Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of auricular acupressure and body acupressure on pain and anxiety in older adults undergoing knee replacement arthroplasty

Protocol summary

Study aim
Determining and comparing the effect of auricular acupressure and Body acupressure on pain and anxiety in female older adults undergoing knee replacement arthroplasty

Design
A clinical trial with a control group, simple randomization, with parallel, and hospital-based. The samples include 141elderly women undergoing knee replacement surgery. There is no trial phase.

Settings and conduct
Patients undergoing Knee Replacement Arthroplasty in Shafa Yahyaian Hospital in Tehran city are divided into three groups: acupressure, auriculotherapy, and control. After surgery, the amount of pain and anxiety are measured, then the intervention is performed. The pain and anxiety will be assessed end of the first day, after the last intervention on the second day, and after the last intervention on the third day. The researcher assistant who is unaware of the groupings and type of interventions in each group .

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 60 years and over, Absence of cognitive impairment, Ability to communicate, Non-alcohol and drug addiction, lack of experience or simultaneous participation in similar training sessions, Lake of history of mental illness, the first experience with knee replacement arthroplasty, Undergoing spinal anesthesia, Lake of malignancy, the lake of inflammatory disease, and vascular disease, Having no active bleeding, sensory disorders, pain, infectious wounds, and skin disease at the intervention site. Exclusion criteria: Unwillingness to cooperate with a patient or physician, Return to the operating room.

Intervention groups
The first Intervention group: patients received auricular acupressure. The second Intervention group: patients who received body acupressure.

Main outcome variables
Pain, Anxiety

General information

Reason for update
Increasing the sample size from 30 to 47 with the approval of the Ethics Committee of Shahed University

Acronym

IRCT registration information
IRCT registration number: **IRCT20110912007529N28**
Registration date: **2023-07-10, 1402/04/19**
Registration timing: **prospective**

Last update: **2024-02-12, 1402/11/23**
Update count: **1**

Registration date
2023-07-10, 1402/04/19

Registrant information

Name
Nahid Rejeh

Name of organization / entity
Shahed University

Country
Iran (Islamic Republic of)

Phone
+98 21 5121 3071

Email address
reje@shahed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01

Expected recruitment end date

2024-05-18, 1403/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of auricular acupressure and body acupressure on pain and anxiety in older adults undergoing knee replacement arthroplasty

Public title
Comparing the effect of auricular acupressure and body acupressure on pain and anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 60 years and over Absence of cognitive impairment Ability to communicate Non-alcohol and drug addiction Lack of experience or simultaneous participation in similar training sessions Lake of history of mental illness The first experience with knee replacement arthroplasty Undergoing spinal anesthesia Lake of malignancy, lake of inflammatory disease, and vascular disease Having no active bleeding, sensory disorders, pain, infectious wounds and skin disease at the intervention site

Exclusion criteria:
Unwillingness to co-operate with a patient or physician Return to the operating room

Age
From **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **141**

Randomization (investigator's opinion)
Randomized

Randomization description
Hundred & one cards (equal to the number of sample volumes) will be prepared. Then A, B, or C will be written on each card (47 cards A, 47 cards B, and 47 cards C). These cards will be placed inside an opaque box so that no one can see the cards inside the box. In this way, three cards are prepared and one of the words A (acupressure), B (auriculotherapy), and C (control) will be written on each card. After shuffling the cards by the researcher, patients are asked to randomly take a card from the box (selected cards will not be returned to the box after selection). This process will continue until the sample size is completed

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 of Shahed University

Street address
Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran. Iran

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2023-06-19, 1402/03/29

Ethics committee reference number
Shahed.REC.1402.024

Health conditions studied

1

Description of health condition studied
Knee joint replacement

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of pain

Timepoint
Before the first intervention on the first day, after the last intervention on the first day, after the last intervention on the second day, and after the last intervention end on the third day.

Method of measurement
Visual Pain Scale

2

Description
Quality of pain

Timepoint
Before the first intervention on the first day, after the last intervention on the first day, after the last intervention on the second day, and after the last intervention end on the third day.

Method of measurement

MacGill questionnaire

3

Description
Intensity of anxiety
Timepoint
Before the first intervention on the first day, after the last intervention on the first day, after the last intervention on the second day, and after the last intervention end on the third day.
Method of measurement
Visual Analogue Scale Anxiety) VASA)

4

Description
Quality of anxiety
Timepoint
Before the first intervention on the first day, after the last intervention on the first day, after the last intervention on the second day, and after the last intervention end on the third day.
Method of measurement
The Spielberger Inventory

Secondary outcomes

1

Description
Blood pressure
Timepoint
Before the first intervention on the first day, after the last intervention on the first day, after the last intervention on the second day, and after the last intervention end on the third day.
Method of measurement
Digital arm l sphygmomanometer

2

Description
Pulse rate
Timepoint
Before the first intervention on the first day, after the last intervention on the first day, after the last intervention on the second day, and after the last intervention end on the third day.
Method of measurement
Enumeration of pulse rate

3

Description
Respiration rate
Timepoint
Before the first intervention on the first day, after the last intervention on the first day, after the last intervention on the second day, and after the last intervention end on the third day.
Method of measurement
Enumeration of Respiration rate

Intervention groups

1

Description
Intervention group: interventional therapy ear acupuncture At first, disinfection of both outer auricles using 70% alcohol, and then during 3 days, every day three times, each time for each point 3 minutes medium equitability on glue ear (ear plaster containing seed) on a three-point on the auricle, Shen Men, knee, Thalamus given
Category
Other

2

Description
Intervention group: interventional therapy body acupuncture including: At first, during 3 days, every day three times, each time for each point 3 minutes (on a three-point on the Hegu LI4 (LargIntestine4), LI10(Shousanli) and Yintang).
Category
Other

3

Description
Control group: This group is provided by routine care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Yahyaian Hospital
Full name of responsible person
Fatemeh.Ghanbari
Street address
Ṣhafa Yahyaian Hospital, Mojahedin-e-Islam St., Baharestan Square, Tehran.
City
Tehran
Province
Tehran
Postal code
3713111576
Phone
+98 21 3354 2041
Email
Emamali@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shahed University

Full name of responsible person
Dr. Shahriar Bijani

Street address
Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
3319118651

Phone
+98 21 5121 3071

Fax

Email
bijani@shahed.ac.ir

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
Dr. Nahid Rejeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran.

City
Tehran

Province
Tehran

Postal code
3319118651

Phone
+98 21 5121 2100

Fax

Email
nrejeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Dr. Nahid Rejeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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City
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Province
Tehran

Postal code
3319118651

Phone
+98 21 5121 000

Email
nrejeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Dr. Nahid Rejeh

Position
Professor

Latest degree
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Other areas of specialty/work
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nrejeh@yahoo.com

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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the original outcome after being unidentifiable is shared.

When the data will become available and for how long

The access period is up to after the publication of the results.

To whom data/document is available

Results is available to academic researchers

Under which criteria data/document could be used

A new analysis of the data can only be done by explaining the reasons for the request for such an analysis and with the knowledge of the researcher.

From where data/document is obtainable

They can correspond with the person responsible for this clinical trial(Nahid Rejeh) to receive the data (nrejeh@yahoo.com.)

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

After receiving the application for having a data file and obtaining permission from the university vice-chancellor, the data file after the publication of the results is shared

Comments