

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of aromatherapy massage with peppermint oil on functional problems in patients with knee osteoarthritis

#### Protocol summary

##### Study aim

Determining the effect of aromatherapy massage with peppermint oil on functional problems in patients with knee osteoarthritis

##### Design

A community-based, pragmatic, control group clinical trial was randomized with parallel groups.

##### Settings and conduct

In the peppermint oil massage group, the knee will be massaged with peppermint oil for 15 minutes during 4 weeks (2 sessions per week). In the paraffin massage group, the knee will be massaged with paraffin for 15 minutes during 4 weeks (2 sessions per week). Control group: will not receive any intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria are: Age between 60-80 years, Definitive diagnosis of knee osteoarthritis by a rheumatologist, Insensitivity to vegetable oils, Absence of sensitivity and open wound on the knee surface, Willingness to participate in research. No entry conditions: Simultaneous use of complementary therapies, Occurrence of any sensitivity during the study, Non-continuance of cooperation of the participants.

##### Intervention groups

Intervention group one: The first researcher will massage the patient's knee with 10 drops of peppermint oil for 15 minutes during 4 weeks (2 sessions per week).

Intervention group two: The first researcher will massage the patient's knee with paraffin oil for 15 minutes during 4 weeks (2 sessions per week). Control group: will not receive any intervention.

##### Main outcome variables

Functional knee problems

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230311057686N1**

Registration date: **2023-04-04, 1402/01/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-04-04, 1402/01/15**

Update count: **0**

#### Registration date

2023-04-04, 1402/01/15

#### Registrant information

##### Name

Zahra Momen Arani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5472 1403

##### Email address

zahramomenn@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-04-04, 1402/01/15

#### Expected recruitment end date

2023-10-07, 1402/07/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of aromatherapy massage with peppermint oil on functional problems in patients with knee osteoarthritis

**Public title**

The effect of aromatherapy massage on functional problems in patients with knee osteoarthritis

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 60-80 years  
Definitive diagnosis of knee osteoarthritis by a rheumatologist  
Insensitivity to vegetable oils  
Absence of sensitivity and open wound on the knee surface  
Willingness to participate in research

**Exclusion criteria:**

Simultaneous use of complementary therapies  
Occurrence of any sensitivity during the study  
Non-continuance of cooperation of the participants

**Age**

From **60 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sampling method will be available and based on inclusion criteria. Then, the samples will be determined by block randomization method with 10 blocks and using the random number table of Allocation Random software. Blocking and allocation sequencing for concealment will be done by the person not involved in the research (Allocation Concealment). The sample allocation ratio (Allocation 1:1) will be in two groups of intervention and control (Assignment). Then, based on the obtained blocks and in the order of allocation, the trainings will be given to the patients. Blinding will not occur in this study.

**Blinding (investigator's opinion)**

Not 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 nursing and midwifery school,  
Kashan University of Medical Sciences

**Street address**

School of Nursing and Midwifery, Kashan university of

medical sciences, Parastar St., Qotbe Ravandi Blv,  
Kashan, Iran

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Approval date**

2023-01-10, 1401/10/20

**Ethics committee reference number**

IR.KAUMS.NUHEPM.REC.1401.075

**Health conditions studied****1****Description of health condition studied**

knee osteoarthritis

**ICD-10 code**

M17

**ICD-10 code description**

Osteoarthritis of knee

**Primary outcomes****1****Description**

Functional problems of knee

**Timepoint**

Before, immediately after the last session and one month after the intervention

**Method of measurement**

Knee injury and osteoarthritis outcome score

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The first researcher will massage the patient's knee with 10 drops of 0.5% peppermint oil for 15 minutes during 4 weeks (2 sessions per week).

**Category**

Prevention

**2****Description**

Intervention group: The first researcher will massage the patient's knee with paraffin oil for 15 minutes during 4 weeks (2 sessions per week)

**Category**

Prevention

### 3

#### Description

Control group: Will not receive any intervention

#### Category

Prevention

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Shahid Beheshti Hospital, Kashan

###### Full name of responsible person

Zahra Momen Arani

###### Street address

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

###### City

Kashan

###### Province

Isfahan

###### Postal code

8715981151

###### Phone

+98 31 5554 0021

###### Email

zahramomenn@gmail.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Kashan University of Medical Sciences

###### Full name of responsible person

Gholam Ali Hamidi

###### Street address

Vice Chancellor of Research & Technology, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

###### City

Kashan

###### Province

Isfahan

###### Postal code

8715981151

###### Phone

+98 31 5554 0021

###### Email

hamidi\_gh@kaums.ac.ir

###### Grant name

###### Grant code / Reference number

###### Is the source of funding the same sponsor organization/entity?

Yes

###### Title of funding source

Kashan 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

Kashan University of Medical Sciences

###### Full name of responsible person

Neda Mirbagher

###### Position

Associate Professor

###### Latest degree

Ph.D.

###### Other areas of specialty/work

Nursery

###### Street address

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

###### City

Kashan

###### Province

Isfahan

###### Postal code

8715981151

###### Phone

+98 31 5554 0021

###### Email

salam\_20012003@yahoo.co.uk

### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Kashan University of Medical Sciences

###### Full name of responsible person

Neda Mirbagher

###### Position

Associate professor

###### Latest degree

Ph.D.

###### Other areas of specialty/work

Nursery

###### Street address

School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran

###### City

Kashan

###### Province

Isfahan

###### Postal code

8715981151

**Phone**

+98 31 5554 0021

**Email**

salam\_20012003@yahoo.co.uk

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zahra Momen Arani

**Position**

Master's degree student in nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery, Kashan university of  
medical sciences, Parastar St., Qotbe Ravandi Blv,  
Kashan, Iran

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715981151

**Phone**

009855540021

**Email**

zahramomenn@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Data of participants are confidential

**Study Protocol**

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

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

No - There is not a plan to make this available