Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of acupressure on the severity of pain and sleep quality in patients with osteoarthritis of the knee.

Protocol summary

Study aim
Determining the effect of acupressure on pain intensity and sleep quality in patients with knee osteoarthritis.

Design
A randomized controlled clinical trial with a control group, in parallel, Single blinded groups, on 126 patients, which will be assigned to the intervention, control and treatment groups using permutation blocking method.

Settings and conduct
The research environment in this study is Rheumatology Clinic affiliated to Birjand University of Medical Sciences. The researcher teaches how to perform acupressure on specific points in person and practical practice and presenting educational pamphlets to patients in groups of 10 people.

Participants/Inclusion and exclusion criteria
Inclusion criteria : -Grade 2 and 3 osteoarthritis of the knee according to the scale (Kellegren-Lawrence) K-L. - Do not take NSAIDs more than 3 times a week (maximum 1500 mg naproxen per week). -Lack of inflammation, infection, or sensory disturbance or neuropathy at the acupressure site. -Not doing acupressure in the last six months, Not being history of joint surgery and steroid injections last month. - BMI less than 35. -Not being take anticoagulants and Lack of history of coagulation disorders -Take more than 5score Petersburg quality sleep questionnaire Not being Mental Illness. Inclusion criteria: Grade 1 osteoarthritis of the knee according to the scale (Kellegren-Lawrence) K-L. BMI more than 35

Intervention groups
The researcher teaches how to perform acupressure on specific points in person and practical practice and presenting educational pamphlets to patients in groups of 10 people. In the facade treatment group, the intervention is taught in the same way on false points. The control group also receives routine care.

Main outcome variables
Pain Sleep Quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211221053475N1**
Registration date: **2022-01-10, 1400/10/20**
Registration timing: **prospective**

Last update: **2022-01-10, 1400/10/20**
Update count: **0**

Registration date
2022-01-10, 1400/10/20

Registrant information

Name
Elaheh Shourabi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-09, 1400/11/20

Expected recruitment end date
2022-06-10, 1401/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of acupressure on the severity of pain and sleep quality in patients with osteoarthritis of the knee.

Public title

The effect of acupressure on pain intensity and sleep quality in patients with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Grade 2 and 3 osteoarthritis of the knee according to the scale (Kellegren-Lawrence) K-L. Not take being NSAIDs more than three times a week (maximum 1500 mg naproxen per week). Patient willingness and satisfaction to participate in research. Not being addicted to drugs. Lack of physical disability and lack of psycho-cognitive dysfunction. Lack of inflammation, infection or sensory disturbance or neuropathy at the site of acupressure. Not doing acupressure in the last six months, Not being history of joint surgery and steroid injections last month. BMI less than 35. Not being pregnant. Not being take anticoagulants and Lack of history of coagulation disorders Take more than 5score Petersburg quality sleep questionnaire Not being Mental Illness.

Exclusion criteria:

Grade 1 osteoarthritis of the knee according to the scale (Kellegren-Lawrence) K-L. BMI more than 35

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

All sample subjects are divided into three equal groups by simple randomized methods. first 126 cards (equal to the number of sample volumes) will be prepared. Then, one of the letters A, B or C will be written on each card (42cards A, 42 cards B and 42cards C).These cards will be placed inside a box. so, no one will be able to see the cards inside the box.After shuffling the cards by the researcher, patients are asked to randomly remove a card from the box (selected cards will not be returned to the box after selection).Thus, Participants are divided into three groups of 42members A, B and C.In this way, three cards are prepared and one of the numbers one, 2 and 3 will be written on each card.Numbers 1, 2 and 3 will belong to intervention, placebo and control, respectively.These cards will be placed in a box and after shuffling, the researcher will randomly select a card for each group (the selected cards will not be returned to the box after selection)

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the assistant researcher will complete the questionnaires to prevent bias in the results. Thus, the assistant researcher will be unaware of the groupings and the type of interventions performed in each group and by each Patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari St., Birjand University of Medical Sciences, Vice Chancellor for Research and Technology

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birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.BUMS.REC.1400.224

Health conditions studied

1

Description of health condition studied

Osteoarthritis of knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Pain intensity in patients with osteoarthritis of the knee

Timepoint

At the beginning of the study, 4 weeks after starting the study, 8 weeks after starting the study

Method of measurement

Womak Questionnaire

2

Description
Sleep quality in patients with knee osteoarthritis
Timepoint
At the beginning of the study, 4 weeks after starting the study, 8 weeks after starting the study.
Method of measurement
Pittsburgh Sleep Quality Questionnaire (PSQI)

Secondary outcomes

1

Description
Fatigue
Timepoint
At the beginning of the study, 4 weeks after starting the study, 8 weeks after starting the study
Method of measurement
FSS Fatigue Intensity Questionnaire

Intervention groups

1

Description
Intervention group: To perform the intervention, the researcher is trained under the supervision of a traditional medicine specialist.After obtaining a certificate and approval from a traditional medicine specialist, the intervention is performed.In this way, in the intervention group, the researcher first teaches the location of the points that are used for pain.In the present study, the points that will be used to reduce pain include ST34 / ST36 / SP 9 / SP 10 / GB 34. Then, the researcher teaches how to perform acupressure on specific points in person and practice and present educational pamphlets to patients in groups of 10 people.Patients are asked to intervene on the trained points every day for a month.Evaluation will be done on the day of the study and 4 weeks after the start and 8 weeks after the start of the study.
Category
Rehabilitation

2

Description
Facade therapy group: The trainings of intervention group 1 are also given to this group, with the difference that the points related to acupressure are taught on false points.
Category
Rehabilitation

3

Description
Control group:This group does not receive any acupressure treatment
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology Clinic
Full name of responsible person
Zeinab Saremi
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Taleghani 20, Shafa Doctors Building, 4th Floor
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Birjand University of Medical Sciences
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
Birjand University of Medical Sciences

Full name of responsible person
Elahe Shourabi

Position
Masters Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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