

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of the effect of foot and hand reflexology massage on pain intensity and sleep quality in patients undergoing total knee arthroplasty

Protocol summary

Study aim

Determining and comparing the effect of foot and hand reflexology massage on pain intensity and sleep quality in patients undergoing total knee arthroplasty surgery.

Design

The clinical trial comprises two intervention groups and one control group, with a sample size of 35 assigned to each group (105 in total). To assign patients to groups, random allocation was performed in a block of three using a random number table.

Settings and conduct

Location: Pasargad Super specialty hospital, Tehran.
Procedure: pain levels are assessed prior to the intervention. For patients in intervention groups 1 and 2, a reflexology massage intervention is administered for 10 minutes on the day of surgery and on the first and second postoperative days (three consecutive days). pain is subsequently assessed ten minutes after the intervention and the following morning, while sleep quality is assessed the following morning. the control group, pain and sleep are assessed alongside routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Ability to understand and complete the questionnaires and measurement scales.-Age over 40 years.-Abbreviated Mental Test Score (AMTS) of 7 or higher for elderly patients aged over 60 years
Non-inclusion criteria: -Absence of knee joint infection, rheumatoid arthritis, or neuropathic diseases -No history of antidepressant, anticonvulsant medication use - Absence of deep vein thrombosis (DVT), open wounds, or severe varicose veins in the limb ipsilateral to the surgical knee -Absence of upper or lower limb amputation on the side ipsilateral to the operated knee

Intervention groups

Intervention Group 1: Foot reflexology massage ipsilateral to the operated knee
Intervention Group 2: Hand reflexology massage ipsilateral to the operated knee
Control Group: Standard care

Main outcome variables

Pain intensity - sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260720070275N1**

Registration date: **2026-08-26, 1405/06/04**

Registration timing: **registered_while_recruiting**

Last update: **2026-08-26, 1405/06/04**

Update count: **0**

Registration date

2026-08-26, 1405/06/04

Registrant information

Name

Alireza Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date

2027-02-19, 1405/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of foot and hand reflexology massage on pain intensity and sleep quality in patients undergoing total knee arthroplasty

Public title

Comparison of the effect of foot and hand reflexology massage on pain intensity and sleep quality in patients undergoing total knee arthroplasty

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

-Ability to understand and complete the questionnaires and measurement scales- Age over 40 years Abbreviated Mental Test Score (AMTS) of 7 or higher for elderly patients aged over 60 years

Exclusion criteria:

-Absence of knee joint infection, rheumatoid arthritis, or neuropathic diseases-- No history of antidepressant or anticonvulsant medication use Absence of deep vein thrombosis (DVT), open wounds, or severe varicose veins in the limb ipsilateral to the surgical knee Absence of upper or lower limb amputation on the side ipsilateral to the operated knee

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be assigned to groups using a block randomization method with blocks of three (each block comprising one participant for each of the three groups: foot reflexology, hand reflexology, and routine care/control). To determine the assignment sequence within each block, random numbers generated via <https://www.randomizer.org> will be used, with settings configured for a single set of three unique numbers and the "place markers across" option selected to define the sequence across all blocks.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessment and analysis of the results will be performed by an individual who is blinded to the patients' group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahed university

Street address

Shahed University, opposite Holy shrine of Imam Khomeini, Khalij Fars Expressway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2026-05-31, 1405/03/10

Ethics committee reference number

IR.SHAHED.MED.REC.1405.033

Health conditions studied

1

Description of health condition studied

pain intensity after total knee Arthroplasty

ICD-10 code

M25.56

ICD-10 code description

Pain in knee

2

Description of health condition studied

Sleep Quality after total knee Arthroplasty

ICD-10 code

G47.01

ICD-10 code description

Insomnia due to medical condition

Primary outcomes

1

Description

Pain intensity

Timepoint

before intervention , 10 minute after intervention and the day after intervention at the morning for 3 days (total : 9 times).

Method of measurement

Pain intensity will be measured using a Visual Analog Scale (VAS), where the patient indicates their pain score on a scale from 0 to 10.

Secondary outcomes

1

Description

Sleep Quality

Timepoint

On the morning after the intervention, for three consecutive days

Method of measurement

Sleep quality will be evaluated using the Richards-Campbell Sleep Questionnaire . The questionnaire is administered to the patient in the morning to assess the previous night's sleep quality, with scores ranging from 0 (worst) to 100 (best).

Intervention groups

1

Description

Intervention Group 1: In addition to receiving standard care, foot reflexology massage will be performed for 10 minutes on the side ipsilateral to the operated knee. Intervention timing: 4 hours after analgesic administration (intramuscular Pethidine 50 mg) on the day of surgery upon arrival at the ward, as well as on the first and second postoperative days (for a total of 3 sessions).

Category

Treatment - Other

2

Description

Intervention Group 2: In addition to receiving standard care, hand reflexology massage will be performed for 10 minutes on the side ipsilateral to the operated knee. Intervention timing: 4 hours after analgesic administration (intramuscular Pethidine 50 mg) on the day of surgery upon arrival at the ward, as well as on the first and second postoperative days (for a total of 3 sessions).

Category

Treatment - Other

3

Description

Control Group: Receives standard care without any intervention. Pain intensity and sleep quality will be assessed at the same time points as the intervention groups: 4 hours after analgesic administration (intramuscular Pethidine 50 mg) on the day of surgery upon arrival at the ward, as well as on the first and second postoperative days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pasargad Hospital

Full name of responsible person

Dr Nahid Khalili

Street address

Pasargad Hospital, between Somayeh and Taleghani Streets, Shariati Street, Tehran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr Hamed Sajedi

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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

Shahed University

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

Shahed University

Full name of responsible person

Nasrin Alaei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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

Anonymized individual data—including age, gender, medical history, and education—are shared.

When the data will become available and for how long

Access begins after the publication of results.

To whom data/document is available

Individuals within the relevant scientific field who intend to study or cite the data are granted access to it.

Under which criteria data/document could be used

The use of data to enhance efficiency in similar studies and to accelerate the relevant research process is approved

From where data/document is obtainable

They can access the data By sending a message to the researcher's email address :
alirezaoliver1380@gmail.com

What processes are involved for a request to access data/document

Upon the requester's application for access to the data _whether for reference or study _ the data will be sent to

them at the earliest opportunity

Comments