Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Comparison Of Aromatherapy And Massage On The Severiety Of Pain؛ Fatigue And Morning Stiffness In Patients With Knee-Osteoarthritis in Shahrekord in 2016.

Protocol summary

Summary

This study is a randomized clinical trial.93 patients with 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. All three groups are receiving physiotherapy. A massage group (N= 31) who receives ten session of twenty minutes of classic massage with 3cc of Sweet oil on knee within 4 weeks. Aromatherapy group (N= 31) In this group for 3 nights a week, for a month, two drops of lavender essential on a cotton ball from 10 pm to 7 am done and control group (N= 31) for this group only physiotherapy used. Changes from before the intervention, after intervention ,fifth session after the intervention and tenth session after intervention are assessed on knee pain intensity,fatigue and stiffness level by VAS (Visual Analogue Scale) and MFI(multidimensional fatigue inventory)and KOOS(Knee injury and Osteoarthritis Outcome Score) questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062113768N8**
Registration date: **2016-12-11, 1395/09/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-11, 1395/09/21

Registrant information

Name

Ali Hassanpour Dehkordi

Name of organization / entity

Shahrekord Medical University of Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison Of Aromatherapy And Massage On The Severiety Of Pain؛ Fatigue And Morning Stiffness In Patients With Knee-Osteoarthritis in Shahrekord in 2016.

Public title

The Effect Of Massage And Aromatherapy On Knee Osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:Having Osteoarthritis of grade 2 or 3 based on the grading system kellgren-lawrence; Approved osteoarthritis knee by Rheumatologist; Having the disease for at least 6 months and a maximum of 5 years; No history of local skin infections, open wounds;

deep vein thrombosis and varicose veins in the areas of massage; Age between 40-65 years; Having a history of other autoimmune diseases such as lupus erythematosus and rheumatoid arthritis; No history of chronic diseases such as diabetes neuropathy; NSAID prescribed for knee pain during the study; Not taking medications intra-articular injection of 3 months ago; No history of knee surgery and severe trauma knee; No history of asthma and heart disease. exclusion criteria: Lack of follow-up ; exacerbation of symptom; Loss of smell.

Age
From **50 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **93**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahrekord University Of Medical Sciences

Street address
Vice Chancellor for research of Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord, Chaharmahal Va Bakhtiari, Islamic Republic Of Iran

City
Shahrekord

Postal code
Iran

Approval date
2016-05-07, 1395/02/18

Ethics committee reference number
IR.SKUMS.REC.1395.43

Health conditions studied

1

Description of health condition studied
osteoarthritis

ICD-10 code
M15, M19

ICD-10 code description
Arthrosis

Primary outcomes

1

Description
Morning stiffness

Timepoint
Before intervention-after intervention(fifth session)-after intervention(tenth session)

Method of measurement
Knee injury and Osteoarthritis Outcome Score (KOOS)

2

Description
Fatigue

Timepoint
Before intervention-after intervention(fifth session)-after intervention(tenth session)

Method of measurement
MFI)) multidimensional fatigue inventory

3

Description
Pain

Timepoint
Before intervention-after intervention(fifth session)-after intervention(tenth session)

Method of measurement
Knee injury and Osteoarthritis Outcome Score (KOOS)-VAS

Secondary outcomes

empty

Intervention groups

1

Description
Massage group ،addition physiotherapy receives ten session of twenty minutes of classic massage with 3cc of Sweet oil on knee within 4 weeks.

Category
Treatment - Other

2

Description
Aromatherapy group: addition physiotherapy for 3 nights a week, , for a month, two drops of lavender essential on a cotton ball from 10 pm to 7 am done

Category
Treatment - Other

3

Description
Control group: for this group only physiotherapy used .
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ethics committee of Shahrekord University Of Medical Sciences
Full name of responsible person
Ali Hassanpour Dehkordi
Street address
Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord, Chaharmahal Va Bakhtiar
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2

Recruitment center
Name of recruitment center
Educational Clinic of rheumatology and orthopedics
Full name of responsible person
Ali Hassanpour Dehkordi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University Of Medical Sciences
Full name of responsible person
Dr Ali Hassapour Dehkordi
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Shahrekord University of Medical Sciences, Kashani Blvd, Shahrekord, Chaharmahal Va Bakhtiari
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrekord 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
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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