Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Isfehan
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
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School of Nursing and Midwifery, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholam Ali Hamidi
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Vice Chancellor of Research & Technology, Kashan university of medical sciences, Parastar St., Qotbe Ravandi Blv, Kashan, Iran
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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
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
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Other areas of specialty/work
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Person responsible for updating data

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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