

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effect of diet combined with nutrition education on metabolic syndrome risk factors, and dietary habits among over weight and obese employees working in Shiraz University of Medical Sciences

#### Protocol summary

##### Study aim

to evaluate the effect of diet combined with nutrition education on metabolic syndrome risk factors, and dietary habits among over weight and obese employees

##### Design

Two arm parallel group randomised trial with blinded statisticians and outcome assessment.

##### Settings and conduct

During a call through the automation system, employees with BMI<sup>≥</sup>25 will be invited to refer to the nutrition improvement group for additional evaluations, and 70 people will be selected based on the entry and exit criteria. At the beginning of the study, informed consent will be obtained from all subjects, and general information will be collected using a demographic questionnaire. One group will receive a diet according to individual characteristics for 4 months, and the other group will receive nutrition education for 4 months in addition to receiving the diet. Metabolic syndrome risk factors will be evaluated before and after the end of the interventions. Also, in order to investigate the impact of the interventions on the eating habits of the employees, before and after the end of the interventions, the eating habits will be measured by a questionnaire.

##### Participants/inclusion and exclusion criteria

Inclusion criteria: participants having BMI>25, having at least 1 year experience, having informed consent to enter the study Exclusion criteria: suffering from comorbidities such as diabetes, thyroid disorders, liver or kidney diseases, and other chronic disorder , being pregnant or lactating, using weight lose diet

##### Intervention groups

One group will receive a diet tailored to individual characteristics for 4 months, and the other group will receive nutrition education for 4 months in addition to receiving the diet. Nutrition education will be done by a nutrition expert in the form of lectures and sending

educational messages

##### Main outcome variables

FBS, weight, HDL, TG

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190831044657N1**

Registration date: **2023-06-12, 1402/03/22**

Registration timing: **prospective**

Last update: **2023-06-12, 1402/03/22**

Update count: **0**

##### Registration date

2023-06-12, 1402/03/22

##### Registrant information

##### Name

Seyedeh Parisa Moosavian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3648 3034

##### Email address

p\_moosavian@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2023-11-22, 1402/09/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of diet combined with nutrition education on metabolic syndrome risk factors, and dietary habits among overweight and obese employees working in Shiraz University of Medical Sciences

**Public title**

diet combined with nutrition education on metabolic syndrome risk factors

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Participants having BMI more than 25 At least have one year work experience Having informed consent to enter the study

**Exclusion criteria:**

suffering from comorbidities such as diabetes, thyroid disorders,, liver or kidney diseases, and other chronic disorder being pregnant or lactating using weight lose diet

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done by random block method. In this method, qualified people who met the study entry criteria will be selected and then they will be randomly divided into two groups using blocks of 4. The randomization tool will be a random sequence generation software, which, in addition to simple randomization, is capable of generating a random sequence using the block method. The randomization unit is the individual. In fact, the number of modes that each block of 4 can be combined for two treatment groups includes 6 different modes (mode 1: AABB, mode 2: ABAB, mode 3: ABBA, mode 4: BAAB, mode 5: BBAA , Mode 6: BABA). Then, one of the blocks will be selected using the dice of any number obtained. The arrangement of people in each block is based on last name and in alphabetical order. In order to conceal, using opaque letter envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card, and the cards are placed inside the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is

numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of the participants, based on the order in which the eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

All people will be coded, and in this case, the outcome assessor and data analyst will not be aware of the groups to which people are assigned and the type of intervention.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences

**City**

Shiraz

**Province**

Fars

**Postal code**

۷۱۳۴۸-۱۴۳۳۶

**Approval date**

2023-01-08, 1401/10/18

**Ethics committee reference number**

IR.SUMS.REC.1402.031

**Health conditions studied****1****Description of health condition studied**

People with obesity and overweight

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

waist circumference

**Timepoint**

At the beginning of the study and 4 months later

### **Method of measurement**

Waist circumference will be measured using a tape measure with an accuracy of 0.1 cm from the middle point between the last rib and the hip bone.

### **2**

#### **Description**

fasting blood sugar

#### **Timepoint**

At the beginning of the study and 4 months later

#### **Method of measurement**

At the beginning and end of the study, a blood sample of 5 cc will be taken from the subjects after 10-12 hours of fasting. Fasting blood sugar (FBS) will be measured by enzymatic methods and using special kits.

### **3**

#### **Description**

TG

#### **Timepoint**

At the beginning of the study and 4 months later

#### **Method of measurement**

At the beginning and end of the study, a blood sample of 5 cc will be taken from the subjects after 10-12 hours of fasting. TG will be measured by enzymatic methods and using special kits.

### **4**

#### **Description**

HDL

#### **Timepoint**

At the beginning of the study and 4 months later

#### **Method of measurement**

At the beginning and end of the study, a blood sample of 5 cc will be taken from the subjects after 10-12 hours of fasting. HDL will be measured by enzymatic methods and using special kits.

### **5**

#### **Description**

Weight

#### **Timepoint**

At the beginning of the study and 4 months later

#### **Method of measurement**

At the beginning and at the end of the study, the height of the subjects will be measured with a seca height meter in a standing position without shoes with an accuracy of 0.1 cm and their weight will be measured with a seca scale with an accuracy of 100 grams in light clothes without shoes.

### **Secondary outcomes**

empty

### **Intervention groups**

### **1**

#### **Description**

Nutrition education along with diet

#### **Category**

Other

### **2**

#### **Description**

Receive the diet

#### **Category**

Other

### **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Shiraz university of medical sciences

##### **Full name of responsible person**

Maryam Maharat

##### **Street address**

Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences

##### **City**

shiraz

##### **Province**

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##### **Postal code**

۷۱۳۳۶ - ۷۱۳۴۸

##### **Phone**

+98 917 100 8508

##### **Email**

Maharatnut@gmail.com

### **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr. Mohammad Hashem Hashempour

##### **Street address**

Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences

##### **City**

shiraz

##### **Province**

Fars

##### **Postal code**

71348-14336

##### **Phone**

+98 71 3235 7282

##### **Email**

hashempurm@sums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

60

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

maryam Maharat

**Position**

Head of Community Nutrition Department of Shiraz  
Health Deputy

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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building of Shiraz University of Medical Sciences

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**Email**

maharatnut@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyedeh Parisa Moosavian

**Position**

Expert of community nutrition group

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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p\_moosavian@yahoo.com

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

Shiraz University of Medical Sciences

**Full name of responsible person**

seyedeh Parisa Moosavian

**Position**

Nutrition improvement group expert

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Phone**

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**Email**

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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**

No - There is not 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**

No - There is not a plan to make this available