Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Four Weeks of Swedish Massage on Knee Joint Biomechanical Parameters During Walking in Adult Women With Knee Osteoarthritis

Protocol summary

Study aim

To determine the effect of four weeks of Swedish massage on knee joint biomechanics during walking in adult women with knee osteoarthritis.

Design

The clinical trial consisted of 30 adult women with knee osteoarthritis. Which had a control and experimental, randomized, double-blind groups. Flip the Coin method was used for randomization.

Settings and conduct

The present study was a quasi-experimental study with a pretest-posttest design in two experimental and control groups, which was performed in the sports biomechanics laboratory of Shahid Bahonar University of Kerman, Iran.

Participants/Inclusion and exclusion criteria

Having radiological symptoms of osteoarthritis in the knee;Chronic knee pain for 1 month or more;Age range 45 to 65 years;Do not take injectable drug for 4 months before;Do not take nonsteroidal anti-inflammatory drugs for one week before enrollment;No history of trauma, injury or surgery or lower limb fracture;No history of drug use affecting the musculoskeletal system.

Intervention groups

The intervention consisted of a 20-minute massage using Swedish massage techniques, performed by a massage therapist for four weeks(three sessions a week)on the affected knee. No special exercises were considered for the control group during this period and we tried to make the control group unaware of the intervention group's treatment program.

Main outcome variables

Spatio-temporal parameters of walking gait; Electrical activity of the quadriceps muscles; Voluntary isometric strength of quadriceps muscles; Proprioception of the knee joint; Symptoms of osteoarthritis of the knee

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181210041914N1**
Registration date: **2021-03-09, 1399/12/19**
Registration timing: **retrospective**

Last update: **2021-03-09, 1399/12/19**
Update count: **0**

Registration date

2021-03-09, 1399/12/19

Registrant information

Name

Fereshteh Sabet

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3325 7265

Email address

fereshteh_sabet@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

2017-01-20, 1395/11/01

Actual recruitment end date

2017-06-20, 1396/03/30

Trial completion date

2017-09-21, 1396/06/30

Scientific title
The Effect of Four Weeks of Swedish Massage on Knee Joint Biomechanical Parameters During Walking in Adult Women With Knee Osteoarthritis

Public title
The Effect of Four Weeks of Swedish Massage on Knee Joint Biomechanical Parameters During Walking in Adult Women With Knee Osteoarthritis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Women in the age range of 45 to 65 years Having radiological symptoms of osteoarthritis in one knee Chronic knee pain for 1 month or more Morning stiffness less than 30 minutes Crepitus

Exclusion criteria:
Any pain or lesion in the lower limb (except osteoarthritis of the knee) Use of energy drinks, drugs and alcohol The presence of wounds, warts, cracks and inflamed acnes in the area of the extensor muscles of the affected knee History of neurological and muscular diseases Existence of any systemic diseases such as rheumatism, diabetes or a history of cardiovascular and pulmonary diseases History of any surgery on the affected knee Intra-articular injection (PRP) during the last six months History of fractures and dislocations in the lower extremities during the past year Have a regular exercise program for the past six months Having knee pain less than one day a month Inability to walk without help

Age
From **45 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the restricted randomization method of block randomization has been used. Blocking is usually used to balance the number of samples assigned to each of the study groups. This feature helps researchers to equate the number of samples assigned to each of the study groups. The size of all blocks was equal and in this two-group experiment, we had 6 blocks (including 3 participants in the massage intervention group and 3 participants in the control group). The randomization tool was one of the software for random sequence generation (software allocation Random) that in addition to simple randomization is able to generate a random sequence by blocking method. Concealment allocation was also used for concealment, which is the method used to execute a random sequence on study participants; So that before the individual is assigned, the assigned group is not known. Also, sequentially numbered, opaque sealed envelopes (SNOSE) were used in which each of the random sequences created on a registration card and the cards inside the envelopes were placed, respectively. In order to maintain a random sequence, the envelopes were numbered in the same way on the outer surface. Finally, the envelopes were glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes was opened and the assigned group of the participant was revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, both participants and researchers were unaware of the allocation of study groups. The participants in the experimental group thought that everyone had received the intervention and the participants in the control group were unaware of the intervention for the experimental group. The researchers also did not know which group received the intervention while evaluating the information.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences

Street address
Kerman, Haft Bagh Alavi axis, campus of University of Medical Sciences

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2016-07-11, 1395/04/21

Ethics committee reference number
IR.KMU.REC.1396.21

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
Kinematics parameters of walking gait
Timepoint
The mentioned variable was measured at the baseline (before the intervention) and 4 weeks after the start of the massage intervention.
Method of measurement
Motion Analysis System

2

Description
Muscle activity of quadriceps
Timepoint
The mentioned variable was measured at the baseline (before the intervention) and 4 weeks after the start of the massage intervention.
Method of measurement
Bio electronica muscle electrical activity recorder made in Italy, Usb2 + model with 16 channels

3

Description
Voluntary isometric strength of quadriceps muscles
Timepoint
The mentioned variable was measured at the baseline (before the intervention) and 4 weeks after the start of the massage intervention.
Method of measurement
Hand Held Dynamometer

Secondary outcomes

1

Description
Symptoms Of Knee Osteoarthritis
Timepoint
The mentioned variable was measured at the baseline (before the intervention) and 4 weeks after the start of the massage intervention.
Method of measurement
The Western Ontario and McMaster Universities Osteoarthritis Index

2

Description
Knee Joint Proprioception
Timepoint
The mentioned variable was measured at the baseline (before the intervention) and 4 weeks after the start of the massage intervention.
Method of measurement
In order to evaluate the knee joint proprioception, a system consisting of skin marking, digital imaging with Canon camera (20 megapixel resolution made in Japan) and AutoCAD software (made by Autodesk USA) was used.

Intervention groups

1

Description
Intervention group: The intervention group received 12 standard sessions of Swedish massage (three interval sessions a week, within 4 weeks, about 20-30 minutes per session) by a professional and licensed massage therapist. The therapist used a standard protocol, involving the petrissage (compression or manipulation of soft tissue between the fingers and thumb), effleurage (gliding of hands over the skin or soft tissues), and tapotement (percussion-based massage where hands strike soft tissue in a repetitive, rhythmic fashion) techniques. These techniques were applied to the quadriceps muscle group of the affected leg by thumb-kneading the rectus femoris, vastus medialis, vastus lateralis, as well as the iliotibial band and the patellar tendon.
Category
Rehabilitation

2

Description
Control group: The control group received only their usual treatment during this period and no training protocol was adopted for them.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics, Medical and Rehabilitation Centers of Kerman, Iran
Full name of responsible person
Fereshteh Sabet
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Imam Khomeini Highway, Shahid Bahonar University Research Square, Kerman, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Bahonar university of Kerman
Full name of responsible person
Hosein Nezamabadipour
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Email
research@uk.ac.ir
Web page address
https://vcresearch.uk.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Bahonar university of Kerman
Proportion provided by this source
10
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 Bahonar University of Kerman
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Fariborz Mohammadipour
Position
Associate professor
Latest degree
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only part of the data, such as information about the main outcome or the like, can be shared.
When the data will become available and for how long
Since 1397
To whom data/document is available
Researchers working in academia and people in industry
Under which criteria data/document could be used
There is no other condition
From where data/document is obtainable
Irandoc
What processes are involved for a request to access data/document
Search in Irandoc
Comments