

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of cognitive-behavioral education combined with motivational interviewing in comparison with cognitive-behavioral education on depression, drug adherence and hemoglobin A1C in patients with type 2 diabetes with depressive symptoms

Protocol summary

Study aim

Determining the effect of cognitive-behavioral education combined with motivational interviewing in comparison with cognitive-behavioral education on depression, drug adherence and hemoglobin A1C in patients with type 2 diabetes with depressive symptoms referred to Zahedan Diabetes Clinic in 2016

Design

Clinical trial with two groups receiving behavioral cognitive training with motivational interview and behavioral cognitive training group, with parallel, non-blind, randomized groups, on 90 patients

Settings and conduct

Diabetes Clinic of Bu Ali Hospital in Zahedan, selecting patients by available sampling method and then dividing them randomly into two groups of cognitive-behavioral training with motivational interview and cognitive-behavioral group

Participants/Inclusion and exclusion criteria

Inclusion criteria Willingness to participate in the study
Diagnosis of type 2 diabetes based on patient records
Hemoglobin A1C in the amount of 8 and more
Age range 60-20 years
Obtain a score of at least 21 from the Beck Depression Inventory and with the Confirmation of Depression in the Mental Status Examination (MSE).
No known other psychiatric illnesses
6 months to a year of illness passed Full consciousness and no communication problem
No addiction and substance abuse
No history of participating in a rehabilitation, counseling or training program at the same time
Exclusion criteria Critical illness, hospitalization, death, or any unexpected occurrence during the study
Do not attend more than one treatment session

Intervention groups

Behavioral cognitive training group with motivational interview and behavioral cognitive training group

Main outcome variables

Depression, hemoglobin a1c, drug adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160924029954N14**

Registration date: **2020-11-23, 1399/09/03**

Registration timing: **retrospective**

Last update: **2020-11-23, 1399/09/03**

Update count: **0**

Registration date

2020-11-23, 1399/09/03

Registrant information

Name

Ali navidian

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 54 3344 2482

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-31, 1399/06/10

Expected recruitment end date

2020-10-06, 1399/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive-behavioral education combined with motivational interviewing in comparison with cognitive-behavioral education on depression, drug adherence and hemoglobin A1C in patients with type 2 diabetes with depressive symptoms

Public title

the effect of cognitive-behavioral training along with motivational interviewing in comparison with cognitive-behavioral training on depression, medication adherence and level of hemoglobin A1C in type 2 diabetic patients with depression signs

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Hemoglobin a1c in the amount of 8 and more Obtaining a score of 21 from the Beck Depression Inventory and confirming depression in the mental state examination No other psychiatric illnesses 6 months to 1 year of illness Full consciousness and no communication problem No addiction and substance abuse No history of participating in a counseling or training rehabilitation program at the same time Willingness to participate in the study Diagnosis of type 2 diabetes based on the patient's record Age range 20 to 60 years

Exclusion criteria:

Critical illness, hospitalization, death, or any unexpected events during the study Do not attend more than one treatment session

AgeFrom **20 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

From patients diagnosed with type 2 diabetes referred to clinics based on inclusion criteria, by available sampling method, the patients will be selected. Due to the fact that the study population is patients with type 2 diabetes with depression, if they have general conditions, first with the help of Beck Depression Inventory, patients with a score above 21 are identified and then with clinical examination and mental status (MSE) of the depressed. The presence of patients with diabetes will be ensured as one of the most important inclusion criteria. Patients with depressive type 2 diabetes who are selected in this way

will be randomly assigned to two groups of cognitive-behavioral education with motivational interview and cognitive-behavioral education. Thus, 90 colored balls (45 white balls for cognitive-behavioral education) And 45 red balls for cognitive-behavioral training combined with motivational interviews) randomly taken out of the container and based on the color of the extracted ball, group membership will be recorded on the list, respectively. By referring to the research environment and selecting and entering eligible patients, gradually and in order of the list, the membership of each patient will be determined in the order of inclusion in the study and the relevant intervention will be performed about him.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

does not have

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee Of Zahedan University Of Medical Sciences & Health Services

Street address

Administrative Complex Of Zahedan Medical Science Campus, Persian Gulf Blvd. Dr. Hesabi Square, Zahedan

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zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2020-08-09, 1399/05/19

Ethics committee reference number

IR.ZAUMS.REC.1399.190

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

Diabetic patients

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

2

Description of health condition studied

depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

People whose Beck questionnaire score is above 21.

Timepoint

"Measurement of depression at the beginning of the study and 3 months after the intervention"

Method of measurement

Beck Depression Inventory

2

Description

The score they get from the Drug Adherence Questionnaire.

Timepoint

Measurement of drug adherence at the beginning of the study and three months after the intervention

Method of measurement

Moriski Drug Adherence Questionnaire

3

Description

Percentage of globin a1c reported by the laboratory

Timepoint

Measurement of hemoglobin a1c at the beginning of the study and three months after the intervention

Method of measurement

Laboratory measurement of hemoglobin a1c

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention procedure: 1: Cognitive-behavioral training with motivational interview: 8 sessions of cognitive-behavioral training with motivational interview Three sessions per week (each session averages 90 to 100 minutes with a break time in each session). Content of motivational interview sessions
Session 1: Start the session, introduce the motivational approach and determine the rules of the group. ● Practice determining the stages of change and determining the stage of change ● Ending the session ●
Session 2: Start the session and introduce the topic ● Describe one by one the self-care behaviors during the

day ● Discuss the activities ● Discuss the Complications of carelessness ● Ending the session ● Session 3: Starting the session and introducing the values and how to determine its hierarchy ● Discovering the conflict between individual values and health-related behaviors ● Introducing and practicing identifying positive dimensions and Negative behavior change ● Measuring the balance of decision-making and ending the session ●
Session 4: Start the session and introduce the topic and identify motivators ● Tempters, confidence in behavior control and self-confidence ● Goal setting, vision and Preparing a plan and behavior change plan. دادن Ending the session. Content of cognitive-behavioral sessions:
First session: ● Starting the session and introducing the cognitive-behavioral model, determining the group rules ● Familiarity with ABC sheets related to RET treatment
Session 2: ● Start the session and introduce the topic of stress and diabetes ● Discuss the effect of stress on diabetes ● Teach stress management techniques ● End the session and present the task of the third session: ● Start the session and introduce Awa Diabetes ● Concern or Anxiety ● Coping with Anxiety ● Ending Session
Session 4: ● Starting the Session and Introducing Diabetes and Social Relations ● Diabetes and Social Support ● Learning Ways to Increase Social Support ● Ending Sessions and Periods.

Category

Behavior

2

Description

Intervention group: Intervention group 4: 2 sessions of cognitive-behavioral training 2 sessions per week (face to face and with the help of audio-visual aids): Content of cognitive-behavioral sessions: First session: ● Start the session and introduce the cognitive-behavioral model ● Familiarity with sections D and E of ABC worksheet ● End the session and assign the second session: ● Start the session and introduce the topic of stress and diabetes ● Discuss the effects of stress on diabetes ● Teach stress management techniques ● End the session and present the task of the third session: ● Start the session and introduce complications ● Worrying or Anxiety ● Coping with Anxiety ● Ending the Session
Session 4: ● Starting the Session and Introducing Diabetes and Social Relations ● Diabetes and Social Support ● Learning Ways to Increase Social Support ● Ending the Session and Period

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan Bu Ali Hospital

Full name of responsible person

Zahra Miri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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bakhshani@zaums.ac.ir
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Zahra Miri
Position

Master Student Of Psychiatric Nursing
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Bachelor
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Person responsible for updating data

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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

Participants information is confidential

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

the method of implementation of the plan is explained in the thesis

When the data will become available and for how long

En The post-graduation study protocol is described in the thesis

To whom data/document is available

The analysis is done in the dissertation.

Under which criteria data/document could be used

There is no plan to publish it

From where data/document is obtainable

The thesis is explained

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

There is no plan to publish it

Comments

There is no plan to publish it