Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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
Comparisonthe 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
Isfehan
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
Isfehan
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
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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
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Person responsible for scientific inquiries

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Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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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