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
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Alireza Akbari
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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
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Pasargad Hospital, between Somayeh and Taleghani Streets, Shariati Street,Tehran.
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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 Alaee

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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