

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effectiveness of nutrition education intervention on nutrition behaviors and weight loss of obese or overweight women using Protection Motivation Theory.

Protocol summary

Summary

Purpose of the study: effectiveness of nutrition education intervention on nutrition behaviors and weight loss of obese or overweight women using Protection Motivation Theory. Study design: randomized clinical trial with two intervention groups and one control group. Study population: obese and overweight women who attended to nutrition clinic. Inclusion criteria: being obese and overweight based on BMI (25-29.9 considered overweight, more than 30 considered obese); lack of diseases such as diabetes, cardiovascular, thyroid and also people who are treating by drugs that may change weight and appetite. Exclusion criteria: pregnancy; being infected with diseases that may occur during intervention and interfere with diet. Sample size: 150 subjects in total, 50 sample per groups. Study design: motivation intervention for two intervention groups (100 women), intention intervention for one intervention group. Outcome: weight loss of overweight and obese women

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051817736N1**

Registration date: **2014-06-12, 1393/03/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-12, 1393/03/22

Registrant information

Name

Seyed Kamaladdin Mirkarimi

Name of organization / entity

Golestan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Deputy of research, Isfahan University of Medical Science

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of nutrition education intervention on nutrition behaviors and weight loss of obese or overweight women using Protection Motivation Theory.

Public title

Nutrition education on weight loss based on protection motivation theory

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being obese and overweight based on BMI (25-29.9 considered overweight, more than 30 considered obese); lack of diseases such as diabetes, cardiovascular, thyroid and also people who are treating

by drugs that may change weight and appetite.
Exclusion criteria: pregnancy; being infected with diseases that may occur during intervention and interfere with diet.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Deputy of Research of Isfahan University of Medical Science

Street address

Azadi Square, Isfahan University of Medical Science

City

Isfahan

Postal code

8174673461

Approval date

2013-10-05, 1392/07/13

Ethics committee reference number

392501

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

Obesity or overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

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

Modification of Protection Motivation Theory Constructs

Timepoint

2 weeks, 2 and 6 month follow up after intervention

Method of measurement

Questionnaire based on Protection Motivation Theory Constructs

Secondary outcomes**1****Description**

weight loss

Timepoint

2 weeks, 2 and 6 month after intervention

Method of measurement

Measuring Body Mass Index

Intervention groups**1****Description**

Motivation intervention group is consisted of 50 women that they were received nutritional education, firstly that these sessions are including 2 sessions in one week that each session is 45 to 60 minutes. In the next stage, motivation intervention was done using a psychologist who is professional; these sessions are including 4 sessions in 2weeks (2 sessions per week) that each session is 45 to 60 minutes. Despite this intervention, a pamphlet regarding obesity and overweight based on protection motivation theory constructs (pamphlet content was proved by 4 authorized people in health education and promotion) was used.

Category

Behavior

2**Description**

Motivation and intention intervention group is consisted of 50 women that they were received nutritional education, firstly that these sessions are including 2 sessions in one week that each session is 45 to 60 minutes. In the next stage, motivation intervention was done using a psychologist who is professional; these sessions are including 4 sessions in 2weeks (2 sessions per week) that each session is 45 to 60 minutes. Despite this intervention, a pamphlet regarding obesity and overweight based on protection motivation theory constructs (pamphlet content was proved by 4 authorized people in health education and promotion) was used. Difference of this group compared to motivation intervention is in this way that women in this group followed a determined plan to lose weight that remind them to lose weigh in a definite timeline.

Category
Behavior

3

Description

Control group is consisted of 50 women that they were received nutritional education, firstly that these sessions are including 2 sessions in one week that each session is 45 to 60 minutes

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition Clinic

Full name of responsible person

Seyed Kamaladdin Mirkarimi

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Dr Eshghinia Department, 5 floor, Sina Apartment, 13 Edalat alley, Valiasr street, Gorgan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research of Isfahan University of Medical Science

Full name of responsible person

Dr Firouzeh Mostafavi, Assiastant Professor Isfahan University of Medical Science

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Isfahan, Azadi Square, Isfahan University of Medical Science, Health education and promotion Department

City

Isfahan

Grant name

از محل برنامه تحقیقات و فناوری دانشگاه علوم پزشکی اصفهان

Grant code / Reference number

Provided by Deputy of research of Isfahan University of Medical Science

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of research of Isfahan University of Medical Science

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

Isfahan University of Medical Science

Full name of responsible person

Seyed Kamaladdin Mirkarimi

Position

Ph.D candidate of Health education and Promotion

Other areas of specialty/work

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Person responsible for updating data

Contact

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