

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Sep 2026

The Effect of TRF and Exercise on Inflammatory, Metabolic and Hormonal Indicators in Overweight Men

Protocol summary

Study aim

Determining the effect of three methods of time restricted feeding (with 6-hour, 8-hour and 10-hour feeding windows) along with low intensity aerobic exercise on appetite regulating factors, body composition, inflammatory and metabolic indicators and hormones in overweight middle-aged men

Design

Interventional clinical trial without a control group, parallel groups with a different feeding window in terms of time but with the same exercise protocol, the number of volunteers is not yet known, there will be randomization, there is no blinding. Sample size in each group is 9 with G power software.

Settings and conduct

The place of study will be Mohaghegh Ardabili University. After selecting the subjects and distributing them randomly in the three groups, and holding training sessions for the groups, pre-intervention tests will be conducted and the study process will begin. After performing the different nutrition protocol and the same exercise in 6 and 12 weeks, the measurements will be done again. Because we need the informed cooperation of the subjects, there is no blinding.

Participants/Inclusion and exclusion criteria

Male with overweight employees working in the offices of Ardabil city

Intervention groups

1-Time restricted feeding (TRF) and low-intensity aerobic exercise group with a 6-hour feeding window (8-14) 2- TRF and low-intensity aerobic exercise group with an 8-hour feeding window (8-16) 3- TRF and low-intensity aerobic exercise group with a 10-hour feeding window (8-18)

Main outcome variables

Leptin, AGRP, ghrelin, insulin, glucose, cortisol, TNF- α , IL-6, CRP, energy intake and expenditure, Vo2 max, weight, fat percentage, waist circumference, hip circumference, waist circumference to hip ratio

General information

Reason for update

Acronym

GTES

IRCT registration information

IRCT registration number: **IRCT20230112057115N1**

Registration date: **2023-03-09, 1401/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-09, 1401/12/18**

Update count: **0**

Registration date

2023-03-09, 1401/12/18

Registrant information

Name

Hamid Vasfi

Name of organization / entity

University of Guilan

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of TRF and Exercise on
Inflammatory, Metabolic and Hormonal Indicators in
Overweight Men

Public title

The effect of TRF and exercise on health indicators

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being male Age 35 to 55 years Body mass index 25 to 30

Exclusion criteria:

Pulmonary disease Having diabetes Suffering from other
metabolic diseases Inflammatory diseases Suffering from
cardiovascular diseases Having liver diseases

Age

From **35 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **9**

More than 1 sample in each individual

Number of samples in each individual: **27**

Blood plasma sampling for measuring the plasma
concentration of blood glucose, insulin, cortisol, TNF- α ,
IL-6, CRP, leptin, AGRP, ghrelin for each person on three
occasions (before the intervention, 6 weeks after the
intervention and 12 weeks later of intervention)

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization model is used for the
study. Subjects are randomly placed in one of the three
study groups with the help of a random number table
and receive the intervention related to the same group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of University of Guilan

Street address

Rasht, Persian Gulf Highway, Kilometer 5 Qazvin

Road, Gilan University Complex

City

Rasht

Province

Guilan

Postal code

۴۱۹۹۶۱۳۷۷۶

Approval date

2022-12-28, 1401/10/07

Ethics committee reference number

IR.GUILAN.REC.1401.087

Health conditions studied

1

Description of health condition studied

Overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Measurement of height, weight and BMI

Timepoint

Before the intervention, 6 weeks after the start of the
intervention, 12 weeks after the intervention

Method of measurement

اندازه گیری توسط وزنه دیجیتال و متر نواری

2

Description

Vo2max

Timepoint

Before the intervention, 6 weeks after the start of the
intervention, 12 weeks after the intervention

Method of measurement

Measuring by tread mill and bulk test

3

Description

Measurement of body composition

Timepoint

Before the intervention, 6 weeks after the start of the
intervention, 12 weeks after the intervention

Method of measurement

Using caliper and 7-point method and "Jackson-Palux"
equation for bone density and "Siris" formula to obtain
fat percentage

Secondary outcomes

1

Description

Fasting plasma concentrations of Glucose, insulin, cortisol

Timepoint

Before the intervention, 6 weeks after the start of the intervention, 12 weeks after the intervention

Method of measurement

Using glucose oxidase method to measure glucose concentration and ELISA technique to measure other blood factors in plasma

2

Description

Measurement of plasma concentration of leptin, AGRP, ghrelin

Timepoint

Before the intervention, 6 weeks after the start of the intervention, 12 weeks after the intervention

Method of measurement

ELISA technique

3

Description

Measurement of plasma concentration of TNF- α , IL6 CRP

Timepoint

Before the intervention, 6 weeks after the start of the intervention, 12 weeks after the intervention

Method of measurement

ELISA technique

Intervention groups

1

Description

Intervention group: The first group: TRF with a 6-hour feeding window (8-14) along with low-intensity aerobic exercise* The second group: TRF with an 8-hour feeding window (8-16) along with low-intensity aerobic exercise * The third group: TRF with a 10-hour feeding window (8-18) along with low-intensity aerobic exercise. There is no control group and the effect of independent variables of TRF and exercise on the study groups are compared with dependent variables in three occasions before the intervention, 6 weeks from the start of the intervention and 12 weeks from the start of the intervention. A comparison is made between the groups themselves in terms of the amount and intensity of changes in the dependent variables in these three times.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

دانشگاه ها، اداره جات

Full name of responsible person

hamid vasfi

Street address

No. 24, Sablan Alley 12, Ahan Foroshan, Sablan Phase I, Ardabil

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Ardabil

Province

Ardabil

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5619766539

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h_vasfi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

عارف نوری

Street address

اردبیل، انتهای خیابان دانشگاه، مجتمع اداری دانشگاه علوم پزشکی اردبیل

City

اردبیل

Province

Ardabil

Postal code

۸۵۹۹۱-۵۶۱۸۹

Phone

+98 45 3353 4790

Email

poshtibani@arums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

1

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

Gilan University

Full name of responsible person

Hamid Mohebbi

Position

Professor of the Faculty of Physical Education and Sports Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Sport physiology

Street address

Rasht, Persian Gulf highway (kilometer 5 of the Rasht-Qazvin road), Gilan University Complex, Faculty of Physical Education and Sports Sciences

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Position

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Other areas of specialty/work

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Full name of responsible person

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Position

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Phone

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Email

mohebbi_h@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Our subjects are not sick, just overweight.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The decision will be made after collecting the data.

When the data will become available and for how long

It is not clear at the moment.

To whom data/document is available

The decision will be made after collecting the data.

Under which criteria data/document could be used

The decision will be made after collecting the data.

From where data/document is obtainable

The decision will be made after collecting the data.

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

The decision will be made after collecting the data.

Comments