

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evalulation of Effect of lymph massage and pilates in the treatment of diabetic peripheral neuropathy

Protocol summary

Study aim

Investigating the effect of lymph massage and pilates exercises on leg pain, sense of touch, quality of life, balance, neuropathy symptoms and metabolic markers in diabetic patients with peripheral neuropathy.

Design

A clinical trial with two intervention groups and a control group, with parallel groups, one-blind, randomized, on 48 patients, block method was used for randomization.

Settings and conduct

This study will be conducted with the voluntary participation of people with diabetic neuropathy in the physiotherapy clinic of the rehabilitation faculty. The sampling is done in the form of convenient sampling. The samples are randomly divided into three groups. The first group is treated with lymph massage, the second group is treated with Pilates exercises, and the control group is also treated with routine foot care. None of the patients know about the groupings and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having type 2 diabetes, symptoms of peripheral neuropathy in the distal lower limbs, body mass index between 20 and 25, age between 40 and 60 years, duration of diabetes more than 5 years, HbA1c between 6 up to 8. Exclusion criteria: insulin use, having diabetic foot ulcers, pregnancy, radiculopathy, any other treatment for peripheral neuropathy in the past three months, skin infection or any skin disease.

Intervention groups

Lymph massage group: In this group, lymph drainage surface massage is performed according to the Vodde technique for 45 minutes per session, 5 sessions per week for 10 sessions. Pilates group: The patients do Pilates exercises for 50 minutes in each session, three sessions every week for 4 weeks. Control group: routine care including foot care training, proper shoes and socks

Main outcome variables

Leg pain, sense of touch, quality of life, balance, neuropathy symptoms and blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042581N5**

Registration date: **2024-05-30, 1403/03/10**

Registration timing: **prospective**

Last update: **2024-05-30, 1403/03/10**

Update count: **0**

Registration date

2024-05-30, 1403/03/10

Registrant information

Name

Mohammad Reza Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effect of lymph massage and pilates in the treatment of diabetic peripheral neuropathy	
Public title	Evaluation of Effect of lymph massage and pilates in the treatment of diabetic peripheral neuropathy
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Having type 2 diabetes Symptoms of peripheral neuropathy in the distal lower limbs Body mass index between 20 and 25 Duration of diabetes more than 5 years HbA1c between 6 and 8 Exclusion criteria: Taking insulin Having diabetic foot ulcers Pregnancy Radiculopathy Having any other treatment for peripheral neuropathy in the past three months Having a skin infection or any skin disease
Age	From 40 years old to 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	Participant
Sample size	Target sample size: 45
Randomization (investigator's opinion)	Randomized
Randomization description	Participants are placed in one of the three study groups by a simple randomization method with the help of a lottery. The researcher gives a special code or number to each participant. Then he writes down the number of each of them on a small piece of paper or cardboard; Then he pours them into a bag or container and stirs them. Then he takes out the beads one by one, writes down their number, and continues until he chooses a number equal to the sample size. Opaque envelopes are also used to conceal randomization allocation.
Blinding (investigator's opinion)	Single blinded
Blinding description	None of the participants will know about the type of intervention.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	<u>1</u> Ethics committee Name of ethics committee Ethics committee of Hamedan University of Medical Sciences Street address Hamedan University of Medical Sciences, Fahmideh Blvd City Hamedan Province Hamadan Postal code 6517838736 Approval date 2024-05-19, 1403/02/30 Ethics committee reference number IR.UMSHA.REC.1403.123
Health conditions studied	<u>1</u> Description of health condition studied Peripheral diabetic neuropathy ICD-10 code E11.4 ICD-10 code description Type 2 diabetes mellitus with neurological complications
Primary outcomes	<u>1</u> Description Pain severity Timepoint First session (before intervention), and 10 day (after intervention) Method of measurement Visual Analogue Scale <u>2</u> Description sense of touch Timepoint First session (before intervention), and 10 day (after intervention) Method of measurement Semmes-Weinstein monofilament 5.07/10g <u>3</u> Description Severity of neuropathy Timepoint First session (before intervention), and 10 day (after intervention) Method of measurement Valk questionnaire

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Description

Balance

Timepoint

First session (before intervention), and 10 day (after intervention)

Method of measurement

Berg Balance Scale

Secondary outcomes

1

Description

Blood suger

Timepoint

First session (before intervention), 5, and 10 day (after intervention)

Method of measurement

Blood sugar measuring device

Intervention groups

1

Description

Intervention group: According to the recommendation of the International Association of Lymphology, daily treatment is carried out for 5 days a week and up to 10 sessions. 45 minutes of manual lymphatic drainage surface massage according to the Vodder technique is performed in each session.

Category

Rehabilitation

2

Description

Intervention group: Patients in this group do Pilates exercises for 50 minutes in each session, three sessions every week for 4 weeks. Pilates training sessions are divided into three phases: warm-up, main exercises and returning to the initial state, and exercises in different positions lying down, sitting and standing.

Category

Rehabilitation

3

Description

Control group: Routine care including foot care training, proper shoes and socks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mobasher clinic

Full name of responsible person

Mohammad Reza Asadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Reza Asadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

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