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
+98 13 3369 0274

Email address
h_vasfi@yahoo.com

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

City

Ardabil

Province

Ardabil

Postal code

5619766539

Phone

+98 45 3363 0332

Email

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
City
Rasht
Province
Guilan
Postal code
۴۱۹۹۶۱۳۷۷۶
Phone
۸ -۳۳۶۹۰۲۷۴-۰۱۳
Email
mohebbi_h@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gilan University
Full name of responsible person
Hamid Mohebbi
Position
Gilan University 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
City
Rasht
Province
Guilan
Postal code
۴۱۹۹۶۱۳۷۷۶
Phone
33690274-013
Email
mohebbi_h@yahoo.com

Person responsible for updating data

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
City
Rasht
Province
Guilan
Postal code
۴۱۹۹۶۱۳۷۷۶
Phone
33690274-013
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