

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of combining cognitive group therapy with dietary therapy versus dietary therapy on self-efficacy and weight loss in obese women

Protocol summary

Summary

Objective: The aim of this study is to compare the efficacy of the combination cognitive group therapy and dietary therapy versus dietary therapy on weight loss and self-efficacy in obese women. Design: A comparative study design with pre and post test, is also semi-experimental method. Setting and conduct: 16 obese women are randomly assigned to a combining cognitive therapy with dietary therapy group (N=8) or dietary therapy group (N=8). Participants including major eligibility criteria: Participants are women with a BMI equal or greater than 30, at least 18 years old and education was at least a diploma. Interventions: Cognitive group therapy is limited to 20 sessions and 2 hours once a week. Dietary intervention also was administrated as usual treatment. Dietary treatment is carried out every two weeks and limits to 8 sessions. Main outcome measure: Weight is measured in both groups of participants at the beginning and after treatment. Self-efficacy: to compare and evaluate self-efficacy, The "Weight Efficacy Life Style Questionnaire" is administrated for both groups at the beginning and after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107317174N1**

Registration date: **2012-05-28, 1391/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-28, 1391/03/08

Registrant information

Name

Hamid Reza Sasanfar

Name of organization / entity

Kordestan University

Country

Iran (Islamic Republic of)

Phone

+98 21 4481 2510

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Minimally Invasive Surgery Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2012-03-18, 1390/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of combining cognitive group therapy with dietary therapy versus dietary therapy on self-efficacy and weight loss in obese women

Public title

Effectiveness of combining cognitive group therapy with dietary therapy versus dietary therapy on self-efficacy and weight loss in obese women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: BMI equal to or greater than 30; at least 18 years old, at least a diploma education; do not

receive a psychotherapy or other applications that are affective on weight loss or gain. Exclusion criteria: Pregnant or planning to pregnancy; menopause; receiving psychotropic drugs; addiction; Axis I: Clinical disorders including major depression disorder, psychotics disorder and substance use disorders. Axis II: Personality disorders and intellectual disabilities. Axis III: Acute medical conditions and physical disorders that affect to the obesity treatment. Axis IV: Psychosocial and environmental factors contributing to the obesity treatment.

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **16**

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Keshavarz Bolvar

City

Tehran

Postal code

Approval date

2012-01-01, 1390/10/11

Ethics committee reference number

40589-14156-14002-90

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Weight

Timepoint

Weight is measured in the beginning and after the treatment.

Method of measurement

Weight is measured by a scale with sensitivity of 100 grams.

2

Description

Self- Efficacy

Timepoint

Self-efficacy is measured at the before and after the treatment.

Method of measurement

weight efficacy life style questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Cognitive group therapy is based on the treatment manual and limited to 20 sessions and 2 hours once a week.

Category

Other

2

Description

Dietary intervention is administrated as usual treatment and carried out every two weeks and limited to 8 sessions.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Minimally Invasive Surgery Research Center

Full name of responsible person

Hamid Reza Sasanfar

Street address

Rasool Akram Hospital, Niaiesh Street

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotohi

Street address

Keshavar blovar, Tehran University of Medical Sciences

City

Tehran

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

Yes

Title of funding source

Vice Chancellor for Research, Tehran 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**

Kurdistan University

Full name of responsible person

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Position

MS. Student

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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