

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of peer support on depression in patients with diabetes type II

Protocol summary

Study aim

Objectives: This research intends to evaluate the effect of peer support on moderate depression in type II diabetics. Peer support can link people sharing experiences to provide the practical, emotional, and ongoing support to control patients' sustained behavior changes.

Design

Design: This study is a randomized clinical trial with pretest - posttest and control group.

Settings and conduct

Sixty-six patients were randomly divided into intervention and control groups. Then, one person with type 2 diabetes was selected as a peer. In the next stage, the test group is divided into three groups. Then, the test group sessions will be held in the form of six 60-minute support sessions for each group with the help of a peer patient in the Diabetes Clinic of Sabzevar University of Medical Sciences. The materials presented in the sessions include familiarizing patients with each other and sharing experiences about the symptoms and problems of the disease in reducing depression and expressing experiences in ways that reduce the physical problems of the disease that can lead to depression. The content and the way the program is run for all groups is the same.

Participants/Inclusion and exclusion criteria

Major entry requirements: Age 18 to 65 years old; reading and writing skills; not having a physical limitation in self-care; having active records in the diabetes clinic; having a type 2 diabetes last at least three months previously; having no problems with hearing and hearing; Written consent for participation in the research; lack of experience of acute and severe stress (such as the death of first degree relatives or the like) in the last six months; the rate of glycosylated hemoglobin was greater than 7%; fasting blood glucose greater than 140 mg; Beck's Beck Depression Inventory Score Between 19-29 (moderate depression) Major exit conditions: lack of mental illness and illnesses that

prevent learning; such as (memory problems, Alzheimer's disease); the use of drugs that affect the level of consciousness and learning; have medical and paramedical education; History of the company in the same research and having severe depression or suicidal thoughts.

Intervention groups

One person with type 2 diabetes is selected as a peer. Choosing this patient based on features such as better adaptation for disease control, the ability to administer meetings, proper social relationships, lesser symptoms of illness with the approval of a clinician, having a history of at least 5 years of illness, having a diploma or higher, and having an interest in leading the group is. In the next stage, the test group is divided into three groups. Then, the faculty group sessions are held face-to-face and held for six consecutive weeks in 6 consecutive 60-minute support sessions. Before the start of the study, immediately after the sessions and Six weeks after the end of the intervention, the Beck questionnaire was completed by both groups. The control group only receives clinic routine care (such as doctor's visits and training classes, etc.).

Main outcome variables

Depression rate; Measures: Before and 45 and 90 days after the intervention began; Variable Measurement Method: Beck Depression Inventory II

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038209N1**

Registration date: **2018-03-15, 1396/12/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-15, 1396/12/24**

Update count: **0**

Registration date

2018-03-15, 1396/12/24

Registrant information**Name**

Zahra Rahimi

Name of organization / entity**Country**

Iran (Islamic Republic of)

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RahimiZ94@medsab.ac.ir

Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2018-03-05, 1396/12/14

Expected recruitment end date

2018-07-05, 1397/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of peer support on depression in patients with diabetes type II

Public title

"The effect of peer support group on depression diabetes"

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Based on patient records in Sabzevar Diabetes Clinic and diagnosis of endocrinologists, and the results of a fasting blood sugar test, they will have type 2 diabetes and will take anti-diabetes medication Have literacy to read and write. There is no vision and hearing problem. Have written consent to participate in the research. The age of the patient is between 18-65 years. Experience of acute and severe stress (such as the death of first degree relatives or the like) in the last six months The patient's glycosylated hemoglobin is greater than 7%. He has been determined for at least three months before diagnosis of diabetes The fasting blood glucose of the patient is more than 140 milligrams. Beck Depression Inventory Score Between 19-29 (Moderate Depression)

Exclusion criteria:

Company history in similar research Use of drugs that affect the level of consciousness and learning Have medical and paramedical education Affected by aging diseases that prevent learning (memory problem, Alzheimer's ...) Having severe depression or suicidal thoughts Disabling physical and mental disabilities

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients with active records in the diabetes clinic of Sabzevar University of Medical Sciences who are eligible to enter the study are selected to access the study. Based on the sample size, 64 patients were divided into two groups of intervention and control in random allocation based on four blocks

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**

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Towhid City, Sabzevar University of Medical Sciences

City

Sabzevar

Province

Razavi Khorasan

Postal code

613873136 9

Approval date

2017-12-07, 1396/09/16

Ethics committee reference number

IR.MEDSAB.REC.1396.82

Health conditions studied**1****Description of health condition studied**

Moderate depression-Type 2 diabetes

ICD-10 code

E10,E11,E1

ICD-10 code description

Moderate depression- Diabetes mellitus

Primary outcomes

1

Description

Moderate depression

Timepoint

At the beginning of the study, 45 and 90 days after the start of the study

Method of measurement

Beck Depression Inventory-2

Secondary outcomes

empty

Intervention groups

1

Description

Interventions: After preparing peers, the participants in the intervention group in the selected center was supported by their peers in face to face meetings for 6 following weeks (6 sessions of 1 hours) whit Instructional content is defined in relation to the identification diabetes, types of diabetes, risk factors, complications, treatment and control, the role of diet, exercise, Self-monitoring of blood glucose and medications to control diabetes by group discussions, asking and answering sessions and sharing their personal experiences and success on the diabetes disease control. whereas the control group received only routine care(such as the periodical doctor visits and pedagogical classes...).

Category

N/A

2

Description

Control group: The control group received only routine care (such as the periodical doctor visits and pedagogical classes).

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Sabzevar University of Medical Sciences

Full name of responsible person

Rahimi Zahra

Street address

Special Clinic of Sabzevar University of Medical Sciences, Tabas Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

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?

Yes

Title of funding source

Sabzevar University of Medical Sciences

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

Sabzevar University of Medical Sciences

Full name of responsible person

Rahimi Zahra

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

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

Data Dictionary

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

Title and more details about the data/document

Only part of the information, such as information on the main outcome or the like, can be shared

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Information will only be available to scholars working in academic and academic institutions.

Under which criteria data/document could be used

Only part of the information, such as information on the main outcome or the like, can be shared

From where data/document is obtainable

Call 989154088549 or send a message to zahra.rahimi1789@gmail.com.

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

Access to information immediately after receiving the email and checking it.

Comments