

# 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

#### Street address

Golestan Highway

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6135715794

#### Phone

+98 61 3373 8317

#### Email

sjafarirad@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Mohammad Badavi

#### Street address

Golestan Highway

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

6135715794

#### Phone

+98 61 3373 8383

#### Email

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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Golestan Highway

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yazdanparast.f@ajums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

#### Full name of responsible person

Sima Jafarirad

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

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

Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Faredeh Yazdanparast

**Position**

Master of Sciences student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Golestan Highway

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 3373 8317

**Email**

yazdanparast.f@ajums.ac.ir

**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**