

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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 Pharmaceutical 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

Country

Iran (Islamic Republic of)

Phone

+98 56 3231 8151

Email address

mahmodi_ems@bums.ac.ir

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

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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

Full name of responsible person

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Position

PhD in Nursing

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

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