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 BMIʿ25 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 over weight 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
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Zand Street, in front of Palestine Street, central building of Shiraz University of Medical Sciences
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Phone
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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
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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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Person responsible for scientific inquiries

Contact
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Seyedeh Parisa Moosavian
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Expert of community nutrition group
Latest degree
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Person responsible for updating data

Contact
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seyedeh Parisa Moosavian
Position
Nutrition improvement group expert
Latest degree
Ph.D.
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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