Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of yoga on the severity of restless legs syndrome in patients with type 2 diabetes in Tohid Hospital diabetic clinic 2017

Protocol summary

Study aim

Determining the effect of yoga on severity of restless legs syndrome in type 2 diabetic patients in diabetes clinic in Sanandaj, 2016

Design

In this research, 114 patients with type 2 diabetes who have restless leg syndrome who go to the Diabetes Clinic were chosen. They are randomly assigned to two groups of control and intervention by Allocate Subjects with Stats Direct

Settings and conduct

he location of the research is the diabetes clinic in Tohid Hospital in Sanandaj. Before the intervention, restless intensity was measured in two groups of control and intervention, based on the standard questionnaire, 10 questions were asked for each patient individually. Then, in the intervention group, they will be trained and practiced during the 60-minute sessions once a week for 8 weeks in 60-minute sessions and they will be given a homework program for each week. At the end of 8 weeks, the rest is measured in two groups of restless leg strength. Study without blindness.

Participants/Inclusion and exclusion criteria

Inclusion criteria: type 2 diabetes, insulin free, infection with restless leg syndrome, age 18-65, ability to do yoga exercises, absence of other chronic severe conditions
Non-compliance criteria: changes in the general condition of the body during the exercise, unwillingness to continue exercises, having a mental disorder, severe seizure of blood glucose

Intervention groups

Case group: A group of people with type 2 diabetes and restless leg syndrome, in which yoga exercises are performed. Control group: There is no intervention in people with type 2 diabetes and restless leg syndrome

Main outcome variables

severity of restless legs syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170815035723N2**
Registration date: **2018-01-27, 1396/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-27, 1396/11/07**
Update count: **0**

Registration date

2018-01-27, 1396/11/07

Registrant information

Name

Ghazal Mohamadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3328 0637

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of yoga on the severity of restless legs syndrome in patients with type 2 diabetes in Tohid Hospital diabetic clinic 2017

Public title

The effect of yoga on the severity of restless legs syndrome in patients with type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

type 2 diabetes insulin free consumption restless leg syndrome, based on the questionnaire for 4 questions for screening restless leg syndrome Age between 18 and 65 years Learning and ability to do yoga exercises non-use of other therapies lack of other chronic diseases and heart disease

Exclusion criteria:

any change in the general condition of the body during exercise unwillingness to continually perform exercises during the study reluctance to continue to participate in research having a mental disorder severe hypoglycemia،seizure، coma and death of the patient

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **57**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization, individual randomization unit, and assignment of samples in the group are done using the random allocation method in Randomized with seed: 2498 Allocate Subjects with Stats Randomization. How to construct the random sequence of the quadrilateral block.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data by the researcher is entered into the spss software and the statistical consultant analyzes the data without knowing how the data is entered. Therefore, this study is blinded by statistical counseling on one side.

Placebo

Not used

Assignment

Parallel

Other design features

Participants in the study were two groups of test and control. Participants in the test group received one type of intervention and compared with the control group who had no intervention at the end of the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Medical Research and Training Hospital Tohid, Hospital Blvd.Pasdaran Street

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2017-07-10, 1396/04/19

Ethics committee reference number

IR.MUK.REC.1396/104

Health conditions studied

1

Description of health condition studied

Restless Legs Syndrome

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Restless Legs Syndrome

Timepoint

Before the intervention, eight weeks after the intervention

Method of measurement

Restless Legs Syndrome Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group": intervention in the intervention group includes eight weeks of yoga exercise. Patients undergo yoga exercise training once a week for 60 minutes under the supervision of a yoga instructor under

the yoga exercise training program, and for doing daily workouts at home, pamphlets A weekly training program that includes a work picture and a brief description of each exercise is received at the end of each session. In addition, to inform the researcher of home training sessions, patients receive home registry checklists containing the number, time, the name of the exercise The column for the name of the week is given and the checklist filled in each session is visible to the researcher Wahid has arrived. Before the onset of the intervention and after the end of the eighth week, the intensity of restless leg syndrome will be measured using the "Restless Pain Standard Inventory".

Category

Treatment - Other

2

Description

Control group: Before the onset of the study, the severity of restless leg syndrome was measured using the "standard restless leg strength" questionnaire, and the patients received routine treatment without any intervention, and at the end of the eighth week, the severity of restless leg syndrome It is measured and compared with the intervention groupup:

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Tohid Hospital in Sanandaj

Full name of responsible person

Mohamad Fathi

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Geryashan Blvd-Tohid Hospital

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Farzin Razaai

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Grant name

1396

Grant code / Reference number

1396

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Ghazal Mohamadi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Kurdistan University of Medical Sciences, lower than Quds Hospital, St.pasdaran, sanandaj

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Sanandaj University of Medical Sciences

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Position
Nursing phd

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Ph.D.

Other areas of specialty/work
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Position
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Latest degree
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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
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Part of the data related to the questionnaire of the severity of restless leg syndrome before and after intervention in the two groups after unidentifiable individuals

When the data will become available and for how long
Starting the access period from 1399

To whom data/document is available
Available only to researchers working in academic and academic institutions

Under which criteria data/document could be used
Just to study the data

From where data/document is obtainable
Ghazal Mohammadi General Respondent Email ghazalmohamadi85@yahoo.com

What processes are involved for a request to access data/document
Call us at 00988732579 or email ghazalmohamadi85@yahoo.com

Comments