

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The Effect of Psychological Educational intervention with progressive muscle relaxation on Depression ,Anxiety, stress, serum Cortisol and HB A1C level in Type 2 diabetic patients

Protocol summary

Study aim

Determining the Effectiveness of Psychological Education on Depression, Anxiety, Stress, Serum Cortisol Level and HBA1C Level in Type 2 Diabetic Patients

Design

People who have a case in diabetes clinic are randomly selected.

Settings and conduct

In Clinic of Diabetes in Rafsanjan City. Questionnaires were provided to two groups of patients and two to two days and performed Hba1c and cortisol tests. Hold the class for the case group, repeat the test and the questionnaire immediately and the next month for both groups.

Participants/Inclusion and exclusion criteria

Login to the study: 1. Type II diabetes mellitus 2 between 20-50 years 3. Minimum cycles 4. No participation in yoga classes, meditation, prayers, specific sports activities, lifestyle and adaptation strategies in the past six months. 5. Iranian 6. No accidents in the last 6 months. 7. No use of corticosteroids Exit: 1. Apply to other Endocrine Disorders 2. Severe diabetes mellitus 3. Not attending two training sessions.

Intervention groups

The samples were randomly divided into test and control groups according to the entrance and exit criteria. Both groups completed a demographic questionnaire and a standardized questionnaire (DASS21) including depression, anxiety, stress. Before the beginning of the study, the endocrinologist and psychologist will be interviewed and examined by the psychologist. 12 training sessions will be held. After the training month, two questionnaires and Hba1c and cortisol tests are checked. In the control group, there is no training alone.

Main outcome variables

Mean score of depression, stress anxiety. Hb a1c, cortisol and ...

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180304038936N4**

Registration date: **2018-09-10, 1397/06/19**

Registration timing: **retrospective**

Last update: **2018-09-10, 1397/06/19**

Update count: **0**

Registration date

2018-09-10, 1397/06/19

Registrant information

Name

Ahmadreza Sayadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

a.sayadi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-28, 1397/02/08

Expected recruitment end date

2018-07-30, 1397/05/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Psychological Educational intervention with progressive muscle relaxation on Depression ,Anxiety, stress, serum Cortisol and HB A1C level in Type 2 diabetic patients

Public title

The effect of Psychological education on diabetes, stress, anxiety and depression

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Registration of Type II Diabetes Mellitus in the medical records of the Diabetes Clinic 2. Lack of injecting insulin. 3. Having informed consent to participate in the study. 4. Not having a history of mental illness 5. Do not use herbal remedies that affect blood sugar levels. 6. Do Not Advanced Neuropathy. 7. Lack of history of physical illness simultaneously 8. At least one year of diabetes 9. Lack of alcohol and drug use 10. between 50-20 years 11. Minimum cycle education 12. Non-use of psychotropic drugs and cognitive therapies during the study 13. Non-attendance at yoga classes, meditation, pacifism, special sports activities, lifestyle and adaptation strategies in the past six months 14. Lack of hearing and speech problems 15. Patients undergoing treatment and without changes to the drug during the study period 16. Iranian nationality 17. No incident in the last 6 months 18. Do not use corticosteroids drugs

Exclusion criteria:

1. It is not participating in training classes 2. Dissatisfaction with continued collaboration during the study period 3. Depending on other endocrine disorders 4. Cancel the continuation of participation in the workshop 5. Changes in the general condition of the patient associated with changes in blood glucose levels 6. Complications Severe diabetes mellitus 7. Not participating in two training sessions

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **30**

Each person is included in the study as a separate sample.

Randomization (investigator's opinion)

Randomized

Randomization description

Of the cases in the Diabetes Clinic, 60 out of 5,000 randomly selected cases (women and men) were randomly selected based on entry and exit criteria, and divided randomly into two groups of control and control as random numbers.

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 Rafsanjan University of Medical Sciences

Street address

Office of Medical University Blvd Imam Ali

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-04-21, 1397/02/01

Ethics committee reference number

IR.RUMS.REC.1397.019

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

Diabetes

ICD-10 code

E08.0

ICD-10 code description

Diabetes mellitus due to underlying condition with hyperosmolarity

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

Study of Depression

Timepoint

Check the variables before, immediately after and three months after the intervention

Method of measurement

DASS21 questionnaire

2**Description**

Check the amount of stress

Timepoint

Before intervention immediately after intervention, and three months after intervention

Method of measurement
DASS21 questionnaire

3

Description
Anxiety Survey

Timepoint
Before intervention immediately after intervention, and three months after intervention

Method of measurement
DASS21 questionnaire

4

Description
Study of HBA1c

Timepoint
Before intervention immediately after intervention, and three months after intervention

Method of measurement
blood test

5

Description
Cortisol levels

Timepoint
Before intervention immediately after intervention, and three months after intervention

Method of measurement
blood test

Secondary outcomes

empty

Intervention groups

1

Description
For the intervention group, 12 sessions of psychological training, along with progressive muscle relaxation, are performed every twoSessions each week.

Category
Rehabilitation

2

Description
Control group: Complete the questionnaire and blood test. To be associated with posting the training sessions after the intervention in the intervention group.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes ClinicAli ibn Abi Talib.Rafsanjan

Full name of responsible person
Aezam Mirmahdi

Street address
Ali ibn Abi Talib Ayatollah Saeedi Square Taleghani Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
Dr.Zare

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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
Rafsanjan University of Medical Sciences

Proportion provided by this source
90

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
Rafsanjan University of Medical Sciences
Full name of responsible person
Aezam Mirmahdi
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

How to do work and shareable results.

When the data will become available and for how long

Probably starting to access 3 months after printing results.

To whom data/document is available

Probably starting to access 3 months after printing results

Under which criteria data/document could be used

If the manufacturer needs documentation, it will be provided.

From where data/document is obtainable

I will be at the service of other people by email or telephone number.

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

I'll explain more below.After review

Comments