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 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
City
Birjand
Province
South Khorasan
Postal code
9188793487
Phone
+98 51 3609 6870
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
City
Birjand
Province
South Khorasan
Postal code
9188793487
Phone
+98 51 3609 6870
Email
Rpanahi.1366@gmail.com
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
City
Birjand
Province
Razavi Khorasan
Postal code
9188793487
Phone
+98 51 3609 6870
Email
rpanahi.1366@gmail.com

Person responsible for scientific 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
City
Birjand
Province
South Khorasan
Postal code
9188793487
Phone
+98 51 3609 6870
Email
RPANAHI.1366@GMAIL.COM

Person responsible for updating data

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
City
Birjand
Province
South Khorasan
Postal code
9188793487
Phone
+98 51 3609 6870
Email
rpanahi.1366@gmail.com

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