Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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

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

Public title
Evalulation 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

1

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

1

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

1

Description
Pain severity
Timepoint
First session (before intervention), and 10 day (after intervention)
Method of measurement
Visual Analogue Scale

2

Description
sense of touch
Timepoint
First session (before intervention), and 10 day (after intervention)
Method of measurement
Semmes-Weinstein monofilament 5.07/10g

3

Description
Severity of neuropathy
Timepoint
First session (before intervention), and 10 day (after intervention)
Method of measurement
Valk questionnaire

4

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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Mahdieh Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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Reza Shokoohi
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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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Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Full name of responsible person

Mohammad Reza Asadi

Position

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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