

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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)

Phone

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Email address

kohandani.m@iums.ac.ir

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

105/5864/93/3

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

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

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of nursing & midwifery of Iran university

Full name of responsible person

Tahere Najafi

Position

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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

City

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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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