

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

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+98 26 3254 9648

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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 therapy Session 1: Performing tests, stating the rules, establishing a therapeutic relationship and proper communication between members Session 2: Explaining the logic of metacognition, teaching documents: blaming or gaining credibility and recognition Session 3: Review the previous session and teach the topic of early conclusion Session 4: Review previous sessions and learn how to change the belief system Session 5: Review previous sessions and empathy training Session 6: Review previous sessions and memory enhancement training Session 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

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Azimiyyeh roads, At the beginning of Chalous road, Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nilloofar Tahmouresi

Position

Consultant

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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