Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of aromatherapy massage with lavender essential oil on pain, stiffness and physical function in patients with osteoarthritis of the knee in comparison with placebo and control groups.

Protocol summary

Summary

This study is a single-blind, randomized clinical trial. This study is performed to determine the effect of aromatherapy massage with lavender oil on pain, stiffness and physical function in patients with osteoarthritis of the knee. Inclusion Criteria are those: Approved osteoarthritis knee by Rheumatologist; having knee joint pain that scored 4 cm or above on a 10 cm visual analog scale in the past 3 months; persons who are able to understand explanations and complete the interview; no having cancer, pregnancy and blood clotting disorders such as hemophilia. Participants which have knee surgery during the study, prescription physiotherapy for the knee joint pain during the study, an allergic reaction towards lavender essential oil during the study and the lack of willingness to continue participation in the study, will be excluded. 90 patients osteoarthritis of the knee who have the inclusion criteria of the study are selected by convenient sampling method and are randomly divided into three groups. An experimental group (N= 30) who receives a session of twenty minutes of effleurage massage with 5 cc of 3% lavender essential oil on both lower limbs nine times within 3 weeks, a placebo group (N= 30) who receives a session of twenty minutes of effleurage massage with 5 cc of almond oil on both lower limbs nine times within 3 weeks, and control group (N= 30) who receives no massage. In this study, Lavender essence and almond oil are provided by the Barij Essence Pharmaceudical Company (Kashan, Iran). Assessment is done at baseline, immediately after the intervention, post 1-week and post 4 weeks after treatment. Changes from baseline to the end of treatment are assessed on knee pain intensity, stiffness level and physical functioning by WOMAC (Western Ontario and McMaster Universities Osteoarthritis index) and VAS (Visual Analogue Scale).In this study, those who are going to fill out the questionnaire are not aware of any experiments on each of participants.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041921839N1**
Registration date: **2015-06-15, 1394/03/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-15, 1394/03/25

Registrant information

Name
Mohamad Azim Mahmodi
Name of organization / entity
Birjand University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of aromatherapy massage with lavender essential oil on pain, stiffness and physical function in patients with osteoarthritis of the knee in comparison with placebo and control groups.

Public title
The effect of aromatherapy massage with lavender essential oil on osteoarthritis of knee.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Approved osteoarthritis knee by Rheumatologist; having knee joint pain that scored 4 cm or above on a 10 cm visual analog scale in the past 3 months; persons who are able to understand explanations and complete the interview; no having cancer, pregnancy and blood clotting disorders such as hemophilia. exclusion criteria: knee surgery during the study prescription physiotherapy for the knee joint pain during the study; have an allergic reaction towards lavender essential oil during the study; unwillingness to continue to participate in the study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
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 Street, Birjand University of Medical Sciences, Birjand, South khorasan
City
Birjand
Postal code
Approval date
2015-04-13, 1394/01/24
Ethics committee reference number
25/10939

Health conditions studied

1

Description of health condition studied
Osteoarthritis of the knee
ICD-10 code
M17
ICD-10 code description
Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description
Knee Pain
Timepoint
at baseline, immediately after the intervention, 1 and 4 weeks after the intervention
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Visual Analogue Scale

2

Description
Stiffness
Timepoint
at baseline, immediately after the intervention, 1 and 4 weeks after the intervention
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

3

Description
physical function
Timepoint
at baseline, immediately after the intervention, 1 and 4 weeks after the intervention
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Secondary outcomes

empty

Intervention groups

1

Description
control group receives no massage.
Category
Other

2

Description
participants in the intervention group receives a session of twenty minutes of effleurage massage with 5 cc of 3% lavender essential oil on both lower limbs nine times within 3 weeks.
Category
Treatment - Other

3

Description
participants in the placebo group receives a session of twenty minutes of effleurage massage with 5 cc of sweet almond oil on both lower limbs nine times within 3 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital clinic
Full name of responsible person
Doctor Zohra Nobakht
Street address
Ghaffari Street, Valiasr hospital clinic, Birjand, South khorasan
City
Birjand

2

Recruitment center
Name of recruitment center
Shohada Clinic
Full name of responsible person
Doctor Zohra Nobakht
Street address
Artesh Street, Shohada Clinic, Birjand, South khorasan
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Gholam Reza Sharif-Zadeh
Street address
Ghaffari Street, Vice chancellor for research, Birjand University of Medical Sciences, Birjand, South khorasan
City
Birjand
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences, School of Nursing and Midwifery
Full name of responsible person
Mohsen Fvaaldyny
Position
Vice Chancellor for Research, School of Nursing and Midwifery
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
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Ahmad Nasiri Foorg

Position

PhD in Nursing

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Mohamad Azim Mahmodi

Position

Nurse

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty