Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 51 4723 4621

Email address

roshd@thums.ac.ir

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
City
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
Mehdi Jafarzade Fakhari
Position
M.Sc in Medical Surgical Nursing
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Asadabadi Street , Sabzevar
City
Sabzevar
Postal code
Phone
+98 514446070
Fax
Email
mjafarzade4@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Mehdi Jafarzade Fakhari
Position
M.Sc in Medical Surgical Nursing
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Asadabadi Street , Sabzevar
City
Sabzevar
Postal code
Phone
+98 915 318 8288
Fax
Email
mjafarzade4@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Salime Azizi
Position
B.Sc of anesthesiology
Other areas of specialty/work
Street address
Sabzevar University of Medical Sciences
City
Sabzevar
Postal code
94716-15995
Phone
+98 512234621
Fax
Email
azizi.s1990@gmail.com
Web page address

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