# 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 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**
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**Postal code**
3713111576
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+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

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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

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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**

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**