

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The Effectiveness of relaxation exercises on decreasing depression, anxiety and stress in elderly people with type 2 diabetes

Protocol summary

Study aim

The Effectiveness of relaxation exercises on decreasing depression, anxiety and stress in elderly people with type 2 diabetes.

Design

Clinical trial with two groups, control and intervention is. In this study, the sample size is 84 people. The control group is 42 and the intervention group is 42. The researcher examines the variables in the intervention group before and after the relaxation exercises by completing the DASS-21 questionnaire. In the control group once at the beginning of the study and then six weeks later, the same questionnaire is completed.

Settings and conduct

The illness sampling is carried out in Isfahan Health Center 1 and the method of randomization is block randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: volunteering; Age 60 and older; Type 2 diabetes for at least six months; Due to respond to the questionnaire DASS-21 stress, anxiety and depression are mild to moderate. Non-inclusion criteria: Not having alcohol and drug addiction; No use of antidepressants; Not having a history of receiving relaxation training; Severe diabetes complications

Intervention groups

Intervention group: Elderly patients with type II diabetes with stress, anxiety and depression are mild to moderate. Relaxation exercises are done for six weeks in this group. control group: Elderly patients with type II diabetes with stress, anxiety and depression are mild to moderate. No relaxation exercises are performed in this group.

Main outcome variables

Stress score; anxiety score; depression score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190119042409N1**

Registration date: **2019-04-19, 1398/01/30**

Registration timing: **retrospective**

Last update: **2019-04-19, 1398/01/30**

Update count: **0**

Registration date

2019-04-19, 1398/01/30

Registrant information

Name

bahareh khajeheyani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3438 0025

Email address

bkhajeheyani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-04-14, 1398/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of relaxation exercises on decreasing depression, anxiety and stress in elderly people with type 2 diabetes

Public title

The Effectiveness of relaxation exercises in elderly people with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being volunteer to participate in the study Age 60 years old and over Type 2 diabetes for at least six months Acceptable listening and speaking ability to learn relaxation techniques The ability to read educational materials or the presence of a family member who agrees to read it for the elderly Mild to moderate stress, anxiety and depression based on the DASS-21 questionnaire scale

Exclusion criteria:

Severe diabetes complications Not having alcohol and drug addiction No use of antidepressants and no known mental illness, including severe depression Not having a history of receiving relaxation training

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is block Randomization, using four blocks. The elderly people From four urban centers which are covered by Health Center number one in Isfahan, with diabetes type 2 who are eligible to enter the study, are randomly divided into two groups of control and intervention. Next the first elderly person who is eligible to enter the study is determined into control or intervention group by the division according to the following table. The sampling is started from right to left respectively. First in block 3 with the admission of the first elderly person who is eligible to enter the study and according to block 3 tabale, the people are placed according following order: the first in the control group, the second in the intervention group, The third in the control group and the fourth in the intervention group. The next block for sampling is number one. The first person placed in the intervention group, the second in the intervention group too, the third and fourth in the control group. As the same way the sampling is done according to the table and specified block from right to left and based on the division of the control and intervention group to reach the sample size to 84 people. Arrangement of the blocks are right to left 3 3 3 1 3 2 1 4 3 2 4 3 3 2 1 4 2 4 4 1 2 4 4 3 2 block1 block2 block3 block4 (Blocks table A: Treatment B: Control) A A B B A B A B B A B A B A B A A

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 Shahid Beheshti University of Medical Sciences

Street address

Thirteenth floor block A- Headquarters of the Ministry of Health and Medical Education- Between South Falamak and Zarafshan- Ghods Town (West)- Tehran

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2019-01-15, 1397/10/25

Ethics committee reference number

IR.SBMU.PHNS.REC.1397.062

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

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

Depression Score

Timepoint

Measurement of depression at the beginning of the study and 6 weeks after the intervention

Method of measurement

DASS-21 questionnaire

2**Description**

Anxiety Score

Timepoint

Measurement of Anxiety at the beginning of the study

and 6 weeks after the intervention

Method of measurement

DASS-21 questionnaire

3

Description

Stress Score

Timepoint

Measurement of stress at the beginning of the study and 6 weeks after the intervention

Method of measurement

DASS-21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Relaxation exercises are taught to the elderly people in 3 sessions by the researcher and then these exercises are practiced twice a day by the elderly people at home for six weeks.

Category

Lifestyle

2

Description

Control group: Relaxation exercises are not done in this group and DASS-21 questionnaire is completed once in the baseline and then 6 weeks after the baseline.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Health Center No 1

Full name of responsible person

Bahareh Khajeheyani

Street address

Faiz Valley

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Isfahan

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Fax

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Bahareh Khajeheyani

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School of Health and Safety- Daneshjoo Boulevard-
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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Bahareh khajeheyani

Position

Student Master

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

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