be blinded

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 of Medical Sciences

Street address

Hezar Jerib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2022-07-22, 1401/04/31

Ethics committee reference number

IR.MUI.MED.REC.1401.168

Health conditions studied**1****Description of health condition studied**

Type1 diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes**1****Description**

Glycemic control

Timepoint

Measurement of Hemoglobin A1c at baseline and 6 months after exercises

Method of measurement

blood test

Secondary outcomes**1****Description**

Metabolic control (lipid profile, fasting blood sugar)

Timepoint

At baseline and 6 month after intervention

Method of measurement

Blood test

Intervention groups

1

Description

Control group: High-intensity interval training(High intensity interval training (HIIT) is a mode of aerobic exercise training that consists of an activity phase and a rest phase. The activity phase includes some exercises that are performed with high intensity and speed, but the period of rest time is short, such as pedaling on a bicycle or any other exercise activity, and then a rest period is considered). The exercises of each session last for 60-90 minutes, for a period of 12 weeks and 3 sessions per week with direct or indirect supervision of researchers or exercise training specialists.

Category

Lifestyle

2

Description

Intervention group: Resistance exercises(The method of selected resistance exercises will include exercises using body weight or other simple equipment such as exercises with elastic bands). The exercises of each session last for 60-90 minutes, for a period of 12 weeks and 3 sessions per week with direct or indirect supervision of researchers or exercise training specialists.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossien Childrens Hospital

Full name of responsible person

Mahin Hashemipou

Street address

Imam Khomeini

City

Isfahan

Province

Isfahan

Postal code

81951-63381

Phone

+98 31 3386 1005

Email

hashemipour@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Hezar jerib

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3061

Email

research@mui.ac.ir

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

Silva Hovsepian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Type 1 diabetes

Street address

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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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

Not applicable

Title and more details about the data/document

Non-identifiable data of the participants and information about the investigated outcomes

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Researchers from academic institutions working in the field of type 1 diabetes mellitus or physical activity

Under which criteria data/document could be used

deidentifiable data Using data to design similar researches Using by health system officials and workers to implement effective interventions at community level and for larger population

From where data/document is obtainable

The applicant can get their requested documents by contacting with the Principle Investigator Silva Hovsepian s.hovsepian@res.mui.ac.ir

What processes are involved for a request to access data/document

After receiving the email with the request to receive the documents, the PI will consult with the project colleagues and if possible, the data will be emailed within 2 weeks.

Comments