Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the effectiveness of metacognition Versus therapeutic reality on the treatment of care, quality of life, depression and biological variables in type 2 diabetes

Protocol summary

Study aim

The main purpose of this study was to determine and compare the effectiveness of metacognitive therapy and reality therapy on depression, self-care, quality of life and biological variables in patients with type 2 diabetes.

Design

The clinical trial will have a parallel control group, single-blind and randomized block groups on 75 patients.

Settings and conduct

This research is a randomized controlled trial and will benefit from three parts : pre - test , intervention and post - test and in Imam Ali hospital in Karaj

Participants/Inclusion and exclusion criteria

Inclusion criteria: completion and signing of written consent; no abuse of drugs and psychotropic drugs; age between 30-60 years old; more than a year has passed since the diagnosis; the minimum depression score is 8; fasting sugar should not exceed 135 mg / dL; HbA1c should not exceed 8%; failure to receive psychological treatment during the last 3 months; absence of severe physical diseases caused by diabetes such as kidney failure, vision and ... Criteria for non-entry: creating severe physical diseases caused by diabetes such as kidney failure, vision and ...; receiving psychological therapies during the intervention; take any sedatives or neuroleptics; increase in the dose of diabetes-related drugs.

Intervention groups

1.Metacognitive therapy group; 2. The reality therapy group that has 8 sessions of intervention each; 3. The control group that will receive the treatments at the end and if they wish.

Main outcome variables

Self-care; quality of life; depression; biomarkers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200916048737N1**
Registration date: **2020-10-16, 1399/07/25**
Registration timing: **retrospective**

Last update: **2020-10-16, 1399/07/25**
Update count: **0**

Registration date

2020-10-16, 1399/07/25

Registrant information

Name

Maryam Nasirdehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3254 9648

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nasirdehghanmaryam58@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-10-06, 1399/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of metacognition Versus therapeutic reality on the treatment of care, quality of life, depression and biological variables in type 2 diabetes

Public title
The effectiveness of metacognitive therapy and reality therapy on self-care behavior, quality of life, depression and biological variables in patients with type 2 diabetes

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Completion and signing of written consent by the subject No abuse of drugs and psychotropic drugs Age between 30-60 years More than a year has passed since the diagnosis of type 2 diabetes The minimum depression score is 8 Fasting sugar should not exceed 135 mg per deciliter HbA1c should not exceed 8% Failure to receive psychological treatment during the last 3 months Absence of severe physical diseases caused by diabetes such as kidney failure, vision and ...

Exclusion criteria:
Development of severe physical diseases caused by diabetes such as kidney failure, vision and ... Receiving psychological therapies during the intervention Consumption of any sedative or neuropsychiatric drugs Increase in the dose of diabetes-related drugs More than two absences

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization; because we have three study groups, name each group with the English letters A. B and C and write the letters A, B and C in three envelopes or three pieces of paper and close them and then randomly remove one of the envelopes. And according to the letter inserted in that person, we attribute it to that group, and with the arrival of the second person, we choose one of the two remaining envelopes and assign that person to that group, and then the third person to the group written in the next envelope. Which has not been selected in the previous two selections will be awarded and for the fourth to sixth persons the steps 2 to 5 will be repeated and then for the next three persons and ... until the required number of samples is completed in all three groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants will be unaware of the allocation of intervention groups, ie which treatment group they will be in.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Karaj Azad University

Street address
Moazzen Boulevard,Rajai Shahr

City
Karaj

Province
Alborz

Postal code
3149968111

Approval date
2020-09-09, 1399/06/19

Ethics committee reference number
IR.IAU.K.REC.1399.040

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Depression

Timepoint
Before the intervention, immediately after the intervention and one month and three months later

Method of measurement
Beck Depression Inventory

Secondary outcomes

1

Description

Quality of life

Timepoint

Before the intervention, immediately after the study and one month and three months later

Method of measurement

SF36 Health Status Questionnaire

2

Description

Self care

Timepoint

Before the intervention, immediately after the study and one month and three months later

Method of measurement

Tobert and Glasgow Self-Care Questionnaire

3

Description

Fasting blood sugar

Timepoint

Before the intervention, immediately after the study and one month and three months later

Method of measurement

blood test

4

Description

Glycosylated hemoglobin

Timepoint

Before the intervention, immediately after the study and one month and three months later

Method of measurement

Blood test

5

Description

Blood pressure

Timepoint

Before the intervention, immediately after the study and one month and three months later

Method of measurement

Analog blood pressure monitor

Intervention groups

1

Description

Intervention group 1: Reality therapy in 8 sessions, Reality therapy protocol: Session 1: Greetings and acquaintance of group members with each other, group rules and establishing emotional relationships between members and therapist and performing tests Session 2: Training Concepts of reality therapy and examining and focusing on self-knowledge, identifying the strengths and weaknesses of people. Session 3: Introducing general behavior and acquainting people with the four components of general behavior (thought, action, feeling and physiology), teaching decision-making skills and The importance of the present in this treatment Session 4: Explain and introduce the four conflicts and forced behaviors of the session 5: Familiarity with emotions such as depression from the perspective of reality therapy and relaxation skills training Session 6: Introducing destructive and constructive behaviors in relationships and life education Session 7: Teaching the ten principles of the theory of choice and responsibility Classification and execution of tests

Category

Lifestyle

2

Description

Intervention group 2: Metacognitive therapy which contains 8 sessions.Therapeutic protocol of metacognitive therapySession 1: Performing tests, stating the rules, establishing a therapeutic relationship and proper communication between membersSession 2: Explaining the logic of metacognition, teaching documents: blaming or gaining credibility and recognitionSession 3: Review the previous session and teach the topic of early conclusionSession 4: Review previous sessions and learn how to change the belief systemSession 5: Review previous sessions and empathy trainingSession 6: Review previous sessions and memory enhancement trainingSession 7: Reviewing previous sessions and learning to avoid prejudice (tagging)Session 8: Review the previous sessions and teach self-esteem and mood and test performance

Category

Lifestyle

3

Description

Control group: Control group: This group does not receive treatment until the end of the sessions and until the quarterly follow-up, but in the end, if desired, metacognitive and reality therapies are performed on them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital in Karaj

Full name of responsible person

Habibe Taghavi Kojidi

Street address

Azimiyeh roads, At the beginning of Chalous road, Karaj

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University, Karaj Branch
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only part of the data, such as information about the main outcome or the like, can be shared.
When the data will become available and for how long
The access period starts after printing
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
In case of similar and complementary researches, the information of the present research will be available
From where data/document is obtainable
Contact by email nasirdehghanmaryam58@gmail.com
What processes are involved for a request to access data/document
The applicant is required to email his / her scientific research documents and after access, he / she can access the information.
Comments