Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessing the effect of progressive muscle relaxation on glycosylated hemoglobin and health- related quality of life in patients with type 2 diabetes

Protocol summary

Summary

1) The objective of present study is determining the effectiveness of progressive muscle relaxation on glycosylated hemoglobin and health- related quality of life in patients with type 2 diabetes. 2) Design: The study is a randomized clinical trial with both control and intervention group. 3) Setting and conduct: 100 patients with type 2 diabetes that referred to the clinic will be randomly placed into intervention and control groups. 4) Participants including major eligibility criteria: They are patients with type 2 diabetes. 5) Intervention: The intervention group will be trained PMR during 3 sessions. Patients will do relaxation techniques for 12 weeks, twice a day at home. The control group will not receive any training. 6) Main outcome measures: The primary outcome variable is glycosylated hemoglobin and secondary outcome variable is health related quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021821134N1**
Registration date: **2015-06-04, 1394/03/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-04, 1394/03/14

Registrant information

Name

Maryam Kohandany

Name of organization / entity

Iran school of nursing and midwifery

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran university of medical science

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of progressive muscle relaxation on glycosylated hemoglobin and health- related quality of life in patients with type 2 diabetes

Public title

Assessing the effect of progressive muscle relaxation on glycosylated hemoglobin and health- related quality of life in patients with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age between 35 to 65 years; Literacy; A definitive diagnosis of type 2 diabetes by a physician; Oral anti-diabetic medication for at least 1 year; No risk of cardiovascular disease, thyroid disease, intermittent

claudication, cerebrovascular accidents, arthritis, diabetic retinopathy, chronic renal failure, chronic pulmonary disease, diabetic foot, severe vision or hearing impairment; Lack of mental illnesses and psychiatric drugs; The absence of sensory perception and communication problems; The absence of limb movement disorders and muscle injury; Not Hype; Lack of relaxation training Exclusion Criteria: The absence of one of the training sessions for the intervention group; Performance progressive muscle relaxation in the house less than 10 sessions per week (record in the self-report check lists); Drug regime change during the 12-week study (in both control and intervention); The use of other complementary therapies during the study; Lack of learning and skill acquisition procedure; Acute complications of diabetes (such as ketoacidosis and hypoglycemia)

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Iran university of medical sciences and health services

Street address
Iran university of medical sciences, Shahid Hemmat highway, Tehran, Iran

City
Tehran

Postal code

Approval date
2015-03-01, 1393/12/10

Ethics committee reference number
105/5864/93/د

Health conditions studied

1

Description of health condition studied
Type2 diabetes

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Glycosylated hemoglobin

Timepoint
Before and three months after intervention

Method of measurement
Lab Kit

Secondary outcomes

1

Description
Health- related quality of life

Timepoint
Before and three months after intervention

Method of measurement
Diabetes Quality Of Life (DQOL) questionnaire

Intervention groups

1

Description
In intervention group, patients do progressive muscle relaxation to themselves twice a day for three months. In this method patients continuously contract and then relax their muscles while they are listening to the music in CD.

Category
Rehabilitation

2

Description
In control group: Routin activities

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrine clinic Firouzgar

Full name of responsible person

Maryam Kohandany

Street address

Firoozgar hospital, Beh Afarin st, Karim khan e Zand st, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran university of medical science

Full name of responsible person

Seyed Ali Javad Moosavi

Street address

Iran university of medical sciences, Shahid Hemmat highway, Tehran

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran university of medical science

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

School of nursing & midwifery of Iran university

Full name of responsible person

Maryam Kohandany

Position

Post graduate student in nursing

Other areas of specialty/work

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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