Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of Swedish massage with and without hydrotherapy on pain intensity, knee range of motion, muscle strength, quality of life, and physical ability in people with knee osteoarthritis.

Protocol summary

Study aim

The overall goal of this study is to compare the effect of Swedish massage with and without hydrotherapy on pain intensity, knee range of motion, muscle strength, quality of life, and physical ability in individuals with knee osteoarthritis.

Design

A randomized, double-blind, controlled clinical trial with parallel groups using Randimizer.org for randomization. The study will have three groups, each consisting of 30 participants.

Settings and conduct

This research will be conducted at the Karaj Branch of Islamic Azad University, and the university's pool and equipment will be used for hydrotherapy procedures. In this study, blinding will be double-blind, such that both participants and outcome assessors will be unaware of the type of intervention and group allocation. The intervention will be implemented by a team separate from the evaluation team.

Participants/Inclusion and exclusion criteria

Subjects will be 90 women aged 45 to 60. Inclusion criteria: Having knee pain of at least three out of ten on a visual analog pain scale, diagnosed with knee osteoarthritis with a grade of three on the Kellgren & Lawrence grading system (in all three groups). Exclusion criteria: Having any contraindications to hydrotherapy such as kidney disorders, use of non-steroidal anti-inflammatory drugs.

Intervention groups

The first intervention group will receive Swedish massage for 8 weeks, 3 sessions per week for 45 minutes. The second intervention group will receive hydrotherapy exercises in addition to Swedish massage. The third group will not receive any intervention and will be the control group.

Main outcome variables

Assessment of pain intensity using the visual analog scale, active range of motion of the knee joint, assessment of quadriceps muscle strength, Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire for quality of life assessment, 6-minute walk test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240907062968N3**
Registration date: **2025-04-07, 1404/01/18**
Registration timing: **prospective**

Last update: **2025-04-07, 1404/01/18**
Update count: **0**

Registration date

2025-04-07, 1404/01/18

Registrant information

Name

Ali Honarvar

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-19, 1404/01/30

Expected recruitment end date

2025-05-05, 1404/02/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of Swedish massage with and without hydrotherapy on pain intensity, knee range of motion, muscle strength, quality of life, and physical ability in people with knee osteoarthritis.

Public title
Investigating the Effect of Swedish Massage and Hydrotherapy on Symptoms and Motor Ability in Individuals with Knee Osteoarthritis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from knee osteoarthritis with grade three from the Kellgren & Lawrence grading system (in all three groups). Having knee pain at least a three out of ten on a visual analog pain scale. General eligibility for participation in the research has been confirmed by a doctor.
Exclusion criteria:
Having any contraindications for hydrotherapy, such as kidney disorders. Use of non-steroidal anti-inflammatory drugs Onset or worsening of pain and disability during assessment and implementation of an exercise program.
Age
From **45 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method will be web-based. Subjects who meet the inclusion criteria for the study will be randomly assigned to the first experimental group, the second experimental group, and the control group using the website randomization method (Social Psychology Network, Connecticut, USA) www.randomizer.org. The randomization will be simple. Concealment of random allocation will be done using a computer-generated blocked random number table where number 1 will be defined for the Swedish massage exercise group, number 2 for the Swedish massage exercise group with hydrotherapy, and number 3 for the control group. Subsequently, the website output will randomly divide individuals into 3 equal groups. Also, according to the assignment of groups, the intervention will be continued by the researcher.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, while reviewing the consent form in a 30-minute session, are informed about the study groups and voluntarily participate in this study without having the option to choose a group. The names of the patients are randomly divided into three equal groups using the website http://randomizer.org by a person unaware of the individuals' identity and physical characteristics, and each group is placed in sealed envelopes separately. Then, appropriate training and exercises are provided to each individual based on their assigned group. The analyst and outcome assessor also evaluate the changes that occur before and after eight weeks without knowledge of the hypotheses, study methods, or patient characteristics.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University Karaj branch
Street address
Karaj Branch, Islamic Azad University, Mo'azen Boulevard, Rajai Shahr, Karaj City Alborz Province
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Postal code
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Approval date
2023-11-07, 1402/08/16
Ethics committee reference number
IR.IAU.K.REC.1402.119

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Active range of motion of the knee
Timepoint
Before and after intervention
Method of measurement
A goniometer was used to measure the active range of motion of the knee joint in flexion and extension movements. The fixed arm of the goniometer was placed along the outer surface of the thigh, and the moving arm was placed along the fibula towards the lateral malleolus. For extension assessment, the participant lay prone on the bed with the knee in a straight position. For flexion, the participant was asked to flex the knee as much as possible, and the resulting angle was recorded.

2

Description
Quadriceps muscle strength assessment
Timepoint
Before and after intervention
Method of measurement
Isometric strength of the quadriceps muscles was measured at a 90-degree knee flexion angle using a dynamometer. The participant sat on a chair, and one end of the dynamometer was connected to their ankle 5 cm above the malleolus, while the other end was fixed to the wall. The participant then performed knee extension through isometric contraction. The average of three repetitions was recorded as the final muscle strength score.

3

Description
Knee injury and Osteoarthritis Outcome Score (KOOS) questionnaire for assessing quality of life
Timepoint
Before and after intervention
Method of measurement
The standardized KOOS questionnaire was used to evaluate therapeutic outcomes in patients with knee osteoarthritis. This tool includes 42 patient-centered questions in five domains: other symptoms (7 questions), pain (9 questions), activities of daily living (17 questions), sports and recreational activities (5 questions), and knee-related quality of life (4 questions). Responses were scored on a five-point Likert scale (from 0 to 4), and the scores for each subscale were calculated as a percentage between 0 and 100; such that a higher score indicates a better condition and fewer problems for the patient. The Persian version of this questionnaire has validated validity and reliability in domestic studies and has been localized for the Iranian population.

4

Description
6-Minute Walk Test
Timepoint
Before and after intervention
Method of measurement
The 6-minute walk test (6MWT) was performed to assess the participant's physical and functional capacity. In this test, the individual walked on a flat surface for 6 minutes at their maximum tolerable speed, and was allowed to rest if needed. At the end, the distance covered in 6 minutes was recorded as an indicator of physical performance.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first intervention group receives Swedish massage for 8 weeks, 3 sessions per week, for 45 minutes.
Category
N/A

2

Description
Intervention group: The second intervention group, which receives Swedish massage plus hydrotherapy, for 8 weeks and 3 sessions per week.
Category
N/A

3

Description
Control group: They will not receive any intervention and will only participate in the pre-test and post-test assessments
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad university Karaj Branch
Full name of responsible person
Ali Honarvar
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Islamic Azad University
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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

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

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

Clinical Study Report
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
The data related to the subjects of the control and intervention groups in the pre-test and post-test are shared in an unidentifiable way

When the data will become available and for how long
Six months after the publication of articles

To whom data/document is available
The data will be available for physiotherapists working in academic institutions, as well as clinicians working in the field of musculoskeletal disorders, and all researchers. Use of the data is permitted with source citation.

Under which criteria data/document could be used
The raw data and results of this study may be used in systematic review studies. Therefore, the raw data and results of this study will be accessible to researchers who are active in the field related to this study.

From where data/document is obtainable
Vahid.mazloum@yahoo.com

What processes are involved for a request to access data/document
Applicants must accurately explain their project and how the data/documents of this study will be used in their project. Subsequently, the data/document files will be sent to the applicants via email upon request. This process may take 10-12 business days.

Comments