

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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
Lack of history of mental illness
The first experience with knee replacement arthroplasty
Undergoing spinal anesthesia
Lack of malignancy, lack 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

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 I 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

Shafa 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

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 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

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

Email

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