

# 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)

##### Phone

+98 51 3890 6149

##### Email address

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 amouzegar 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

**City**

Mashhad

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**Email**

ramin.arminn@gmail.com

**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**

Psychology

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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**

University Student

**Latest degree**

Master

**Other areas of specialty/work**

Psychology

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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