

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effectiveness of Foot Bathing, Massage, and Range of Motion Exercise on Diabetic Patients' Peripheral Neuropathy: A Randomized Controlled Trial

Protocol summary

Study aim

To compare the effectiveness of foot bathing, foot massage, and range-of-motion exercises on diabetic patients' peripheral neuropathy

Design

An experimental comparative design with a minimum sample size of 25 for each group will be used. The total sample size would be 100 subjects, followed for 2 weeks.

Settings and conduct

The study was conducted in the Al-Hassan specialization Center for Endocrinology and Diabetes in Karbala, Iraq

Participants/Inclusion and exclusion criteria

All adult patients (over 18) who have been diagnosed with diabetes for more than 10 years and admitted to diabetes centers will be included in the study. Patients with 5 or less in Toronto Clinical Neuropathy Score, foot gangrene, an amputated right or left foot, or paralysis Patients with any disease or condition that causes neuropathy and interferes with study results will be excluded

Intervention groups

Data will be collected using a pre-test and post-test method. After assessing the level of diabetic peripheral neuropathy based on the Toronto Clinical Neuropathy Score (TCNS), the samples will be allocated into four groups, including a group that applied foot massage for 25 minutes per session, a group that applied bathing to the foot for 15 minutes, a group that applied range-of-motion exercises for the feet for 30 minutes per session, and a control group that did not receive any intervention. Each participant in the intervention group attends three sessions per week for two weeks. Then patients in all groups were evaluated prior to the intervention (post-test assessment) after two weeks by using TCNS

Main outcome variables

Reducing DPN level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221220056877N1**

Registration date: **2022-12-25, 1401/10/04**

Registration timing: **prospective**

Last update: **2022-12-25, 1401/10/04**

Update count: **0**

Registration date

2022-12-25, 1401/10/04

Registrant information

Name

Taher Alfaham

Name of organization / entity

Kerbala University/College of Nursing

Country

Iraq

Phone

+964 783 906 5883

Email address

taher.m@uokerbala.edu.iq

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-10, 1401/10/20

Expected recruitment end date

2023-03-01, 1401/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Foot Bathing, Massage, and Range of Motion Exercise on Diabetic Patients' Peripheral Neuropathy: A Randomized Controlled Trial

Public title

Effectiveness of Foot Bathing, Massage, and Range of Motion Exercise on patients with Diabetic Peripheral Neuropathy: A Clinical Trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are more than or equal to 18 years old
Patients who have been diagnosed with diabetes for 10 years and more
Patients who have Diabetic Peripheral Neuropathy (DPN) of more than 5 on Toronto Clinical neuropathy score (TCNS)
Patients with Type-1 and Type-2 Diabetes Mellitus

Exclusion criteria:

Patients with score of 5 and less than in TCNS scale
Patients who have Chemotherapy-Induced Peripheral Neuropathy
Patients with foot gangrene
Patients with amputated right or left foot
Patients who refused to participate in the study
Patients with paralysis, partly or entirely unable to move the affected parts of the body
patients with osteoarthritis and osteomyelitis, rheumatoid arthritis
Patient with certain viral or bacterial infections, including Lyme disease, shingles, Epstein-Barr virus, hepatitis B and C, leprosy, Diphtheria, and HIV)
Patients who are receiving any physiotherapy intervention
Patients with inherited disorders, such as Charcot-Marie-Tooth disease are hereditary types of neuropathy;
Patients with autoimmune diseases, include lupus, Guillain-Barre syndrome, demyelinating polyneuropathy and vasculitis
Patients with bone marrow disorders, These include Multiple myeloma, lymphoma and amyloidosis
Patients with other diseases, include kidney and liver disease, connective tissue disorders and hypothyroidism)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to maintain a transparent and scientifically based randomization process, stratified randomization will be used in assigning participants (individuals: diabetic patients with peripheral neuropathy) to intervention (foot bathing, foot massage, and range of motion exercise) and control groups, assuming that each participant has an equal chance of being assigned to any group. The simple randomization procedure would involve choosing a color from a sealed envelope that

contains four numbers: blue, yellow, green, and red (blue would be in the foot bathing group, yellow would be in the foot massage group, green would be in the range of motion exercises group, and red would be in the control group). Indeed, four groups will be allocated randomly.

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**

Ethics committee in College of Nursing at University of Baghdad

Street address

Bab-ALMuadham

City

Baghdad

Postal code

10053

Approval date

2022-12-19, 1401/09/28

Ethics committee reference number

4626

Health conditions studied**1****Description of health condition studied**

Diabetes Mellitus

ICD-10 code

G90.0

ICD-10 code description

Idiopathic peripheral autonomic neuropathy

Primary outcomes**1****Description**

The primary outcome variable is the level of Diabetic Peripheral Neuropathy that can be changed based on foot bathing, foot massage, and ROM exercises

Timepoint

Before intervention and two weeks after intervention

Method of measurement

The Toronto Clinical Neuropathy Score will be used to assess the level of DPN

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After assessing the level of diabetic peripheral neuropathy, the sample will be allocated into four groups: the foot bathing group, which involves immersing both patients' feet in 5 liters of tolerably warm water (between 40 and 45 °C) with 250 grams of powdered mineral salt added and dissolved; the foot massage group, in which the researcher's thumb is used to apply gentle, gradually increasing pressure along the three meridians lines on the feet. Pressure is also applied to the area of the knee in the supine and side-lying positions and to the lower leg, ankle, and foot of the participants. The range-of-motion exercise group combined ROM with plantar exercise and placed a tennis ball for 30 minutes every two days. The active ROM procedure covered flexion-extension-adduction-abduction in the hips and toes, flexion-extension of the knees, dorsiflexion and plantar flexion in the ankles, and inversion-eversion of the legs. Place a tennis ball on the ground and ask patients to gently roll it underfoot, backward and forward, and rotate it along the plantar for five minutes to relax the muscles in the plantar fascia. Then patients in all groups were evaluated prior to the intervention (post-test assessment) after two weeks by using the Toronto Clinical Neuropathy Score.

Category

Treatment - Other

2

Description

Control group: The control group received no interventions; instead, they received pre-test and post-test assessments after two weeks, as did the other groups, and they will be compared to the other groups in the study. Then patients in all groups were evaluated prior to the intervention (post-test assessment) after two weeks by using the TCNS.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Hassan specialization Center for Endocrinology and Diabetes

Full name of responsible person

Karbala Health Directorate

Street address

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Baghdad

Full name of responsible person

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Web page address

<http://conursing.uobaghdad.edu.iq/>

Grant name

Grant code / Reference number

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

No

Title of funding source

The author of the trial is the funding source

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

University of Kerbala

Full name of responsible person

Taher Mohsin Hashim Al-Fahham

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The data will be the results of the TCNS that measure patients' DPN levels in both the control and intervention groups.

When the data will become available and for how long

God Willing, once the article is published, the data will be available after 6 months of publication. If the article will be published in a subscribed journal, the data will be available after one year because of the policy of the subscribed journals.

To whom data/document is available

with academic nurses and any researcher who is interested in the data.

Under which criteria data/document could be used

The data could be used after getting permission via email. Also, users need to acknowledge the owner.

From where data/document is obtainable

Users can ask for the data and permission via email. Taher Al-Fahham is the corresponding author. He will contact whoever he requests the information from. His email is taher.m@uokerbala.edu.iq Taher Al-Fahham works at the University of Kerbala/College of Nursing. The address is Al-Muadhafeen district, Karbala, Iraq. What processes are involved for a request to access data/document

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Comments