

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparing the effectiveness of home-based high-intensity interval training and moderate intensity continuous 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

Sedayin 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 week

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 occurs 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 12 hours 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 12 hours 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411734141

Phone

+98 21 8833 0032

Email

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

No1, Poursina St, Ghods St , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email

tumspr@tums.ac.ir

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411734141

Phone

+98 21 8833 0032

Email

ayin.meimand@gmail.com

Web page address

<https://ni.tums.ac.ir/smrc>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Behnaz Mahdavian

Position

Medical specialist

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

Street address

No.7, Al-e Ahmad Highway , Sports and Exercise

Medicine Research Center, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411734141

Phone

+98 21 8833 0032

Email

behnazmahdaviyani@gmail.com

Person responsible for updating data

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1411734141

Phone

+98 21 8833 0032

Email

ayin.meimand@gmail.com

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