

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Low Calorie Diet alone and combined with Yoga training on basal metabolic, Anthropometric indices, Adiponectin and Leptin in Overweight and Obese Women

Protocol summary

Study aim

Determination and comparison of the effects of low calorie diet alone and combined with Yoga training on basal metabolic rate, Anthropometric indices, and Adiponectin and Leptin

Design

In this study, 36 overweight and obese women who are eligible for inclusion criteria of the study are selected, and the participants are divided into two groups of diet and yoga, with each participant assigned a code.

Settings and conduct

The target group is overweight and obese women who are randomly assigned into two groups of diet alone and combined with Yoga and followed for 2 months. In diet group, 500 Kilo-calorie will be reduced after calculating the individual's energy requirement and in the yoga and diet group, 7 days workshop will be done and after that Hatha Yoga will be performed every day under the supervision of coach. In this group, a 300 Kilo-calorie reduced diet, and 200 calories from the yoga exercise will be designed. Through an indirect calorie meter, the duration of the yoga will be determined to find 200 Kilo-calorie expenditure.

Participants/Inclusion and exclusion criteria

Inclusion criteria: overweight and obese women, age range between 30 and 55 years old Exclusion criteria: diabetes, hypertension, and coronary heart disease, thyroid disorders, using dietary supplements that have effect on metabolism, smoking.

Intervention groups

intervention group: Yoga and diet control group: diet

Main outcome variables

Basal metabolic rate, Anthropometric Indices, Leptin, Adiponectin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140107016123N12**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **retrospective**

Last update: **2018-01-22, 1396/11/02**

Update count: **1**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Sima Jafarirad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8317

Email address

jafarirad-s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-10, 1396/09/19

Expected recruitment end date

2017-12-30, 1396/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Low Calorie Diet alone and combined with Yoga training on basal metabolic, Anthropometric indices, Adiponectin and Leptin in Overweight and Obese Women

Public title
Comparison of Diet with Yoga accompanying Diet on body Metabolism in Obese people

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
age 30-55 Female 25 < BMI Failure to follow a continuous exercise program Lack of Pregnancy, lactation and menopause Lack of Hypertension, Diabetes, Coronary artery Disease, stroke, thyroid disorders, Mental disorders Lack of weight loss over 5% in the last 6 months Failure to follow a special Diet plan Non-use of statin drugs, beta-blockers, fluorescent Drugs Lack of unhealthy weight
Exclusion criteria:
Smoking and And tobacco Eating any supplement that has an Effect on the Metabolism Failure to follow the plan

Age
From **30 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will done using 6 subjects per block. Statistical software (Minitab) will use to perform randomized block. For the nature of intervention (Yoga+diet and diet), blinding will not perform.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of

Medical Sciences
Street address
Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2017-11-24, 1396/09/03
Ethics committee reference number
IR.AJUMS.REC.1396.735

Health conditions studied

1

Description of health condition studied
Obesity
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Basal Metabolic Rate
Timepoint
Before and after intervention
Method of measurement
Indirect calorie meter

2

Description
Leptin
Timepoint
Before and after intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA)

3

Description
Adiponectin
Timepoint
Before and after intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Yoga and diet

Category

Treatment - Other

2

Description

Control group: Diet

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sima Jafarirad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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badavi-m@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Faredeh Yazdanparast

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

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Ph.D.

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Person responsible for updating data**Contact****Name of organization / entity**

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Master of Sciences student

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Bachelor

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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

Yes - There is 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

A part of data will be able to share

When the data will become available and for how long

From 2019

To whom data/document is available

Researchers in universities

Under which criteria data/document could be used

Only for personal studying, not sharing

From where data/document is obtainable

via email: jafarirad-s@ajums.ac.ir

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

a valid confirmation letter from university which the researcher works in it and then must be confirmed by Ahvaz Jundishapur University of Medical Sciences

Comments