

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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)

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+98 45 1551 0806

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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

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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

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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