

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparison of the effectiveness of a balanced low calorie diet with and without the transtheoretical model on weight loss in obese women

Protocol summary

Summary

The success of weight loss programs resulting from various behavioral factors has always been doubted. As such, some behavior change theories have been introduced into weight loss interventions. The present study investigates the efficacy of the transtheoretical model, a behavior change in combined with a balanced low calorie diet on weight loss in obese women. The results of this study can be effective in the weight management of the obese. This study is a randomized clinical trial conducted on 80 obese women (body mass index 30-40 Kg/m²) on their first visit to nutrition clinic who volunteered to participate in this study. Initially, the demographic and anthropometric data, nutritional behavior and the transtheoretical model constructs data, the stages and process of changes, decision balance and self efficacy and 3-day food records were collected using the questionnaires. Next, blood samples were obtained for the measurement of fasting blood sugar and insulin. Subjects will be randomly assigned to two groups with a balanced low calorie diet, one with a transtheoretical model and the other without. Balanced low calorie diet is an individualized diet with an energy deficit of 500 calories of daily energy intake calculated from 3-day food records for every subject. In the intervention group with the model, nutrition education will be conducted over six one-hour sessions per week for each individual. Questionnaires will be completed at 3 and 6 months after intervention and re-sampling of blood will be taken 6 months after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012102911299N1**

Registration date: **2012-12-18, 1391/09/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-18, 1391/09/28

Registrant information

Name

Fatemeh Ghannadiasl

Name of organization / entity

Mohaghegh Ardabili University

Country

Iran (Islamic Republic of)

Phone

+98 45 1551 0806

Email address

ghannadiasl@uma.ac.ir

Recruitment status

Recruitment complete

Funding source

Nutritional Research Center, Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-06-20, 1392/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effectiveness of a balanced low calorie diet with and without the transtheoretical model on weight loss in obese women

Public title

Effectiveness of nutritional education on weight loss

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- Apparently healthy women in their first visit to nutrition clinic 2- Aged 18-50 years 3- BMI ranging from 30 to 40 kg/m² 4- Education: at least a diploma 5- Non- pregnant, Non- lactating, Non- menopause 6- Lack of participation in any program of weight loss over the past 6 months 7- Participate in the study until the end of intervention
Exclusion criteria: 1- Use of dietary supplement 2- Use of laxatives 3- Use of diuretics 4- Pregnancy or menopause 5- Not using recommended diet

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, the subjects will be assigned to intervention or control group based on even/odd numbers of admission. Also the subjects and the outcomes assessor are blind to allocated treatment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz, East Azarbaijan, Iran

City

Tabriz

Postal code

Approval date

2012-11-12, 1391/08/22

Ethics committee reference number

91132

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

Processes of Change

Timepoint

At baseline, 3 and 6 months after intervention

Method of measurement

Processes of Change Questionnaire

2

Description

Stages of Change

Timepoint

At baseline, 3 and 6 months after intervention

Method of measurement

URICA Questionnaire

3

Description

Decisional Balance

Timepoint

At baseline, 3 and 6 months after intervention

Method of measurement

Decisional Balance Questionnaire

4

Description

Self efficacy

Timepoint

At baseline, 3 and 6 months after intervention

Method of measurement

WEL Questionnaire

5

Description

Anthropometric parameters (weight, waist circumference, hip circumference, body mass index, waist to hip ratio)

Timepoint

At baseline, 3 and 6 months after intervention

Method of measurement

Standard procedures using scale, tape and formula

6

Description

Dietary intake
Timepoint
At baseline, 3 and 6 months after intervention
Method of measurement
3-day food records Questionnaire

7

Description
Nutritional behaviors
Timepoint
At baseline, 3 and 6 months after intervention
Method of measurement
Nutritional behaviors Questionnaire

8

Description
Biochemical parameters: fasting blood sugar and insulin and HOMA-IR index
Timepoint
At baseline and 6 months after intervention
Method of measurement
FBS (Auto analyzer), Fasting insulin (ELISA), HOMA-IR (Formula)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Individual balanced low calorie diet (an energy deficit of 500 calories of daily energy intake calculated from 3-day food records for every subject and the distribution of energy: <30% from fat, 55-60% from carbohydrate and 10-15% from protein) with six one-hour nutritional education sessions per week about Food Guide Pyramid, Food Exchange Systems, goal setting for weight loss, self monitoring, and stimulus control
Category
Lifestyle

2

Description
Control group: Individual balanced low calorie diet(an energy deficit of 500 calories of daily energy intake calculated from 3-day food records for every subject and the distribution of energy: <30% from fat, 55-60% from carbohydrate and 10-15% from protein)
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center

Nutrition Clinic
Full name of responsible person
Fatemeh Ghannadiasl
Street address
Shams Alley, Sarcheshmeh Square, Ardabil
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutritional Research Center, Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostadrahimi
Street address
Nutritional Research Center, Atar-Neishaboori Street, Golgasht Street, Tabriz, East Azarbaijan, Iran
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutritional Research Center, Vice chancellor for research, Tabriz 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
Mohaghegh Ardabili University
Full name of responsible person
Fatemeh Ghannadiasl
Position
PhD Student
Other areas of specialty/work
Street address
Shams Alley, Sarcheshmeh Square, Ardabil
City
Ardabil
Postal code
Phone
+98 45 1223 3048
Fax
Email

Ghannadiasl@uma.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Reza Mahdavi

Position

Professor, Nutrition and Biochemistry Department

Other areas of specialty/work

Street address

Faculty of Health and Nutrition, Atar-Neishaboori
Street, Golgasht Street, Tabriz, East Azarbaijan, Iran

City

Tabriz

Postal code

Phone

+98 41 1334 1113

Fax

Email

mahdavis@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mohaghegh Ardabili University

Full name of responsible person

Fatemeh Ghannadiasl

Position

PhD Student

Other areas of specialty/work

Street address

Shams Alley, Sarcheshmeh Square, Ardabil

City

Ardabil

Postal code

Phone

+98 45 1223 3048

Fax

Email

Ghannadiasl@uma.ac.ir

Web page address

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