

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing the effect of counseling on diet quality and physical activity enhancement with or without behavior counseling on body mass index, body composition and lipid profile of obese and overweight women

Protocol summary

Study aim

Comparing the effect of counseling on diet quality and physical activity enhancement with or without behavior counseling on body mass index, body composition and lipid profile of obese and overweight women

Design

A randomized trial including two groups of intervention and an overall 61 participants who were followed up from the beginning of the study until three subsequent months

Settings and conduct

This study which was held in Urmia city (located in West Azerbaijan state of Iran), 61 eligible women who had been announced of the study through flyers were randomized into two groups of intervention. Both groups received counseling on improving diet quality and increasing physical activity. Only one group received psychological counseling for behavior change. Characteristics of both groups were compared at baseline and after 3 months of followup in regard to BMI, body composition, lipid profile, etc.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being female BMI=25-40 Being within the age of 18 to 65 years Exclusion criteria: lactation or being pregnant or deciding to become pregnant from beginning of the study until the next 4 months Taking corticosteroid drugs (like prednisolon) and psychotherapeutic medications including tricyclic drugs (like amitriptyline, imipramine, nortriptyline) Getting more than 61 scores in General health questionnaire

Intervention groups

The intervention group receiving counseling on diet quality, increasing physical activity and psychological counseling for behavior change The intervention group receiving counseling on diet quality and increasing physical activity

Main outcome variables

BMI Body composition Physical activity level Lipid profile
Calorie intake Healthy Eating Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160824029508N7**

Registration date: **2019-09-17, 1398/06/26**

Registration timing: **retrospective**

Last update: **2019-09-17, 1398/06/26**

Update count: **0**

Registration date

2019-09-17, 1398/06/26

Registrant information

Name

Rasoul Zarrin

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9935

Email address

rasoul.zarrin@uqconnect.edu.au

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

2019-01-05, 1397/10/15

Actual recruitment end date

2019-02-04, 1397/11/15

Trial completion date

2019-05-01, 1398/02/11

Scientific title

Comparing the effect of counseling on diet quality and physical activity enhancement with or without behavior counseling on body mass index, body composition and lipid profile of obese and overweight women

Public title

Comparing the effect of two types of lifestyle intervention on health measures

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being female BMI=25-40 Being within the age of 18 to 65 years

Exclusion criteria:

Lactation or being pregnant Planning to become pregnant from beginning of the study until the next 4 months Having cancer or kidney diseases Taking corticosteroid drugs (like prednisolone) or psychothrapic medications including tricyclic drugs (like amitriptyline, imipramine, nortriptyline) Getting scores from 61 to 84 on the General Health Questionnaire

AgeFrom **18 years** old to **65 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **61**Actual sample size reached: **61****Randomization (investigator's opinion)**

Randomized

Randomization description

After recognition of 61 eligible participants, due to the small sample size of the population (<200), in order to have two groups with equal sizes, restricted randomization, random allocation rule, was applied to randomize the participants into two groups.

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 Urmia University of Medical Sciences

Street address

Umia University of Medical Sciences, Oorjans Alley, Resalat Blvd, URMIA, IRAN

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Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.UMSU.REC.1397.355

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

Overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

2**Description of health condition studied**

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes**1****Description**

Weight

Timepoint

At baseline and after 3 months

Method of measurement

Measured in kg using digital Scale

2**Description**

Body mass index

Timepoint

At baseline and after 3 months

Method of measurement

kg/m2, using formula

3

Description

Triglyceride

Timepoint

At baseline and after 3 months

Method of measurement

Measured in milligram per deciliter, using auto-analyzer BT1500

4

Description

Total cholesterol

Timepoint

At baseline and after 3 months

Method of measurement

Measured in milligram per deciliter using auto-analyzer BT1500

5

Description

Low density lipoprotein (LDL-C)

Timepoint

At baseline and after 3 months

Method of measurement

Measured in milligram per deciliter, using auto-analyzer BT1500

6

Description

High density lipoprotein (HDL-C)

Timepoint

At baseline and after 3 months

Method of measurement

Measured in milligram per deciliter using auto-analyzer BT1500

7

Description

Fat free mass

Timepoint

At baseline and after 3 months

Method of measurement

Measured in kg, using InBody770

8

Description

Fat mass

Timepoint

At baseline and after 3 months

Method of measurement

Measured in kg, using InBody770

Secondary outcomes

1

Description

Physical activity level

Timepoint

At baseline and after 3 months

Method of measurement

International physical activity questionnaire short form (IPAQ-SF)

2

Description

Eating behavior

Timepoint

At baseline and after 3 months

Method of measurement

Three Factor Eating Questionnaire-R18 (TFEQ-R18)

3

Description

Calorie intake

Timepoint

At baseline and after 3 months

Method of measurement

Measured in Kcal, using 24 hour diet recall

4

Description

Healthy eating index

Timepoint

At baseline and after 3 months

Method of measurement

Scores measured using 24 hour diet recall

Intervention groups

1

Description

First intervention group: 31 overweight or obese women received counseling on diet quality improvement, increasing physical activity and psychological counseling for behavior change. Demographic characteristics of the participants were recorded at baseline. Health measures including physical activity level, body composition, weight, Body mass index, lipid profile, eating behavior, Healthy Eating Index and calorie intake were assessed at baseline and after 3 months of follow up.

Category

Lifestyle

2

Description

Second intervention group: 30 overweight or obese women received counseling on diet quality improvement and increasing physical activity. Demographic characteristics of the participants were recorded at baseline. Health measures including physical activity level, body composition, weight, Body mass index, lipid profile, eating behavior, Healthy Eating Index and calorie intake were assessed at baseline and after 3 months of follow up.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Urmia Imam Khomeini Hospital
Full name of responsible person
Rasoul Zarrin
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Rasoul Zarrin
Position
Assistant professor
Latest degree
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Person responsible for updating data

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Full name of responsible person

Fateme Dowran

Position

MSc student of Nutrition

Latest degree

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

Undecided - It is not yet known if there will be 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