

# 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

**City**

Yazd

**Postal code****Phone**

00

**Fax****Email**

farzad\_farhoodi@yahoo.com

**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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raihane.azizi@yahoo.com

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Diabete Research Center

**Full name of responsible person**

Frariba Sepehri

**Position**

MA Clinical Psychology. Researcher and Psychologist

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

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sepehri\_f66@yahoo.com

**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*