

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The Effect of Cognitive-Behavioral Intervention on Depression, Anxiety and Self-Management in Patients with Diabetes

Protocol summary

Study aim

Determining the effect of well-being therapy on depression, anxiety, self-management in women with type 2 diabetes

Design

A Randomized, Controlled, Double-Blind, Parallel-Group Clinical Trial

Settings and conduct

Therapy is provided at Mashhad Diabetes Center. Samples are selected according to the inclusion criteria and are divided into control and intervention groups. Depression, anxiety and self-management inventory are completed as pretest. The inventories are completed again after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: gender: female; age limit: minimum 35 and maximum 65 years old; scores of higher than 19 on the Beck Depression Inventory (BDI); scores of higher than 16 on the Beck Anxiety Inventory (BAI). Exclusion criteria: exhibiting signs and symptoms of severe mental disorders including personality disorder; receiving other psychological and pharmacological treatments at the time of the research; taking psychiatric medications.

Intervention groups

Intervention group: the well-being therapy program for diabetic patients is composed of 12 sessions of 90 minutes held once a week for three months. Early sessions (1-2): preparing the group, building relationships, and introducing the logic of treatment. Middle session (2-6): identifying existing barriers and removing irrelevant beliefs with the aim of self-observation of care seekers to achieve psychological well-being Last sessions (6-12): introducing multi dimensions of cognitive behavioral model.

Main outcome variables

Self Management; depression; anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191115045451N1**

Registration date: **2019-12-17, 1398/09/26**

Registration timing: **retrospective**

Last update: **2019-12-17, 1398/09/26**

Update count: **0**

Registration date

2019-12-17, 1398/09/26

Registrant information

Name

amin zafaralahyari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3890 6149

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a.zafaralahyari@iautj.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-19, 1398/07/27

Expected recruitment end date

2019-11-19, 1398/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Cognitive-Behavioral Intervention on Depression, Anxiety and Self-Management in Patients with Diabetes

Public title

The effect of cognitive-behavioral therapy on diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Gender: female Age: Minimum 35 and maximum 65 years old Depression score of higher than 19 in the 21-item Beck Depression Inventory (BDI-21) Anxiety score of higher than 16 in the 21-item Beck Anxiety Inventory (BAI-21) Minimum level of Education: high school diploma

Exclusion criteria:

Evidence of severe mental disorder (including personality disorder), Other simultaneous psychological and medicinal treatments Psychiatric medications.

Age

From **35 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocking is used to make balance amongst the samples of each group under examination. This feature might be useful when meso-level analysis is needed during sampling process, so that each group is allocated the same amount of samples. In this design randomizing shall take place based on permuted blocking. Thus, patients will be grouped in 15 blocks, each comprising two people from the experimental group and two people from the control group. Finally, group 1 will be treated using cognitive behavioral therapy (CBT) and the control group shall receive no treatment.

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

National Committee on Ethics in Biomedical Research

Street address

Boulevard âmouzegar 17

City

Mashhad

Province

Razavi Khorasan

Postal code

9189895163

Approval date

2019-08-13, 1398/05/22

Ethics committee reference number

IR.IAU.MSHD.REC.1398.083

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Diabetes

Primary outcomes

1

Description

Depression

Timepoint

At the beginning of the study, both experimental and control groups will be measured before and after the intervention.

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The cbt program for diabetic patients is composed of 12 sessions of 90 minutes held once a week for three months. Early sessions (1-2): Preparing the group, building relationships, and introducing the logic of treatment. Clinical interview, getting identification data, information about feelings, current distress, previous distress, defining the curriculum process, defining the structure and conditions of cbt, including the number of sessions, duration of sessions, interval between sessions Middle session (2-6): Identifying existing barriers and removing irrelevant beliefs with the aim of self-observation of care seekers to achieve psychological cbt the role of lack of positive emotions, giving the first home workout, explaining the concept of optimal

experiences, describing thoughts and behaviors that are detrimental to cbt, explaining the concept of self-therapy, explaining problem solving, self-acceptance and its role in mental relaxation Last sessions (6-12):Introduction and explanation of cognitive errors and Modifying maladaptive behavior patterns, Teaching the implementation of behavioral activation technique Anger management training and anti-anxiety management strategy.

Category

N/A

2**Description**

Control group:This group receives routine caring actions like glycemic control, medical advice, and prescription of medication from the physician of Diabetes Center. However, it does not receive cbt therapy intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mashhad Diabetes Center

Full name of responsible person

Dr. Reza Mohamadi

Street address

9th Vakilabad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr, Hamid Shahabi

Street address

No. 2, Behvarz 9, Dr. Hesabi 4, Jam Junc., Daneshgah St

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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

1

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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Amin Zafaralahyari

Position

student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mohammad Hossein Biyazi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable