Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of the Effect of Acupressure on Sleep Quality and Fatigue in Patients with Diabetic Neuropathy

Protocol summary

Study aim
Determining the effect of acupressure on sleep quality and fatigue in individuals with diabetic neuropathy

Design
This clinical trial is randomized, double-blind, and controlled, involving 66 patients. Participants are randomly assigned to the intervention and control groups using a coin toss method.

Settings and conduct
The study is conducted at Khomein health centers with diabetic neuropathy patients. Patients are randomly assigned to intervention (home-based acupressure) and control groups. The study is double-blind, and neither the participants nor the statistical analyst are aware of the group assignments.

Participants/Inclusion and exclusion criteria
Main Inclusion Criteria Age between 40 and 79 years، Confirmed type 2 diabetes، HbA1c below 7% (up to 8% for elderly or high hypoglycemia risk patients)، Confirmed peripheral neuropathy. Main Exclusion Criteria Unrelated neurological disorders; foot wounds; pregnancy or breastfeeding; use of drugs affecting sleep or fatigue; lower limb injury or surgery; stimulant or alcohol use; recent similar interventions.

Intervention groups
In the intervention group, acupressure is applied at home for four weeks, three sessions per week, each lasting 26 minutes, focusing on specific points chosen to reduce fatigue and improve sleep quality. Pressure is applied with the thumb at a defined speed and duration. The control group receives a similar acupressure intervention but on sham points to control for placebo effects. All procedures are conducted under trained supervision with standardized conditions maintained during sessions.

Main outcome variables
Sleep quality؛ fatigue

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250607066101N2**
Registration date: **2025-10-20, 1404/07/28**
Registration timing: **prospective**

Last update: **2025-10-20, 1404/07/28**
Update count: **0**

Registration date
2025-10-20, 1404/07/28

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-10-22, 1404/07/30
Expected recruitment end date
2026-09-21, 1405/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the Effect of Acupressure on Sleep Quality and Fatigue in Patients with Diabetic Neuropathy

Public title
Effect of acupressure on sleep and fatigue in diabetic neuropathy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Participants must be aged between 40 and 79 years. Participants must have type 2 diabetes. Diabetes diagnosis must be confirmed and registered at the health center. HbA1c level in adults must be below 7%. In elderly patients or those with a high risk of hypoglycemia, HbA1c should be below 8% to maintain safety. Peripheral neuropathy must be confirmed by diagnostic tests. Pittsburgh Sleep Quality Index score indicating poor sleep must be greater than 6. Total fatigue questionnaire score must be equal to or greater than 60. Physical fatigue score must be equal to or greater than 9. Mental fatigue score must be equal to or greater than 9. Reduced motivation score must be equal to or greater than 9. Reduced activity score must be equal to or greater than 10. General fatigue score must be equal to or greater than 11. Participant must be able to complete the questionnaire. Participant must provide informed consent to participate in the study.

Exclusion criteria:
Neurological disorders unrelated to the study (e.g., Multiple Sclerosis, spinal cord injury). Presence of any active foot wound or skin lesion that interferes with the intervention. Current use of medications that affect sleep or fatigue. History of injury or surgery in the lower limbs. History of stimulant drug use. Pregnancy or lactation. History of alcohol consumption. Participation in similar interventions (e.g., massage therapy, physiotherapy) during the past three months.

Age
From **40 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to the intervention and control groups using a coin toss method."

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, for blinding purposes, sham points will be used for the control group. These points are located near the main points used in the intervention group but do not have therapeutic effects. This approach is intended to maintain participant blinding and allow for a more accurate assessment of the intervention's effects.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Khomein University of Medical Sciences Ethics Committee

Street address
Khomein University of Medical Sciences, Ghods Boulevard, Khomein, Iran

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Province
Markazi

Postal code
3881743364

Approval date
2025-09-20, 1404/06/29

Ethics committee reference number
IR.KHOMEIN.REC.1404.026

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy

ICD-10 code
E08.21

ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic nephropathy

Primary outcomes

1

Description
Sleep Quality

Timepoint
The primary outcome measurement time points in this study include assessing sleep quality at baseline (before intervention) and at the end of weeks 1, 2, 3, and 4 of the intervention.

Method of measurement
In this study, sleep quality is measured using the

Pittsburgh Sleep Quality Index questionnaire. This questionnaire consists of 19 items assessing sleep quality across seven dimensions, including subjective sleep quality, sleep duration, and sleep disturbances.

Secondary outcomes

1

Description
Fatigue
Timepoint
It is at the beginning (before the intervention starts) and at the end of the first, second, third, and fourth weeks of the intervention.
Method of measurement
Fatigue is assessed using the Multidimensional Fatigue Inventory questionnaire.

Intervention groups

1

Description
Intervention group: The intervention consists of home-based acupressure for diabetic neuropathy patients. It involves pressing specific foot points with the thumb at a rate of two rotations per second for 26 minutes, three times a week, over four weeks. The selected points aim to reduce fatigue and improve sleep quality. The applied pressure ranges from 3 to 5 kilograms and is administered by a trained researcher.
Category
Rehabilitation

2

Description
Control group: The intervention is similar to group 1 but pressure is applied on sham points with no therapeutic effect, serving as placebo control.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health Center No. 4, Khomein County
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Khomein 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

Khomein University of Medical Sciences

Full name of responsible person

Marzieh Mousivand

Position

Graduate student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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