

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The comparison effect of progressive muscle relaxation with guided imagery on depression in patients with type 2 diabetes

Protocol summary

Summary

Objective: The aim of this study was to compare the effects of muscle relaxation with guided imagery on depression in patients with type 2 diabetes. Design, Setting and conduct: In this clinical trial, 120 patients referred to the center of Sabzevar diabetes were randomly divided into three groups; progressive muscle relaxation, guided imagery and control. Inclusion and Exclusion criteria: Patients with type 2 diabetes, 65-35 years old and Beck depression score 28-14 was enrolled. Patients with a history of drug use because of depression, people with underlying chronic medical conditions such as heart disease, respiratory, kidney, high blood pressure or epilepsy and patients with stressful events of life evident during the last six months was excluded. Intervention: In progressive muscle relaxation group, exercise 20-30 minutes twice a week for 6 weeks was executed. In the guided imagery group, for 6 weeks, two sessions per week for 30-20 minutes, guided imagery exercises are done. In the control group not conducted a specific intervention. At the end of six weeks, all three groups will complete the Beck Depression Inventory scores will be compared three groups this week again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015100624380N1**

Registration date: **2016-03-22, 1395/01/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-22, 1395/01/03

Registrant information

Name

Salime Azizi

Name of organization / entity

Sabzevar University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effect of progressive muscle relaxation with guided imagery on depression in patients with type 2 diabetes

Public title

Comparison of the effects of muscle relaxation with guided imagery on depression in diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Type 2 diabetes; Beck depression score 28-14; aged 35 to 65 years; no known pre-diabetes

depression; at least fifth-grade education; consent to participate in the study; Iranians living in Sabzevar, no severe depression or suicidal thoughts; a contact telephone number. Exclusion criteria: History of drug use due to mental disorders including depression; drugs that cause similar symptoms of depression during the past month; heart disease; respiratory, kidney, high blood pressure or seizure; stressful major life events (death of relatives class 1, family member illness, financial ruin, accident, intense domestic dispute with his wife) over the past six months, the bad memories of the sea; absence of more than two sessions of classes; opting to participate in the study; Severe depressive symptoms; stressful life events during the study; use of narcotic drugs and sedatives during follow-up.

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization data is done using random numbers table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Sabzevar, Street Asadabadi, School of Nursing and Midwifery

City

Sabzevar

Postal code

94716-15995

Approval date

2015-06-26, 1394/04/05

Ethics committee reference number

IR.MEDSAB.REC.1394.31

Health conditions studied

1

Description of health condition studied

diabete Depression

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Depression

Timepoint

Before and 6 weeks after intervention

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Interventions 1: The Progressive Muscle Relaxation group (contracting and relaxing the 16groupmuscles) During the first two sessions, taught to patients by researcher, and then the next four weeks, two sessions a week for 20-30 minutes using training tape will be done with the researcher.6 weeks after starting the study, Beck Depression Inventory will be completed again

Category

Behavior

2

Description

Intervention 2: In guided imagery group , how doimagery during the first two sessions by the researcherwas taught to the patients and then two sessions a week, imagery of beach will take with the researcher in 30-20 minutes.6 weeks after the start of the study will be completed Beck Depression Inventory.

Category

Behavior

3

Description

Control group: In the control group, denied any involvement. 6 weeks after the start of the study will be completed Beck Depression Inventory.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Center city of Sabzevar

Full name of responsible person

Mahdi Jafarzade Fakhari

Street address

Sabzevar, Street Asadabadi, Diabetes Center

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Sabzevar University of Medical Sciences

Street address

School of Nursing and Midwifery, Asadabadi Street , Sabzevar

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Sabzevar

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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M.Sc in Medical Surgical Nursing

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty