Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

The effect of eight weeks of High intensity interval training versus Moderate intensity continuous training with supplementation of sodium alginate on CCK and PYY in men with metabolic syndrome.

Protocol summary

Study aim

The effect of eight weeks of High intensity interval training versus Moderate intensity continuous training with supplementation of sodium alginate on CCK and PYY in young men with metabolic syndrome.

Design

2 groups of subjects will complete 24 sessions of HIIT practice during this research period. And two other groups of subjects will complete 24 sessions of MICT training during the study. Participants in the study will be divided into 4 groups of 10 individuals each for exercise activity after determining VO2peak and obtaining baseline scales, and the other 1 groups of 10 individuals will be included in the study as the control group.

Settings and conduct

2 groups of subjects will complete 24 sessions of HIIT practice during this research period. And two other groups of subjects will complete 24 sessions of MICT training during the study. Participants in the study will be divided into 4 groups of 10 individuals each for exercise activity after determining VO2peak and obtaining baseline scales, and the other 1 groups of 10 individuals will be included in the study as the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria are defined as having three factors out of a total of 5 factors: abdominal obesity risk, increased fasting triglyceride levels, decreased fasting HDL cholesterol, fasting glucose impairment, and hypertension.

Intervention groups

Subjects were randomly divided into 6 groups including: Group 1: Intermittent Exercise; Group 2: Intermittent Exercise with Sodium Alginate Supplement; Group 3: Continuous Exercise; Group 4: Continuous Exercise with Sodium Alginate Supplement Group 5:Control will be divided.

Main outcome variables

PYY, CCK

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190916044788N1**
Registration date: **2020-03-12, 1398/12/22**
Registration timing: **retrospective**

Last update: **2020-03-12, 1398/12/22**
Update count: **0**

Registration date

2020-03-12, 1398/12/22

Registrant information

Name

Alireza Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 4512 4466

Email address

ebrahimialireza720@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2019-09-11, 1398/06/20

Actual recruitment start date

2019-08-06, 1398/05/15

Actual recruitment end date

2019-09-21, 1398/06/30

Trial completion date
2019-12-31, 1398/10/10

Scientific title
The effect of eight weeks of High intensity interval training versus Moderate intensity continuous training with supplementation of sodium alginate on CCK and PYY in men with metabolic syndrome.

Public title
The effect of eight weeks of High intensity interval training versus Moderate intensity continuous training with supplementation of sodium alginate on CCK and PYY in men with metabolic syndrome.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having no regular exercise for the past six months Having at least 3 of 5 metabolic syndrome factors Diagnosis of metabolic syndrome
Exclusion criteria:
Being absent more than 3 sessions during 24 practice sessions Having cardiovascular disease, cancer, diabetes, and other dangerous diseases
Age
From **18 years** old to **34 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Random simple, personal, table of random numbers
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Committee on Ethics in Biomedical Research
Street address
Last passport - Nick Friedman Complex
City
kermanshah
Province
Kermanshah
Postal code
3257970692
Approval date
2019-06-12, 1398/03/22
Ethics committee reference number
IR.KUMS.REC.1398.214

Health conditions studied

1

Description of health condition studied
Metabolic Syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
PYY, CCK - of the hormones of appetite that was measured in this study to control appetite in people with metabolic syndrome.
Timepoint
3
Method of measurement
By blood measurements

Secondary outcomes

1

Description
A high-intensity intermittent exercise group that exercises people on a treadmill based on their heart rate and receives sodium alginate supplements before the three main meals. Exercise involves 30 minutes of running on a treadmill.
Timepoint
All training sessions
Method of measurement
Hour

Intervention groups

1

Description
Intervention group: Medium-intensity Continuous Exercise Group The participants in this group will be performing a continuous exercise based on heart rate and treadmill and taking sodium alginate supplement before each meal.
Category
Other

2

Description
Control group: The control group received placebo in only three servings for 8 weeks.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi university
Full name of responsible person
Alireza ebrahimi
Street address
Al Akha St-gozarname
City
kermanshah
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3257970692
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
mohhamad azizi
Street address
Al Agha Street-gozar name
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kermanshah
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3257970692
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ebrahimialireza720@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Alireza ebrahimi
Position
Master of student
Latest degree
Bachelor
Other areas of specialty/work
Physiology
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Person responsible for updating data

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master of student

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3257970692

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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
No - There is not 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
Yes - There is 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

Title and more details about the data/document
Undecided - It is not yet known if there will be a plan to make this available.

When the data will become available and for how long
Undecided - It is not yet known if there will be a plan to make this available.

To whom data/document is available
Undecided - It is not yet known if there will be a plan to make this available.

Under which criteria data/document could be used
Undecided - It is not yet known if there will be a plan to make this available.

From where data/document is obtainable
Undecided - It is not yet known if there will be a plan to make this available.

What processes are involved for a request to access data/document
Undecided - It is not yet known if there will be a plan to make this available.

Comments