

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparative Effectiveness of group therapy Beck cognitive interventions and motivational interviewing on reduction of overweight, glycemic and lipids control and quality of life in overweight and obese women with type 2 diabetes

Protocol summary

Summary

This was an experimental single-blind randomized controlled trial (RCT) to determine comparative effectiveness of group therapy Beck cognitive interventions and motivational interviewing on reduction of overweight, glycemic and lipids control and quality of life in overweight and obese women with type 2 diabetes the effect of referring to Yazd Diabetes Research Center. Forty patients who meet the inclusion criteria (having BMI \geq 25, aged 18 to 65 years, female gender, diabetes, HbA1C \geq 7, the minimum cycle level of education, the signing of moral consent to participate in research) and exclusion criteria (the risk of psychiatric disorders such as eating disorders , personality disorder, bipolar disorder, obsessive-compulsive disorder on interview and according to the criteria of DSM-V, under psychiatric treatment or psychotherapy, having a program of moderate exercise at least 20 minutes a day, three days a week regularly for weight loss in the past six months based on self-reported, weight loss diet under the supervision of specialists in the past six months based on self-reported, debilitating diseases, diabetic complications such as advanced retinopathy and nephropathy. Also mutilation, drugs affecting the metabolism or weight body examination by a general practitioner and individual reports) are selected and put into two groups randomly (each group consisted of 20 patients). The intervention groups in addition their usual medication or diet therapy gets 8 sessions of group therapy cognitive intervention or motivational interviewing. In each group, before and after intervention also, four months after intervention the ORWELL and quality of life questionnaires will complete and blood samples will be compared to those of the patients themselves, or to the other group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022132698N1**

Registration date: **2017-04-08, 1396/01/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-08, 1396/01/19

Registrant information

Name

Raihane Azizi

Name of organization / entity

University of Medical Science of Yazd

Country

Iran (Islamic Republic of)

Phone

+98 35372802215

Email address

r.azizi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness of group therapy Beck cognitive interventions and motivational interviewing on reduction of overweight, glycemic and lipids control and quality of life in overweight and obese women with type 2 diabetes

Public title

Comparative Effectiveness of group therapy Beck cognitive interventions and motivational interviewing in overweight and obese women with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having BMI \geq 25; aged 18 to 65 years; female gender; diabetes; HbA1C \geq 7; the minimum cycle level of education; the signing of moral consent to participate in research. Exclusion criteria: The risk of psychiatric disorders such as eating disorders; personality disorder; bipolar disorder; obsessive-compulsive disorder on interview and according to the criteria of DSM-V; under psychiatric treatment or psychotherapy; having a program of moderate exercise at least 20 minutes a day; three days a week regularly for weight loss in the past six months based on self-reported; weight loss diet under the supervision of specialists in the past six months based on self-reported, debilitating diseases, diabetic complications such as advanced retinopathy and nephropathy; mutilation; drugs affecting the metabolism or weight body examination by a general practitioner and individual reports

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Yazd University of Medical Sciences

Street address

Bahonar square, Yazd, Iran

City

Yazd

Postal code

8917693571

Approval date

2017-01-01, 1395/10/12

Ethics committee reference number

IR.SSU.REC.1395.205

Health conditions studied

1

Description of health condition studied

Type 2 diabete

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

hemoglobin A1c (HbA1c)

Timepoint

Before the intervention, After intervention, 4 months after intervention

Method of measurement

blood test

2

Description

BMI

Timepoint

Before the intervention, After intervention, 4 months after intervention

Method of measurement

blood test

3

Description

Triglisirid

Timepoint

Before the intervention, After intervention, 4 months after intervention

Method of measurement

blood test

4

Description

Total Cholesterol

Timepoint

Before the intervention, After intervention, 4 months after intervention

Method of measurement

blood test

5

Description

HDL

Timepoint

Before the intervention, After intervention, 4 months after intervention

Method of measurement

blood test

6

Description

LDL

Timepoint

Before the intervention, After intervention, 4 months after intervention

Method of measurement

blood test

Secondary outcomes

1

Description

Quality of life

Timepoint

Before the intervention, After intervention, 4 months after intervention

Method of measurement

questionnaire

2

Description

Obesity-Related WELL-being

Timepoint

Before the intervention, After intervention, 4 months after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

The intervention groups in addition their usual medication or diet therapy gets 8 sessions of group therapy cognitive intervention.

Category

Behavior

2

Description

The intervention groups in addition their usual medication or diet therapy gets 8 sessions of group therapy motivational interviewing.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabete Research Center

Full name of responsible person

Masoud Rahmanian

Street address

Talar Honar alley, Bahonar square, Yazd, Iran

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Yazd University of Medical Sciences

Full name of responsible person

Hooshang Mehrparvar

Street address

Bahonar Square, Yazd, Iran

City

Yazd

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 of Yazd 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

Yazd Azad University

Full name of responsible person

Farzad Farhoodi

Position

PhD

Other areas of specialty/work**Street address**

Daneshgah Boolvar, Yazd, Iran

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00

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Diabete Research Center

Full name of responsible person

Raihane Azizi

Position

Endocrinologist, Assistant Professor

Other areas of specialty/work**Street address**

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Diabete Research Center

Full name of responsible person

Frariba Sepehri

Position

MA Clinical Psychology. Researcher and Psychologist

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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