Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The comparison of the effectiveness of Emotion-Focused Cognitive Behavioral Therapy and Metacognitive Therapy on Psychological Helplessness, Psychological Cohesion, Social Health, Fasting Blood Sugar (FBS) and Glycated Hemoglobin (HbA1c) in Patients with Diabetes

Protocol summary

Study aim
Comparison of the effectiveness of ECBT and MCT on Psychological Helplessness, Psychological Cohesion, Social Health, FBS and HbA1c in Patients with Diabetes

Design
A controlled, parallel-group, single-blind, randomized clinical trial on 55 patients. Lottery was used for randomization.

Settings and conduct
Questionnaires of psychological helplessness, psychological cohesion, social health and blood test results were collected from the subjects and randomly assigned in the experimental and control groups (each group, 20 people). The ECBT and MCT courses were held in Karaj city at Saman Clinic in ten 90-minute sessions. After the end of the interventions, the post-test was taken from the subjects. For follow-up, blood tests and three psychological scales were also taken three months after the end of the interventions. During the whole period of the implementation of the intervention, the subjects were blinded to the way of distribution in the groups, assumptions and possible results of the interventions.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmation of type 2 diabetes by a doctor, treated with oral drugs, glycosylated hemoglobin level between 6.5% and 8.5%, age range 45 to 60 years, not suffering from other physical and mental illnesses and not substance abuse Exclusion criteria: Absence of more than two sessions in treatment sessions, non-compliance with the treatment plan, failure to respond to the research questionnaires and or tests in one of the stages of pre-test, post-test and follow-up

Intervention groups
The first intervention group: emotion-focused cognitive behavioral therapy (behavior) The second intervention group: Metacognitive (behavioral) therapy The third intervention group: control group (no example)

Main outcome variables
Psychological Helplessness, Psychological Cohesion, Social Health, FBS, and HbA1c

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230831059310N1**
Registration date: **2023-10-25, 1402/08/03**
Registration timing: **retrospective**

Last update: **2023-10-25, 1402/08/03**
Update count: **0**

Registration date
2023-10-25, 1402/08/03

Registrant information

Name
Samira Jelodari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 26 3455 1635
Email address
samira.jelodari@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2022-09-01, 1401/06/10
Actual recruitment start date
2022-09-03, 1401/06/12
Actual recruitment end date
2022-09-15, 1401/06/24
Trial completion date
2023-02-22, 1401/12/03

Scientific title
The comparison of the effectiveness of Emotion-Focused Cognitive Behavioral Therapy and Metacognitive Therapy on Psychological Helplessness, Psychological Cohesion, Social Health, Fasting Blood Sugar (FBS) and Glycated Hemoglobin (HbA1c) in Patients with Diabetes

Public title
Effectiveness of ECBT and MCT on Psychological Helplessness, Psychological Cohesion, Social Health, FBS and HbA1c in Patients with Diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of type 2 diabetes by a doctor, treated with oral drugs, glycosylated hemoglobin level between 6.5% and 8.5%, age range 45 to 60 years, having at least a diploma education, not receiving other psychological treatments, not suffering from other physical and mental illnesses and not taking psychoactive drugs or substance abuse
Exclusion criteria:
Age
From **45 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **55**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients to intervention and control groups was done by lottery. For this purpose, the names of all the people were written on small pieces of paper and put into a box. 3 different sheets with the names of 3 intervention and control groups were also prepared. First, open the sheet of the first intervention group and write the names of the first 20 subjects who came out of the box. For other groups, this process continued until the end (20 people in the second intervention group and 20 people in the control group).
Blinding (investigator's opinion)
Single blinded
Blinding description
All participants were blinded to the way of distribution in groups, possible and expected results, and research assumptions, and no information was provided to them.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad University Ethic Committee-Karaj Branch
Street address
Amir almomenin university complex, Moazen Blvd, Rajaee Shahr.
City
Karaj
Province
Alborz
Postal code
3149968111
Approval date
2022-08-31, 1401/06/09
Ethics committee reference number
IR.IAU.K.REC.1401.089

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
Psychological Helplessness
Timepoint
Before the start of the intervention, after the end of the intervention and three months after the end of the intervention
Method of measurement
Depression, Anxiety, Stress Scale (DASS-21)

2

Description
Psychological Cohesion
Timepoint
Before the start of the intervention, after the end of the

intervention and three months after the end of the intervention

Method of measurement

Sense of Coherence Questionnaire

3

Description

Social Health

Timepoint

Before the start of the intervention, after the end of the intervention and three months after the end of the intervention

Method of measurement

Social Well-Being Questionnaire

4

Description

Fasting Blood Sugar (FBS)

Timepoint

Before the start of the intervention, after the end of the intervention and three months after the end of the intervention

Method of measurement

Blood Test

5

Description

Glycated Hemoglobin (HbA1c)

Timepoint

Before the start of the intervention, after the end of the intervention and three months after the end of the intervention

Method of measurement

Blood Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group, Emotion-Focused Cognitive Behavioral Therapy (ECBT) Group: In this intervention, the ECBT treatment protocol of Sovag, Kendall, Komer and Rubin was used in 10 sessions, each session lasting 90 minutes, one session per week. These sessions were held in person at Saman Clinic. After the initial introduction and establishing communication and creating treatment commitment, we worked on identifying basic emotions, evaluating the degree of vulnerability and emotional skills, identifying specific emotions that are difficult to understand and regulate, identifying and examining the main beliefs related to emotions, Facilitation in the expression and description of feelings, needs and desires, mental confrontation and coping training, behavioral and physiological consequences of excitement and progressive relaxation training.

Category

Treatment - Devices

2

Description

Intervention group, Metacognitive Therapy (MCT): The metacognitive therapy protocol of the University of Hamburg, taken from the research of Rajabi, Malihiozakreni, Asadi et al. (2019), was used for 10 sessions, each session lasting 90 minutes, one session per week in person at the Saman clinic. After getting to know the members and the therapist with each other, the following issues were discussed in the therapy sessions: Familiarity with the metacognitive model, identification of metacognitive beliefs related to the definition of memory, hasty conclusions, identification of irrational metacognitive beliefs about exaggerating negative events and minimizing positive events and the cycle defective thoughts, identification of values and strategies for living based on values, assessment of negative metacognitive beliefs related to risk and examination of negative feelings about illness and identification of negative sculptural thoughts

Category

Treatment - Devices

3

Description

Control group: This group did not receive any intervention during the research.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Abbasi Sharghi Diabetes Clinic

Full name of responsible person

Dr. Sasan Abbasi Sharghi

Street address

Sabz building, Ground floor, Corner of Einollahi Alley, South Taleghani Blvd.

City

Karaj

Province

Alborz

Postal code

3136696591

Phone

+98 21 3270 8609

Email

sharghisasan@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. AliReza Hozhabri
Street address
Amir almomenin university complex, Moazen Blvd., Rajaee Shahr.
City
Karaj
Province
Alborz
Postal code
3149968111
Phone
+98 26 3425 9571
Email
karaj@iau.ece.ir
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
Samira Jelodari
Position
Ph.D. Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Amir almomenin university complex, Moazen Blvd., Rajaee Shahr.
City
Karaj
Province
Alborz
Postal code
3149968111
Phone
+98 26 3425 9571
Email
samira.jelodari@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Samira Jelodari
Position
Ph.D. Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Amir almomenin university complex, Moazen Blvd., Rajaee Shahr.
City
Karaj
Province
Alborz
Postal code
3149968111
Phone
+98 26 3425 9571
Email
samira.jelodari@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Samira Jelodari
Position
Ph.D. Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Amir almomenin university complex, Moazen Blvd., Rajaee Shahr.
City
Karaj
Province
Alborz
Postal code
3149968111
Phone
+98 26 3425 9571
Email
Samira.jelodari@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Some information about the main outcome is shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

All researchers are able to access the study results.

Under which criteria data/document could be used

The information is not provided to the organization or to another person.

From where data/document is obtainable

Samira Jelodari Samira.jelodari@yahoo.com

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

The study data are published in the article and other data are not available to the applicants.

Comments