

# 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

##### 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

##### Street address

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Birjand University of Medical Sciences

##### Full name of responsible person

Ahmad Nasiri Foorg

**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**

**Street address**

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**Web page address**

**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*