Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 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)

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+98 74 3222 5945

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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
Kohgilouyeh-va-Boyrahmad
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
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Sponsors / Funding sources

1

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Health.epid@gmail.com
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
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Other areas of specialty/work
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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