

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of positive psychology's effect on depression, anxiety, stress and glycemic control in diabetic type 2 patients

Protocol summary

Study aim

Determining the Effect of 8-Week Psychological Therapy on Positive Depression, Anxiety, Stress and Glycemic Control Indicators in Type 2 Diabetes

Design

Clinical trials with control group, with parallel groups, randomized

Settings and conduct

The study was conducted in 1398 in Isfahan. The target population of type 2 diabetes mellitus, referred to the Imam Ali Hospital's comprehensive health center (Isfahan).

Participants/Inclusion and exclusion criteria

Type 2 diabetes with the approval of a specialist The history of regular visits to the center for at least the past 6 months Age between 30 and 59 years HbA1C between 9-7% Absence of alcohol and substance abuse Have at least high school education level Exclusion Criteria Absence in more than 3 sessions in the treatment process Unwillingness to continue treatment The occurrence of major stresses and unexpected accidents in each stage of the study Acute psychological illness in each stage of the study Having chronic illnesses, such as cancer or any other serious medical condition, except diseases associated with complications of diabetes or diseases associated with diabetes Need to start insulin treatment during the design Participate in psychotherapy sessions outside the research project protocol.

Intervention groups

A total of 40 people are randomly selected for each group, and then the participants are allocated to intervention and control groups. For the intervention group, eight sessions of 2 hours a week, once a positive psychological education is conducted by a psychologist with a skill in this field. And then they will do homework for 4 weeks, which is reported weekly in the form of a self report.

Main outcome variables

HbA1C; FBS; The amount of anxiety; Depression and

stress levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N27**

Registration date: **2019-02-26, 1397/12/07**

Registration timing: **prospective**

Last update: **2019-02-26, 1397/12/07**

Update count: **0**

Registration date

2019-02-26, 1397/12/07

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of positive psychology's effect on depression, anxiety, stress and glycemic control in diabetic type 2 patients

Public title

Evaluation of positive psychology's effect on depression, anxiety, stress and glycemic control in diabetic type 2 patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 2 diabetes with the approval of a specialist The history of regular visits to the center for at least the past 6 months Age between 30 and 59 years HbA1C between 9-7% Absence of alcohol and substance abuse Have at least high school education level Ability to attend medical sessions Lack of pregnancy and lactation The history of diabetes for at least 6 months Earn a minimum score of 7 from the DASS 21 questionnaire before starting the study Failure to receive psychological treatment in the past year

Exclusion criteria:

Absence in more than 3 sessions in the treatment process Unwillingness to continue treatment The occurrence of major stresses and unexpected accidents in each stage of the study Acute psychological illness in each stage of the study Having chronic illnesses, such as cancer or any other serious medical condition, except diseases associated with complications of diabetes or diseases associated with diabetes Need to start insulin treatment during the design Participate in psychotherapy sessions outside the research project protocol.

Age

From **30 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Randomization block, randomization unit: Individual, Random layer: not done Randomization, tool: Random sequence generation software (Excel), How to create random sequence: Using random blocks, each block contains 4 people And assign a number from 1 to 6 to each block.

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical sciences, Hezar Jareeb street, Isfahan, Iran

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Postal code

8174675731

Approval date

2018-02-09, 1396/11/20

Ethics committee reference number

IR.MUI.REC.1396.3.369

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

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Fasting Blood Sugar

Timepoint

beginning of study and 8 weeks after intervention

Method of measurement

Using the Pars Test Kit, Made by Iran

2**Description**

HbA1C

Timepoint

beginning of study and 8 weeks after intervention

Method of measurement

Using the Pars Test Kit, Made by Iran

3

Description

Anxiety, depression and stress

Timepoint

beginning of study and 8 weeks after intervention

Method of measurement

DASS 21 anxiety, depression and stress questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 8 weekly 2-hour sessions of Positive Psychology Training is conducted by a PhD in Psychology. And then they will do homework for 4 weeks, which is reported weekly in the form of a self report.

Category

Rehabilitation

2

Description

Control group: There is no treatment on this group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali City Comprehensive Health Center

Full name of responsible person

Dr Anahita Babak

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W Toosi St, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjooe Javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr Anahita Babal

Position

Associated Proffessor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Web page address

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

whole data will be available

When the data will become available and for how long

immediately after publishing manuscript

To whom data/document is available

to whom is in need of this data

Under which criteria data/document could be used

Email to Dr Anahita Babak E.Mail:

babakanahita@yahoo.com

From where data/document is obtainable

Dr Anahita Babak E.Mail: babakanahita@yahoo.com

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

send an Email to Dr Anahita Babak

Comments

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Anahita Babak

Position

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Latest degree

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Other areas of specialty/work

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