Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 17 3254 4924

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Gholamreza Roshandel
Street address
5 Azar Avenue, 5 Azar Hospital
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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
Fateme Zargarani
Position
Nurse
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

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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