Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of modified foot reflexology massage on the intensity of peripheral neuropathy in the elderly with type 2 diabetes induced neuropathy

Protocol summary

Study aim
Determining the effect of modified reflexology massage on the severity of peripheral neuropathy in elderly patients with type 2 diabetes

Design
A clinical trial with a control group, with parallel groups, single blind, randomized, on 60 patients. For randomization, the software for generating random codes in the form of permutation blocks is used.

Settings and conduct
Place of study: Health centers of Quchan city; Study population: elderly with peripheral neuropathy caused by type 2 diabetes; Type of blinding: single blind; How to blind: the elderly are unaware of the grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: elderly at the age of 60 years and older with diabetic neuropathy; Having a health record in health centers; Having a knowledgeable caregiver; At least one week has passed since the start of insulin treatment. Exclusion criteria: Receiving massage before starting the study; Use of mobility aids; Having orthopedic, rheumatology, vascular, nervous and mental system disorders affecting neuropathy; The presence of a wound or amputation in the leg

Intervention groups
Intervention group: After performing the preparation techniques, the caregiver massages points on the legs related to pancreas, liver, kidney and stomach. Control group: the caregiver massages the same points without pressure, to the extent of touching the skin.

Main outcome variables
Intensity of peripheral neuropathy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210612051553N1**
Registration date: **2023-09-12, 1402/06/21**
Registration timing: **prospective**

Last update: **2023-09-12, 1402/06/21**
Update count: **0**

Registration date
2023-09-12, 1402/06/21

Registrant information

Name
Fateme Bakzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4724 2185

Email address
fatimabakzadeh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of modified foot reflexology massage on the intensity of peripheral neuropathy in the

elderly with type 2 diabetes induced neuropathy

Public title
Effect of modified foot reflexology massage on the intensity of peripheral neuropathy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Being 60 years old and over Having a health record in the health center (Includes demographic information and medical records) Having diabetic neuropathy diagnosed by a physician Having a knowledgeable and trainable caregiver Passing at least one week since the start of insulin treatment
Exclusion criteria:
Having orthopedic, rheumatological, vascular disorders, disorders of the nervous and mental system affecting neuropathy (such as deep vein thrombosis, varicose veins, gout, diagnosis of stroke, multiple sclerosis, Parkinson's, spinal cord injury, and Guillen are diagnosed) based on physician's approval Having a wound and amputation in the leg Receiving any message before study initiation Being on medications effective on sympathetic system
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
First, a purposive sampling will be done; then eligible subjects will be randomly allocated into two groups, using permutation blocks randomization approach and the codes generated by the relevant software. Subjects will be randomized individually.
Blinding (investigator's opinion)
Single blinded
Blinding description
After selecting and entering the eligible elderly to study, they will be informed that they will receive one of the two types of massage in this study. But the elderly will not be informed about how people are placed in the groups until the end of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of North Khorasan University of Medical Sciences
Street address
Central Building of North Khorasan University of Medical Sciences, Dolat Blvd, Bojnurd
City
Bojnurd
Province
North Khorasan
Postal code
9414974877
Approval date
2022-01-10, 1400/10/20
Ethics committee reference number
IR.NKUMS.REC.1400.157

Health conditions studied

1

Description of health condition studied
Peripheral neuropathy in the elderly with type 2 diabetes
ICD-10 code
E11.4
ICD-10 code description
Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description
Intensity of peripheral neuropathy based on the Michigan instrument
Timepoint
Study onset (day 0) , days 10, 20, 30 and 40 (Ten days after the end of the intervention).
Method of measurement
Michigan Instrument

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The members of the intervention group will be trained in modified foot reflexology massage in such a way that the caregiver, after performing the preparation techniques, massages the points in the legs related to the pancreas, liver, kidney and stomach. The intervention protocol is 10 minutes each time (for each leg, which includes 2 minutes of

preparation and 8 minutes of massaging the defined points) during the first 30 days.

Category

Treatment - Other

2

Description

Control group: The members of the control group are given false foot massage training in such a way that the caregiver, after performing the preparation techniques, massages the points on the legs related to the pancreas, liver, kidneys and stomach by touching the skin of the feet without pressure. The intervention protocol, during the first 30 days, is 10 minutes each time (for each leg, which includes 2 minutes of preparation and 8 minutes of massaging the defined points).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Quchan urban health centers

Full name of responsible person

Farshid Fathi

Street address

Imam St., Shahid Rahwareh

City

Quchan

Province

Razavi Khorasan

Postal code

9471954643

Phone

+98 51 4722 4060

Email

fathirf1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Ali Esmaili

Street address

Central Building of North Khorasan University of Medical Science, Dolat Blvd

City

Bojnurd

Province

North Khorasan

Postal code

9417696786

Phone

+98 58 3151 1206

Fax

Email

research@nkums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Fatemeh Bakzadeh

Position

Graduate student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Bojnurd School of Nursing and Midwifery, Shahriar St.

City

Bojnurd

Province

North Khorasan

Postal code

9414974877

Phone

+98 58 4724 2185

Email

fatimabakzadeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Armat

Position

Academic member - Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address
Bojnurd School of Nursing and Midwifery, Shahriar St.
City
Bojnurd
Province
North Khorasan
Postal code
9414974877
Phone
+98 58 3229 7097
Email
armat@nkums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Fatemeh Bakzadeh
Position
Graduate student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Bojnurd School of Nursing and Midwifery, Shahriar St.
City
Bojnurd
Province
North Khorasan
Postal code
9417696786
Phone
+98 58 3222 1910
Email
fatimabakzadeh@gmail.com

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
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