Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of a complementary medicine-based self-care bundle on symptoms of diabetic peripheral neuropathy: a randomized controlled trial

Protocol summary

Study aim
Determining the effect of a complementary medicine-based self-care bundle on diabetic neuropathy symptoms

Design
An unblinded, randomized, parallel-group (intervention and control) trial involving 60 diabetic neuropathy patients.

Settings and conduct
Diabetes Clinic, Baqiyatallah Hospital, Tehran, Iran

Participants/Inclusion and exclusion criteria
This study will enroll male and female patients aged at least 20 years with type 1 or type 2 diabetes who have at least mild diabetic neuropathy. Conversely, patients with other types of neuropathy, active diabetic foot ulcers, or an inability to perform diabetic foot self-care will be excluded.

Intervention groups
Patients in the intervention group will receive face-to-face training on a complementary medicine-based self-care package; this includes foot massage, acupressure (on ST36, SP6, LR3, BL60, and KI3 acupoints), and daily diabetic foot care (such as maintaining foot hygiene, daily skin inspection, and selecting appropriate footwear and socks). Additionally, these patients will receive two short instructional videos and two educational pamphlets, the contents of which have already been validated by ten experts in the field, including faculty members in nursing, traditional medicine, endocrinology/diabetes, and wound care. The intervention will be performed daily for 2 months. Each session will consist of a 10-minute foot massage (from the ankle down), acupressure on both feet (two minutes for each acupoint), and daily diabetic foot care. No specific intervention will be administered to the control group. Study outcomes will be assessed for all patients before and after the intervention period.

Main outcome variables
Severity of peripheral neuropathy (0-10) based on the United Kingdom Screening Test; Severity of neuropathic pain (0-10) based on the Visual Analogue Scale; Health-related quality of life based on the SF-12 questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240306061197N3**
Registration date: **2026-07-23, 1405/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-23, 1405/05/01**
Update count: **0**

Registration date
2026-07-23, 1405/05/01

Registrant information

Name
Amirhossein Nasirmoghadas

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-18, 1405/04/27

Expected recruitment end date
2026-08-22, 1405/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a complementary medicine-based self-care bundle on symptoms of diabetic peripheral neuropathy: a randomized controlled trial

Public title

The effect of a complementary medicine-based self-care bundle on symptoms of diabetic peripheral neuropathy: a randomized controlled trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having type 1 or 2 diabetes Ability to perform diabetic foot self-care Presence of at least mild neuropathy based on the Michigan Neuropathy Screening Instrument (total score > 2) Over 20 years old

Exclusion criteria:

Absence of neuropathy caused by other conditions such as chronic alcohol use; peripheral nerve damage (e.g., due to injury or surgery); chronic liver or kidney disease; uncontrolled hypothyroidism; history of cancer or chemotherapy; HIV/immunodeficiency; multiple sclerosis (MS), Guillain-Barré syndrome, ALS, Parkinson's disease, stroke, spinal cord injury, gout, or deep vein thrombosis (DVT). Absence of active diabetic foot ulcers or any injuries, wounds, or skin lesions on the feet. Abcence of movement disabilities in the limbs

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, subject to informed consent, each participant is assigned to either the intervention or the control group via a coin toss; "heads" designates the intervention group, while "tails" designates the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Baqiyatallah Hospital

Street address

Mollasadra St, Vanak Sq ,Tehran, Iran

City

Tehran

Province

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Postal code

1435915371

Approval date

2026-06-29, 1405/04/08

Ethics committee reference number

IR.BMSU.BAQ.REC.1405.019

Health conditions studied

1

Description of health condition studied

Diabetic Neuropathy

ICD-10 code

E08.40

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description

Severity of peripheral neuropathy based on the United Kingdom Screening Test (UKST)

Timepoint

Before and after the intervention

Method of measurement

The United Kingdom Screening Test will be used, comprising two sections: symptoms and physical findings. Each section is scored separately, with a higher score indicating more severe neuropathy. The symptoms section consists of five questions regarding the symptoms experienced by patients, yielding a total score ranging from 0 to 9. The physical findings section assesses the Achilles tendon reflex, pinprick sensation, vibration sensation, and temperature sensation, resulting in a total score between 0 and 10.

2

Description

Severity of neuropathic pain

Timepoint

Before and after the intervention

Method of measurement

Using the Visual Analogue Scale (VAS), the patient rates the severity of neuropathic pain experienced over the past week on a scale of 0 to 10; a higher score indicates more severe pain.

3

Description

Health-related quality of life

Timepoint

Before and after the intervention

Method of measurement

Using the SF-12 questionnaire, which comprises 12 items covering both mental and physical dimensions, the total score ranges from 12 to 48, with higher scores indicating better quality of life.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive face-to-face training on a complementary medicine-based self-care package; this includes foot massage, acupressure (on ST36, SP6, LR3, BL60, and KI3 acupoints), and daily diabetic foot care (such as maintaining foot hygiene, daily skin inspection, and selecting appropriate footwear and socks). Additionally, these patients will receive two short instructional videos and two educational pamphlets, the contents of which have already been validated by ten experts in the field, including faculty members in nursing, traditional medicine, endocrinology/diabetes, and wound care. The intervention will be performed daily for 2 months. Each session will consist of a 10-minute foot massage (from the ankle down), acupressure on both feet (2 minutes per acupoint), and daily diabetic foot care. No specific intervention will be administered to the control group. Study outcomes will be assessed for all patients before and after the intervention period.

Category

Other

2

Description

Control group: No specific intervention is performed in the control group, and patients will continue with their previously prescribed treatments and care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Saeed Hashemi

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Mollasadra St, Vanak Sq, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Reza Kachuei

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Mollasadra St, Vanak Sq, Tehran, Iran

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researchcenter@bmsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Amirhossein Nasirmoghadas

Position
Researcher

Latest degree
Master

Other areas of specialty/work
Nursery

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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