

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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

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Razavi Khorasan

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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

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**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**

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**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**

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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**

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