

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of education of dietary healthy eating index on serum levels of inflammation markers in obese women.

Protocol summary

Summary

object: Effect of education of dietary healthy eating index on serum levels of inflammation markers in obese women. This study is a randomized, single-blind, single center clinical trial with control group. inclusion criteria: women with body mass index (BMI) ≥ 30 ; having an initial HEI score < 80 , under conditions of weight stability for at least 3 month; and subject satisfaction. Exclusion criteria: chronic disease (diabetes, cardiovascular disease,...); being active in exercise or weight reduction programs; taking weight loss medications; taking drugs that are known to affect the immune system; consumption of nutritional supplements at least 6 month before sampling; alcohol consumption; vegan diet; smoking and lack of subject follow-up . sixty obese women (BMI >30) were randomly divided into two groups, education group and control (non-education) group; individuals in education group will receive all recommendations concerning the healthy eating and healthy diet through receiving training package and having small group training sessions (12 sessions) conducted by a registered dietitian for 3 months. The control group won't receive the nutrition education program. The primary expected outcomes are changes in HEI score and serum concentration of inflammatory markers (adiponectin, TNF-a, hs-CRP) compared with baseline in the intervention group and the control before and after of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062610181N4**

Registration date: **2014-06-28, 1393/04/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-28, 1393/04/07

Registrant information

Name

Fatemeh Heidari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arvand International Division of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education of dietary healthy eating index on serum levels of inflammation markers in obese women.

Public title

Effect of education of dietary healthy eating index on serum levels of inflammation markers in obese women.

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: women with body mass index (BMI) \geq 30; having an initial HEI score $<$ 80, under conditions of weight stability for at least 3 month; and subject satisfaction. Exclusion criteria: chronic disease (diabetes, cardiovascular disease,...); being active in exercise or weight reduction programs; taking weight loss medications;taking drugs that are known to affect the immune system; consumption of nutritional supplements at least 6 month before sampling; alcohol consumption; vegan diet; smoking and lack of subject follow-up

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan St, Ahvaz

City

Ahvaz

Postal code

Approval date

2012-10-13, 1391/07/22

Ethics committee reference number

ETH-9115

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Healthy Eating Index

Timepoint

Before and after intervention

Method of measurement

Scoring method defined by the USDA

2

Description

Adiponectin

Timepoint

Before and after intervention

Method of measurement

Enzymatic

3

Description

TNF- α

Timepoint

Before and after intervention

Method of measurement

Enzymatic

4

Description

hs-CRP

Timepoint

Before and after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

weight

Timepoint

Before and after intervention

Method of measurement

scale

2

Description

height

Timepoint

Before and after intervention

Method of measurement

meter

3

Description

Waist circumference

Timepoint

Before and after intervention

Method of measurement

Non-elastic meter

4

Description

Body Mass Index(BMI)

Timepoint

Before and after intervention

Method of measurement

mathematics

5

Description

Waist to hip ratio (WHR)

Timepoint

Before and after intervention

Method of measurement

mathematics

6

Description

Percent of body fat mass

Timepoint

Before and after intervention

Method of measurement

Body state set

Intervention groups

1

Description

Intervention group/ Training sessions about healthy diet and HEI recommendations in small groups (12 sessions) for 3 months

Category

Other

2

Description

control group/ Without nutrition education program

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ahvaz Jundishapur University of Medical Sciences
(Health and Nutrition Clinic of Ahvaz)

Full name of responsible person

Dr Majid Mohammad Shahi

Street address

School of Paramedicine, Ahvaz Jundishapur University of Medical Sciences, Golestan St, ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Arvand International Division of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Bahram Abdali

Street address

Education section, Arvand International Division of Ahvaz Jundishapur University of Medical Sciences , Opposite the international airport of Abadan, Parastar Square, Abadan, Khuzestan,Iran

City

Abadan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arvand International Division of Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Majid Mohammad Shahi

Position

PhD of Nutrition sciences/Assistant Professor

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty