

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of progressive muscle relaxation technique on the quality of sleep and Quality of Life in Patients with Diabetes Type II

Protocol summary

Study aim

Determining the effect of progressive muscle relaxation techniques on sleep quality and quality of life related to the health of patients with type 2 diabetes

Design

Clinical trial with control group, patients with type 2 diabetes, Two arm parallel groups, simple randomized trial without blindness.

Settings and conduct

This clinical trial study was carried out on 50 diabetic patients randomly assigned to intervention and control groups in Gorgan 5th Azar Hospital, which will undergo muscle relaxation techniques during 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being between 15 and 60 years of age, Having reading and writing skills, Living in Gorgan city , Having Type 2 Diabetes Exclusion criteria: Drug Addiction, History of performing muscle relaxant technique, Acute physical abnormalities, Acute psychiatric disorder, Sleeping medications, The mental health score more than 23

Intervention groups

Intervention group: In addition to the standard diabetes treatment, they will train progressive muscle relaxation technique. Control group: Only receive standard diabetes treatment, and no progressive muscle relaxation technique will be implemented for this group.

Main outcome variables

Relaxation; Sleep quality; Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040367N1**

Registration date: **2019-04-11, 1398/01/22**

Registration timing: **retrospective**

Last update: **2019-04-11, 1398/01/22**

Update count: **0**

Registration date

2019-04-11, 1398/01/22

Registrant information

Name

Fatemeh Zargarani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 4924

Email address

zargaranif@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

2015-09-01, 1394/06/10

Actual recruitment end date

2015-11-01, 1394/08/10

Trial completion date

2015-11-11, 1394/08/20

Scientific title

The Effect of progressive muscle relaxation technique on the quality of sleep and Quality of Life in Patients with Diabetes Type II

Public title

The Effect of Progressive Muscle Relaxation Technique on Type 2 Diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being between 15 and 60 years old
Have reading and writing skills
Living in Gorgan city
Having Type 2 Diabetes

Exclusion criteria:

Drug Addiction
History of performing muscle relaxant technique
Cause of other acute physical abnormalities
Severe psychiatric disorder
Taking hypnotic drugs
Mental health score i more than 23

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 50 patients with type 2 diabetes after easy sampling, Using a preset Simple random list that made by Excel was assigned to two groups of control (25 people) and intervention (25 people).

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 Golestan University of Medical Sciences

Street address

5 Azar Hospital, 5 Azar Avenue

City

Gorgan

Province

Golestan

Postal code

4917716551

Approval date

2015-08-14, 1394/05/23

Ethics committee reference number

IR.GOUMS.REC.1394.280

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

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

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

sleep quality

Timepoint

At the beginning of the study (before the intervention), the first month of training

Method of measurement

Pittsburgh Sleep Quality Questionnaire

2**Description**

Quality of life

Timepoint

At the beginning of the study (before the intervention), the first month of training

Method of measurement

Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group will do the relaxation exercises at home according to the set out schedule, 2 times a day for 2 months

Category

Behavior

2**Description**

Control group: No special intervention will be done in the control group and routine process will be carried out

Category

Other

Recruitment centers**1****Recruitment center**

Name of recruitment center

Diabetes Clinic of Golestan Province
Full name of responsible person
Fateme Zargarani
Street address
5 Azar Avenue, 5 Azar Hospital
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Fateme Zargarani
Position
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Master
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Gholamreza Roshandel
Street address
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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

Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Fateme Zargarani
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

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

Data Dictionary

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

Title and more details about the data/document

The data on the effect of muscle relaxation technique on the quality of life and quality of sleep can be shared.

When the data will become available and for how long

A week

To whom data/document is available

Only available to scholars working in academia and academia

Under which criteria data/document could be used

For use by academic researchers with reference to this study

From where data/document is obtainable

zargaranif@goums.ac.ir

What processes are involved for a request to access data/document

By sending the following email and requesting documentation will be answered within a week;
zargaranif@goums.ac.ir

Comments