

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Study of the effect of Iranian traditional massage (Kermanshahi style) on clinical signs of knee osteoarthritis

Protocol summary

Study aim

The aim of this study is to evaluate the effectiveness of Kermanshahian Persian massage in relation to knee osteoarthritis.

Design

Blocked Randomization Clinical trial study Sample size 42 for each of the treatment and control groups

Settings and conduct

Patients in the orthopedic clinic of Imam Hossein Hospital, diagnosed mild to moderate arthritis The treatment group undergoes massage therapy by the researcher once a week and daily by the individual. In the control group, liquid paraffin is supplied to patients for daily use. The duration of the study is 6 weeks and the WOMC and VAS questionnaires are completed at the beginning and after 3 and 6 weeks and 2 weeks after the completion of the treatment.

Participants/Inclusion and exclusion criteria

Inclusion: 40 to 80 year old patients with mild to moderate osteoarthritis Exclusion: Secondary osteoarthritis to rheumatoid diseases, History of Surgery on the knee, BMI higher than 35, Intra-articular or oral corticosteroid ingestion in the 3 months before and 2 weeks before, Pregnancy and breastfeeding

Intervention groups

The treatment group undergoes Kermanshahi's massage style The control group, uses liquid paraffin for daily rubbing on the knee

Main outcome variables

VAS; WOMAC Pain; WOMAC Stiffness; WOMAC Physical Function; WOMAC Total; Number of Acetaminophen 500 per day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190121042438N1**

Registration date: **2019-09-21, 1398/06/30**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-24, 1398/07/02**

Update count: **1**

Registration date

2019-09-21, 1398/06/30

Registrant information

Name

SaraSadat SeyedEsfahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

esfahani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2020-01-10, 1398/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Iranian traditional massage (Kermanshahi style) on clinical signs of knee osteoarthritis

Public title

Study of the effect of traditional massage on the

symptoms of knee osteoarthritis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 All 40 to 80 year old patients with mild to moderate osteoarthritis (according to ACR criteria) referring to Imam Hossein Orthopedic Clinic
Exclusion criteria:
 Secondary osteoarthritis due to rheumatologic diseases
 History of Surgery on the affected knee BMI higher than 35
 Intra-articular or oral corticosteroid ingestion in the 3 months before and 2 weeks before Pregnancy and breastfeeding

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked Randomization with the help of computer software

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 Shahid Beheshti University of Medical Sciences
Street address
 Shahid Beheshti University of medical sciences Aarabi St Yemen Ave. Chamran Highway Tehran Iran
City
 Tehran
Province
 Tehran
Postal code
 1516745811
Approval date
 2019-01-08, 1397/10/18
Ethics committee reference number

IR.SBMU.RETECH.REC.1397.829

Health conditions studied

1

Description of health condition studied

knee Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

2

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Score of knee pain intensity

Timepoint

Before the intervention, weeks 3 and 6 , and 2 weeks after the intervention

Method of measurement

Visual Analogue Scale and Western Ontario and McMaster universities osteoarthritis questionnaire

2

Description

Score of knee Stiffness intensity

Timepoint

Before the intervention, weeks 3 and 6 , and 2 weeks after the intervention

Method of measurement

Western Ontario and McMaster universities osteoarthritis questionnaire

Secondary outcomes

1

Description

score of daily physical activity

Timepoint

Before the intervention, weeks 3 and 6 , and 2 weeks after the intervention

Method of measurement

Western Ontario and McMaster universities osteoarthritis questionnaire

2

Description

Number of Acetaminophen tab 500mg used
Timepoint
At the beginning of the intervention, weeks 3 and 6
Method of measurement
Question from patient

Intervention groups

1

Description
Intervention group: Six weeks of weekly massage with chamomile oil by the researcher and daily massage by the patient
Category
Rehabilitation

2

Description
Control group: Six weeks of daily oil rubbing with liquid paraffin
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hosein Hospital
Full name of responsible person
Mahmood Khodadoost
Street address
Madani St.
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 3000
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahmood Khodadoost
Street address
No,8, Shams Alley, Opposite Tavanir, Valiasr Ave.
City
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Email
mkhodadoost@sbmu.ac.ir
Web page address
http://traditional.sbmu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
SaraSadat SeyedEsfahani
Position
Phd student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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No.8, Shams Alley, Opposite Tavanir, Valiasr Ave
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Email
esfahani@sbmu.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahmood Khodadoost

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Position

Phd student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Email

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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

Patients have been given consent for information confidentiality.

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available