Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparing the effectiveness of home-based high-intensity interval training and moderate intensity continues training on weight loss in overweight and obese adults

Protocol summary

Study aim

Comparing the effectiveness of home-based high-intensity interval training(HIIT)and moderate-intensity continuous training(MICT)with diet-only plan on weight loss in overweight and obese adults

Design

Randomized clinical trial with a control group and 3 parallel groups,single-blind(blinded outcome assessment and statistician)on72patients.The"rand"function of Excel software is used for randomization

Settings and conduct

Each person receive relevant training package based on placement in HIIT/MICT group.training package include training exercises,assure to exercising truly,checking exercise intensity including heart rate& Rate of Perceived Exertion,how to file training sessions in logbook.Exercises provide at sports medicine research center.Exercise programs will done at home without supervision.Followup will be virtual and in person at certain times.intake of macronutrients and calories consumed check at certain time.people are asked to avoid other nutritional and sports during this intervention.After 4and8 weeks resetting exercise program and hypocaloric diet plan for all

Participants/Inclusion and exclusion criteria

Age of18-50,BMI of25-35,no participation in weight loss program in past year,no regular participation in physical activity in past 6 months,no pregnancy/breastfeeding,absence of cardiovascular,respiratory,neurological,psychiatric,endocrine,musculoskeletal,absence of drugs affecting metabolism,able to do sports

Intervention groups

Control group:Nutrition counseling only HIIT intervention group:Nutrition counseling+home based high intensity interval training MICT intervention group:Nutrition counseling+home based moderate intensity continuous training

Main outcome variables

weight changes;Anthropometric findings(waist circumference,hip circumference,waist/hip circumference ratio);body fat percentage;blood pressure;Biochemistry findings(TG,LDL,HDL,FBS,HOMA-IR);Maximal O2 uptake

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230129057269N1**
Registration date: **2023-02-21, 1401/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-21, 1401/12/02**
Update count: **0**

Registration date

2023-02-21, 1401/12/02

Registrant information

Name

Seyedayin Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 2534

Email address

ayin.meimand@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-14, 1401/11/25

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of home-based high-intensity interval training and moderate intensity continues training on weight loss in overweight and obese adults

Public title
Comparing the effectiveness of HIIT and moderate intensity continues training on weight loss

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Adults between the ages of 18 to 50 BMI between 25 to 35 No participation in a weight loss program in the past year Lack of regular participation in physical activity in the last 6 months (via SF-IPAQ questionnaire) Absence of pregnancy and breastfeeding Not taking drugs affecting metabolism Absence of musculoskeletal diseases that result in limitations of performing workouts Absence of cardiovascular, respiratory, neurological, psychiatric (via HADS questionnaire), endocrine diseases Being affected by any other weight loss intervention (including receiving nutritional or exercise regimens further than the assigned treatment, receiving supplements and drugs that affect metabolism, using other alternative methods) during the study will lead to exclusion from the study.

Exclusion criteria:

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
The participants are randomly divided to one of the 3 groups of High Intensity Interval Training (HIIT) (receiving a high intensity interval exercise program + nutrition counseling), Moderate Intensity Continues Training (MICT) (receiving a continuous exercise program + nutrition counseling) or only nutrition counseling with a 1:1:1 ratio.The randomization method is based by computer generated random numbers. This will be done by someone outside the research team.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the intervention, it is not possible to blind the participants, but the person responsible for the evaluations and the statistical analyst will not be aware of the assignment of people to the groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Neuroscience Institute

Street address
No.7, Al-e Ahmad Highway , Sports and Exercise Medicine Research Center,Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1411734141

Approval date
2023-01-16, 1401/10/26

Ethics committee reference number
IR.TUMS.NI.REC.1401.080

Health conditions studied

1

Description of health condition studied
Overweight and obesity

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Weight

Timepoint
The start of the study (before the intervention) and the 12th week

Method of measurement
Using the same standard method and scale

2

Description
Maximal O2 uptake
Timepoint
The start of the study (before the intervention) and the 12th we
Method of measurement
The step test will be performed using the Queen's college method, and the maximal O2 uptake will be estimated via the formula.

Secondary outcomes

1

Description
Adherence rate
Timepoint
Weeks 4,8 and 12
Method of measurement
The percentage of the number of training sessions that have been performed completely to the total sessions

2

Description
Drop out rate
Timepoint
Weeks 4,8 and 12
Method of measurement
The number of people who dropped out during the study

3

Description
Adverse events
Timepoint
Weeks 4,8 and 12
Method of measurement
Any complication related to the intervention that occur during the study is recorded in the exercise log book

4

Description
Anthropometric findings(waist circumference, hip circumference, waist/hip circumference ratio)
Timepoint
At the start of the study (before the intervention) and the 12th week
Method of measurement
Using the same standard method and metric tool

5

Description
Blood pressure
Timepoint
At the start of the study (before the intervention) and the 12th week
Method of measurement
In a sitting position and after 5 minutes of rest, with the same sphygmomanometer, the average of two measurements will be recorded. If there is a difference of more than 5mmHg in the measurements, whether systolic or diastolic pressure, the measurement will be repeated for the third time. .

6

Description
Lipid profile including TG, LDL and HDL
Timepoint
At the start of the study (before the intervention) and the 12th week
Method of measurement
Examined at the same laboratory for biochemical evaluations after 12hours of fasting.

7

Description
Factors related to glucose metabolism including FBS and HOMA-IR
Timepoint
At the start of the study (before the intervention) and the 12th week
Method of measurement
Examined at the same laboratory for biochemical evaluations after 12hours of fasting.

8

Description
Body composition (body fat percentage)
Timepoint
At the start of the study (before the intervention) and the 12th week
Method of measurement
The percentage of body fat and other components will be determined by the Bioelectrical Impedance Analysis method using the relevant device.

Intervention groups

1

Description
First intervention group: Exercising 3 days a week, performing intermittent aerobic activities with high intensity 85-95% of Heart Rate Maximum (HRMax), equivalent to RPE 7-9 on the Borg scale, in the form of 10-12 repetitions of bouts of 30-90 seconds with 30-60 seconds of rest. Each bout is performed in one station and a combination of running, running in place, going up and down the stairs, walking high knees, jumping jack, jumping rope, etc.Before performing workouts, 5 minutes of warm-up (W/U) including brisk walking, flexibility exercises, and 5 minutes of cooling down (C/D) will be performed at the end of the training session.
Category
Lifestyle

2

Description
Second intervention group: Exercising 3 days a week, doing aerobic activity with moderate intensity of 85-70% of Heart Rate Maximum (HRMax), equivalent to RPE 4-6 on the Borg scale, doing continuous exercises for 30 minutes, the type of activity can be one or a combination of fast walking , treadmill, bicycle (if there are available home equipments). Before performing workouts, 5 minutes of warm-up (W/U) including brisk walking, flexibility exercises, and 5 minutes of cooling down (C/D) will be performed at the end of the training session.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Sports Medicine Research Center (SMRC)

Full name of responsible person
Seyedayin Hosseini

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No.7, Al-e Ahmad Highway , Sports and Exercise Medicine Research Center,Tehran, Iran

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sportpsych@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ali Sahraian

Street address
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1417653761

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Seyedayin Hosseini

Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
Sport Medicine

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No.7, Al-e Ahmad Highway , Sports and Exercise Medicine Research Center,Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Behnaz Mahdaviani

Position
Medical specialist

Latest degree
Specialist

Other areas of specialty/work
Sport Medicine

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Person responsible for updating data

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Name of organization / entity
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Full name of responsible person
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Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
Sport Medicine

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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