

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Clinical Practice Investigating the effect of foot reflexology massage on the quality of sleep in type 2 diabetic women

Protocol summary

Summary

This study is a randomized clinical trial. The aim of this study is to investigate the effect of foot reflexology massage on the quality of sleep of type 2 diabetic women. The sample size is 54 patients who randomly select from the diabetic center of Amirmomenin hospital in Arak. They randomly divide into control and intervention groups. Inclusion criteria include people between the ages of 30- 65 and having no diabetic neuropathy, and exit criteria include unwillingness to continue cooperation. In the Massage group, the foot massage perform for four weeks, twice a week for 30 minutes on both legs, while the control group only receives care for the disease. Before and after intervention, Pittsburg Sleep Quality Standard Questionnaire is considered.

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Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091236148N1**

Registration date: **2017-10-15, 1396/07/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name

Fatemeh Bagheri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

Scientific title

Clinical Practice Investigating the effect of foot reflexology massage on the quality of sleep in type 2 diabetic women

Public title

The effect of massage on sleep

Purpose

Supportive

Inclusion/Exclusion criteria

Entry Criteria: Individuals aged 30-65; People not afflicted with diabetic neuropathy; Non-chronic diseases such as rheumatoid arthritis; the absence of any complication in the leg; full awareness of time, place and person. Exit criteria: Unwillingness to continue cooperation with the researcher; the presence of complications or disorders or specific illness during the study.

Age

From **30 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tehran University of Medical Sciences

Street address

Tohid Street, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-11-05, 1395/08/15

Ethics committee reference number

IR.TUMS.FNM.REC.1395.1654

Health conditions studied

1

Description of health condition studied

Diabet

ICD-10 code

(E00-E90)

ICD-10 code description

Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

Sleep quality

Timepoint

One Month

Method of measurement

Standard Pittsburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the massage group, the foot massage is performed eight sessions. Twice a week, 30 minutes each session, for one month.

Category

Treatment - Other

2

Description

In the control group, only disease-related care is provided.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Amiralmomenin Hospital

Full name of responsible person

Fatemeh Bagheri

Street address

Sardasht, basij square, Arak, Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shadan Pedramrazi

Street address

Nursing University, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Faculty of Nursing and Midwifery, Tehran University of
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty