

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the effectiveness of cognitive behavioral modeling by peer and nurse on anxiety in type 2 diabetic patients .

Protocol summary

Study aim

Determine and compare the effectiveness of cognitive behavior training by peer and nurse on anxiety in patients with type-2 diabetes

Design

Clinical trials, control group and two intervention groups, based on counseling, randomized.

Settings and conduct

This study was performed on type 2 diabetic patients referred to the diabetes clinic in Gachsaran city. Patients were randomly divided into three groups: control, nurse intervention, and intervention by peer group.

Participants/Inclusion and exclusion criteria

Entry Criteria: Type 2 diabetes Duration of more than one year The patient's score, according to the Hamilton Saxa Anxiety Inventory, is above 25 Literacy reading and writing Inclination to study and have enough time to participate in the study Not having physical and mental disabilities Not having medical and pharmaceutical education Lack of company background in the same study The ability of the patient to take care of yourself Exit criteria: Patient withdrawal from the company for further research More absenteeism in educational classes Failure to complete the data collection tool

Intervention groups

An interventional study is a type of clinical trial. Patients were divided into two groups of intervention and one control group. One of the intervention groups was trained by the nurse and other group members. Before training, Hamilton's Sachs 'anxiety questionnaire was answered by both the experimental and control groups and one week after the intervention (teaching cognitive behavioral model), the Hamilton Sachs' anxiety questionnaire was again run on both groups. The control group also receives diabetes routine clinic care, and the two other groups of Hamilton anxiety inventory are also filled in.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190211042681N1**

Registration date: **2019-06-01, 1398/03/11**

Registration timing: **retrospective**

Last update: **2019-06-01, 1398/03/11**

Update count: **0**

Registration date

2019-06-01, 1398/03/11

Registrant information

Name

Ali Niknam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3222 5945

Email address

ali.niknam@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2019-05-25, 1398/03/04

Actual recruitment start date

2019-03-02, 1397/12/11

Actual recruitment end date

2019-05-21, 1398/02/31

Trial completion date

2019-05-21, 1398/02/31

Scientific title

Comparison of the effectiveness of cognitive behavioral modeling by peer and nurse on anxiety in type 2 diabetic patients .

Public title

Comparison of the effectiveness of cognitive behavioral modeling by peer and nurse on anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes with a history of over one year. According to the Hamilton Sachs Anxiety Inventory, the patients' score is higher than 25.

Exclusion criteria:

Lack of reading and writing skills. Unwillingness to participate in the study and not having enough time to participate in the study. Disabling physical and mental illness. Have medical and pharmaceutical education. Having a company background in the same study. Inability of the patient to take care of himself.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected in an accessible sampling form, demographic information form and tools for key variables will be completed by interviewing everyone. Subjects were assigned to three groups using permutation blocking method: training by nurse (25), training by peer (25) and control group (25 people).

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 Yasouj University of Medical Sciences

Street address

Shahid Motahari Blvd.

City

Yasouj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2019-02-16, 1397/11/27

Ethics committee reference number

IR.yums.REC.1397.140

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Anxiety Score Based on Hamilton's Anxiety Rating Scale

Timepoint

The anxiety level of the patients is measured before intervention and one week after intervention

Method of measurement

Hamilton's Anxiety Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Control group: The control group receives only routine training related to its illness, including self-care, nutrition, exercise, and drug training.

Category

Prevention

2

Description

Intervention group 1: Trained by 4 nurses who have been trained in cognitive-behavioral behavioral techniques by psychologists for 16 sessions, they are trained in methodological behavioral techniques. Before the intervention and one week after the intervention, the rate Their anxiety is measured by Hamilton's Anxiety Rating Scale.

Category

Behavior

3

Description

Intervention group: Intervention group 2: Trained by 4 diabetic patients as "peers" previously trained by a psychologist in the cognitive-behavioral model, trained for 16 sessions of methodological behavioral techniques. Before the intervention and One week after the intervention, their anxiety levels are measured by Hamilton's Anxiety Rating Scale.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Gachsaran City

Full name of responsible person

Parvin Masnoei

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Ali Mousavi Zadeh

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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

Yasouj 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

Yasouj University of Medical Sciences

Full name of responsible person

Dr. Shir Ali Kharamin

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

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Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

After making a clinical trial and identifying the results, we will decide to publish.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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