

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### **Lipid and Plasma lipo proteins, Blood glucose index, Negative process self-referral psychological syndrome:the effectiveness of Acceptance and Commitment Therapy with treatment based on Compassion in Diabetic non-clinical patients Depressed**

#### **Protocol summary**

##### **Study aim**

The effectiveness of acceptance and commitment therapy with treatment based on compassion in diabetic non-clinical

##### **Design**

two group intervention and one group control, simple randome, with 33 size of commity

##### **Settings and conduct**

Valiasr Hospital, Birjand, field and clinical study

##### **Participants/Inclusion and exclusion criteria**

Entry conditions: Willingness to participate, no obvious psychological disorder, diabetes for at least two years, fasting blood sugar less than 110, hemoglobin A and C less than 5.5, low fat lipoprotein between 100 to 130, high fat lipoprotein for women less From 60 and for men less than 40, cholesterol less than 200, triglycerides between 150 and 160 No entry conditions: kidney, heart, liver, lung, inflammatory, chronic gastrointestinal disease, thyroid disorder Insulin-dependent injection Taking estrogen and progesterone Addiction Lactase intolerance Taking herbal medicines obvious psychology disorder

##### **Intervention groups**

Acceptance and commitment-based treatment group of 11 people (experimental group of the effectiveness of acceptance and commitment treatment on biological factors plus psychological symptoms and negative self-efficacy processes in non-clinical depressed diabetic patients),11-person compassionate treatment group(experimental group of acceptance and treatment therapy)And commitment with compassion treatment and a control group of 11 people (without any intervention or receiving psychological treatment to compare the two experimental groups for the effectiveness of psychological interventions)

##### **Main outcome variables**

Plasma Lipids and Lipoproteins, Blood Glucose Index, Psychological Symptoms, Negative Self-Reference Processing,

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20191012045072N1**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **retrospective**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

##### **Registration date**

2020-10-28, 1399/08/07

##### **Registrant information**

##### **Name**

Reyhaneh Panahi

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 51 3609 6870

##### **Email address**

rpanahi.1366@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2019-05-02, 1398/02/12

##### **Expected recruitment end date**

2020-01-20, 1398/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Lipid and Plasma lipo proteins, Blood glucose index, Negative process self-referral psychological syndrome:the effectiveness of Acceptance and Commitment Therapy with treatment based on Compassion in Diabetic non-clinical patients Depressed

**Public title**

the effectiveness of ACT & CFT in Diabetic non-clinical patients Depressed

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness to participate Diabetes disease at least for 2 years High-fat lipoprotein( for women less than 60 mg/dl, for man less than 40 mg/dl) Low-Fat lipoprotein (100-130 mg/dl) Cholesterol less than 200 mg/dl Triglycerides (150 -160) Fasting blood sugar less than 110 Hemoglobin A1c less than 5.5

**Exclusion criteria:**

kidney, heart, liver, lung, inflammatory, chronic gastrointestinal disease, thyroid disorder Insulin-dependent injection Taking estrogen and progesterone Addiction Lactase intolerance Taking herbal medicines obvious psychology disorder

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **33**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to select and place people in two experimental groups and a control group, a simple random method was used. In order to place people in groups, the number of people, ie 33 people, was defined from 1 to 33 codes and the codes were written on paper and in They were placed in a container. Finally, each person randomly removed a code from the container and the selected code was written in the desired group (codes 1 to 11: intervention group 1, codes 12 to 22: intervention group 2, codes 23 to 33: control group).

**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 Committe of Birjand University of medical science

**Street address**

Nasrin 7.3, Ghafarri ave, Birjand city

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9188793487

**Approval date**

2019-05-02, 1398/02/12

**Ethics committee reference number**

IR.BUMS.REC.1398.001

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

Diabetics

**ICD-10 code**

E11.00

**ICD-10 code description**

Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)

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

Plasma lipids and lipoproteins

**Timepoint**

One month before the intervention, 7 and 30 days after the intervention

**Method of measurement**

CBC test and use of Pars Azmon laboratory kits

**2****Description**

Negative self-referential processors

**Timepoint**

7 and 30 days after the intervention

**Method of measurement**

Anger rumination scale, self-critical rumination, Diabetes distress screening scale Questionnaire

### 3

**Description**

Psychological symptoms

**Timepoint**

30 days before the intervention and 7 and 30 after the intervention

**Method of measurement**

Pennsylvania Worry Questionnaire, Diabetes Anxiety - Depression scale type 2 , Patient Health

### 4

**Description**

Blood sugar index

**Timepoint**

One month before the intervention, 7 and 30 after the intervention

**Method of measurement**

CBC test and use of Pars Azmon laboratory kits

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

"Intervention group 1: acceptance, commitment and practice, 8 sessions per week and each session of 90 minutes of psychological treatment in connection with the acceptance of thoughts and commitment of the patient to positive change in order to achieve the goals"

**Category**

Treatment - Other

### 2

**Description**

Intervention group 2: Acceptance, commitment and action with compassion, including 16 sessions twice a week for 2 hours, to increase self-compassion, knowledge of emotional systems, etc. to improve the quality of life In order to achieve the goals.

**Category**

Treatment - Other

### 3

**Description**

Control group: This group does not receive any psychological interventions and treatment. "

**Category**

Treatment - Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Valiasr Hospital, Birjand

**Full name of responsible person**

Reyhane Panahi

**Street address**

Ghaffari St., Nasrin 7-3. Number 4

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Birjand

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**Phone**

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**Email**

Rpanahi.1366@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Omid Shariati

**Street address**

No.7, Nasrin Ave., Ghafari Blvd., Birjand Town

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Birjand

**Province**

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

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Reyhane Panahi  
**Position**  
Resident  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**  
Birjand, Ghaffari St., Nasrin 7, No. 4  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

all personal data of study participants are identifiable after identifiable individuals are shared

### When the data will become available and for how long

Start the course after six months the result are published

### To whom data/document is available

personal in academic in institutions

### Under which criteria data/document could be used

drama counselling centers and hospitals

### From where data/document is obtainable

refer to my personal email adress

rpanahi.1366@gmail.com

### What processes are involved for a request to access data/document

responding to your request after 10 business days

### Comments

thanks for your cooperation