

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effect of Cognitive behavior group training on HbA1C self efficacy, depression, illness perception and quality of life in patient with diabetes type II

Protocol summary

Summary

The aim of current study is the effect of Cognitive-behavioral group training on HbA1c (glycosylated hemoglobin), self-efficacy, depression, illness perception and quality of life on patients with type II diabetes. This study is a pretest- post test study with control group. The sample consisted of 30 patients with diabetes type II from 4000 diabetes population with file in Sari. they will dividing randomly into 15 people in control and experimental groups. The main inclusion criteria are:1) type II diabetes patients with file 2) live in Sari,3) patients eligible criteria of Major depressive disorder 4)patients Having at least a high school diploma 5) age of patients between 20-55 years old. The main exclusion criteria are: Non-use of psychiatric antidepressant medications during the intervention. The experimental group receive 10 sessions of cognitive-behavioral training with Beck approach with 1.5 hours duration two times a week. The control group did not receive any intervention. In both control and experimental groups before the intervention, HbA1c testing will done and by all patients, the Beck Depression Inventory, diabetic self-efficacy, illness perception, diabetic quality of life will filled. In the follow-up, immediately after the intervention and one month later questionnaires will complete by patients but HbA1c testing will done only a month after the intervention. The primary outcomes of the study will include HbA1c and 4 psychological variables of, diabetic self-efficacy depression, illness perception and quality of life .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021832637N1**
Registration date: **2017-05-12, 1396/02/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-12, 1396/02/22

Registrant information

Name

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Name of organization / entity

Islamic Azad University - Sari Branch

Country

Iran (Islamic Republic of)

Phone

+98 11 4204 4744

Email address

mbarzegar2020@gmail.com

Recruitment status

Recruitment complete

Funding source

with first writer MOHAMMAD ALI BARZEGAR DAMADI .
00989111241563

Expected recruitment start date

2012-04-29, 1391/02/10

Expected recruitment end date

2012-07-30, 1391/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Cognitive behavior group training on HbA1C self efficacy, depression, illness perception and quality of

life in patient with diabetes type II

Public title

Effect of cognitive behavior therapy on HbA1c and psychological factor on patient with diabetic type 2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients have diabetes type II; at least a diploma ; resident of Sari city; HbA1C between 6.5 – 8 % FBS \geq 126 mg/dl , 2hrpp \geq 180 mg / dl ; patients have depression disorder Exclusion criteria: Patients who received antidepressants.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

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

IAU- AZAD University

Street address

sari sea road

City

sari

Postal code

48164194

Approval date

2017-02-07, 1395/11/19

Ethics committee reference number

IR.IAU.SARI.REC.1395.12

Health conditions studied

1

Description of health condition studied

Diabetes type 2 - Depression

ICD-10 code

E11,F32

ICD-10 code description

Non-insulin-dependent diabetes mellitus, Depressive episode

Primary outcomes

1

Description

HbA1c

Timepoint

pretest-posttest control group

Method of measurement

in medical lab with Nicocard kit

2

Description

Depression

Timepoint

pretest-posttest control group and one month follow-up.

Method of measurement

Beck depression Inventory

3

Description

Self- efficacy

Timepoint

pretest-posttest control group and one month follow-up.

Method of measurement

DMSES questionnaire

4

Description

Quality Of life

Timepoint

pretest-posttest control group and one month follow-up.

Method of measurement

D39 questionnaire

5

Description

Illness Perception

Timepoint

pretest-posttest control group and one month follow-up.

Method of measurement

IPQ questionnaire

Secondary outcomes

1

Description

without secondary measure

Timepoint

none

Method of measurement

none

Intervention groups**1****Description**

Type of intervention: Cognitive- Behavioral group training ,5 weeks ,10 sessions, two days a week ,duration 1.5 hours/ Sessions

Category

Other

2**Description**

The control group does not receive any treatment

Category

N/A

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

Emam Hospital - Diabetes clinic

Full name of responsible person

Miss Akbardokht

Street address

Mostafavian Clinic Emam Hospital Sari

City

Sari

2**Recruitment center****Name of recruitment center**

Dr akha MD- clinic

Full name of responsible person

Miss Doctor Akha MD

Street address

Gharan Street Sari

City

Sari

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

Islamic Azad University - Sari Branch

Full name of responsible person

Mohammad Farsi

Street address

Sea Road Kilometer 7

City

SARI

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Islamic Azad University - Sari Branch

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

with me corresponding writer

Full name of responsible person

mohammad ali barzegar damadi

Position

clinical psychologist MA

Other areas of specialty/work**Street address**

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

IAU

Full name of responsible person

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Position

General psychologist PHD

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

this research is a thesis for Master degree in IAU in sari

Full name of responsible person

mohammad ali barzegar damadi

Position

clinical psychologist MA

Other areas of specialty/work**Street address****City**

sari

Postal code**Phone****Fax****Email**

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty