Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating The effect of foot exercise on the pain of diabetic foot neuropathy in the selected medical center affiliated to Tehran University of Medical Sciences in 2023

Protocol summary

Study aim

This study aims to determine the effect of foot exercise on the pain of diabetic foot neuropathy in patients referred to a selected medical center affiliated to Tehran University of Medical Sciences.

Design

This experimental study has a pre-test-post-test design with a randomized control group in two groups (intervention group and control group).The sampling method in this research is gradual random. The number of samples for the intervention group was 30 people and for the control group was 30 people, which were randomly selected from among the clients. Among the clients of the days in the intervention group and the clients of the even days are included in the control group.

Settings and conduct

This study will be conducted on outpatients referred to the super-specialized endocrinology and diabetes clinic of Tehran University of Medical Sciences. In the intervention group, for 12 consecutive weeks and three days a week, between 8:00 and 13:00, one exercise set with 8-10 repetitions per hour is performed individually for each person, at the patient's bedside, in the presence of the researcher. At home, these exercises should be performed 2-3 times a day, 10 repetitions each time, and gradually the number of times increases. Patients in the control group will receive routine blood sugar control training.

Participants/Inclusion and exclusion criteria

Entry conditions: people who have HbA1C below 9/ have symptoms of neuropathy pain and have been diagnosed with neuropathy by a treating doctor/ have the ability to do foot exercises. Conditions of non-entry: unwillingness to continue cooperation/unfavorable clinical condition of the patient.

Intervention groups

In addition to following treatment regimens (following diet, taking medications), the intervention group performs leg exercises. The control group only follows the center's routine care.

Main outcome variables

neuropathic pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230429058020N1**
Registration date: **2023-05-07, 1402/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-07, 1402/02/17**
Update count: **0**

Registration date

2023-05-07, 1402/02/17

Registrant information

Name

Mohsen Agharazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3372 4401

Email address

mohsenagharazzi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-02, 1402/02/12

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The effect of foot exercise on the pain of diabetic foot neuropathy in the selected medical center affiliated to Tehran University of Medical Sciences in 2023

Public title

The effect of foot exercises on the pain of diabetic foot neuropathy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

People who have HbA1C below 9 (under control of disease complications). Fasting blood sugar should be above 126 and blood sugar two hours after eating should be above 200. Symptoms of leg tingling, constant burning pain, and at the same time constant numbness, and the diagnosis of neuropathy has been given by the attending physician. Have the ability to do foot exercises.

Exclusion criteria:

Unwillingness to continue cooperation. Unfavorable clinical condition of the patient (such as hypoglycemia during exercise that leads to hospitalization of the patient).

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling of this research is random and gradual, that is, qualified people will enter the research after knowing the steps and objectives of the research and completing the consent form if they have the conditions to enter and if they do not have the conditions to not enter the research. This sampling is gradual, that is, it is done during at least one week. Eligible samples will be divided into two control and test groups by simple random sampling method. Out of the clients on odd days, they are in the intervention group and the clients on even days are in the control group

Blinding (investigator's opinion)

Single blinded

Blinding description

The number of samples for the intervention group was 30 people and for the control group 30 people, which were randomly selected from among the clients. Out of the clients on odd days, they are in the intervention group and the clients on even days are in the control group. And in this way, people do not know that they are in the intervention or control group, and the researcher knows about the condition of the participants.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشکده پزشکی دانشگاه علوم پزشکی آزاد اسلامی تهران

Street address

تهران، خیابان شریعتی، خیابان خاقانی

City

Tehran

Province

Tehran

Postal code

193951495

Approval date

2023-04-26, 1402/02/06

Ethics committee reference number

IR.IAU.TMU.REC.1402.034

Health conditions studied

1

Description of health condition studied

Diabetic neuropathy pain

ICD-10 code

E00–E90

ICD-10 code description

Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

Diabetic neuropathy pain

Timepoint

Before and after the intervention of foot exercises

Method of measurement

Brief standardized pain intensity questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, after selecting the qualified samples and explaining about the research stages, the required concepts and the benefits of leg exercises and how to perform them, the patient's consent is obtained, and then after obtaining a written consent, in the same session, the personal information form and the questionnaire A summary of the pain intensity will be provided to the patient and after going through the above steps, for 12 consecutive weeks and three days a week between 8:00 and 13:00, one training set with 8-10 repetitions per hour individually for each person, in the bed. The patient performs leg exercises in the presence of the researcher, which will take 5-10 minutes. At home, these exercises should be performed 2-3 times a day, 10 repetitions each time, and the number of times will gradually increase, and the patients will be monitored and guided by phone calls at least once a week.Before and after performing leg exercises (before the intervention and then 12 weeks later), the patient's diabetes indicators (glycosylated hemoglobin, fasting blood sugar, blood sugar 2 hours after a meal and body mass index) are measured and recorded. Also, before and after the completion of 12 weeks, the patient's pain level is measured by a questionnaire.

Category

Behavior

2

Description

Control group: In the control group, the patient's consent will be obtained after the necessary explanations about the research steps. Then, in the same meeting, the personal information form and the brief pain intensity questionnaire form will be completed by the patient. Patients in the control group will receive routine blood sugar control training. In the twelfth week of the visit, the pain assessment form will be provided to them again for completion. The diabetes indicators of the control group patients will be measured and recorded in the same time intervals and exactly at the same time of the day and night (similar to the intervention group), pain and disease symptoms for 12 weeks as the first appointment (first session) and after 12 weeks. Then the results will be compared in two intervention and control groups.Also, after conducting the research in order to comply with the ethical points and if the patients wish, all the cases done for the intervention group will be provided to the patients of the control group in the form of a CD.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

کلینیک فوق تخصصی غدد و دیابت دانشگاه علوم پزشکی تهران

Full name of responsible person

محسن اقارضی

Street address

تهران - خیابان انقلاب ، خیابان استاد نجات اللهی ، پلاک 4 ، درمانگاه فوق تخصصی دیابت تهران

City

تهران

Province

Tehran

Postal code

1411713119

Phone

+98 21 8863 1298

Fax

+98 21 8822 0052

Email

dmclinic@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Medicine, Islamic Azad University of Medical Sciences, Tehran

Full name of responsible person

Mehdi Vahid Dastjardi

Street address

Tehran, Khaghani St

City

Tehran

Province

Tehran

Postal code

193951495

Phone

+98 21 2200 4355

Email

tms.tehran@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Faculty of Medicine, Islamic Azad University of Medical Sciences, Tehran

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

Faculty of Nursing and Midwifery, Azad University of Medical Sciences, Tehran

Full name of responsible person

Beheshte Tabarsi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

The end of Shahid Sattari highway, Tehran

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 4355

Email

btabarsi@iautmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Azad University of Medical Sciences, Tehran

Full name of responsible person

Beheshte Tabarsi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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City

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Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 4355

Email

btabarsi@iautmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohsen Agharazi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 10 Khavaran Street, Tamdan Street, Khob Bakht Street, Guderzi Street

City

Tehran

Province

Tehran

Postal code

1797885461

Phone

+98 21 3372 4401

Fax

Email

mohsenagharazzi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

There is no further information.

When the data will become available and for how long

There is no further information.

To whom data/document is available

There is no further information.

Under which criteria data/document could be used

There is no further information.

From where data/document is obtainable

There is no further information.

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

There is no further information.

Comments