Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Instrument-Assisted Soft Tissue Mobilization on Muscular Activity during Walking and Sit to Stand Task in Individuals with Knee Osteoarthritis

Protocol summary

Study aim

Investigate the effect of Instrument Assisted Soft Tissue Mobilization on function, quality of life and activity of muscles around the knee joint at different preferential and high walking speeds and sit to stand task in people with knee osteoarthritis

Design

Clinical trial with control group, double-blind, randomized by block design, on 34 patients

Settings and conduct

The location of this intervention will be in the research therapeutic center of movement disorders, Department of physiotherapy, Tarbiat Modares University. After an introductory session, people will enter the intervention phase. Individuals will be randomly assigned to the treatment and placebo groups. Participants and outcome assessors are unaware of the allocation of study groups. The intervention will be performed in four sessions over two weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women and men with knee osteoarthritis, a positive Clark test, and two and three degrees of osteoarthritis, according to the kellgren Lawrence scale؛ Exclusion criteria: Having a history of hip or knee joint fracture or ligament injury on the affected side that resulted in permanent injury

Intervention groups

In the intervention group, soft tissue mobilization will be performed with the instrument, but the control group will receive the instrument as a placebo. Both groups will do strengthening and stretching exercises. The intervention will be performed for both groups in four sessions over two weeks.

Main outcome variables

Muscle activity around the knee joint during walking and sit to stand task; Pain; Function; Strength

General information

Reason for update

Updating to provide accurate and up-to-date information about the study

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049511N3**
Registration date: **2022-01-14, 1400/10/24**
Registration timing: **prospective**

Last update: **2025-07-27, 1404/05/05**
Update count: **2**

Registration date

2022-01-14, 1400/10/24

Registrant information

Name
Sahar Boozari
Name of organization / entity
Tarbiat Modares University
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-14, 1400/10/24

Expected recruitment end date

2022-08-20, 1401/05/29

Actual recruitment start date

2022-05-17, 1401/02/27

Actual recruitment end date

2023-08-15, 1402/05/24

Trial completion date

2023-08-15, 1402/05/24

Scientific title

Effect of Instrument-Assisted Soft Tissue Mobilization on Muscular Activity during Walking and Sit to Stand Task in Individuals with Knee Osteoarthritis

Public title

Effect of Instrument Assisted Soft Tissue Mobilization on the Muscles around the Knee in People with Knee Osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women and men with osteoarthritis of the knee Ability to walk without the use of assistive devices Pain between three and six in one knee, according to the visual analogue scale A positive clark test result Grade two and three osteoarthritis according to the Kellgren-Lawrence scale

Exclusion criteria:

Have a history of a hip or knee joint fracture or ligament injury on the affected side that has resulted in permanent injury Candidate for knee replacement surgery Any congenital disease of the lower extremities or lower back, or any orthopedic, neurological, or rheumatic disease that interferes with a person's normal gait or sit to stand task The difference in the length of the lower limbs is more than one and a half centimeters Body mass index above 30 Genovarum with a knee angle greater than 10 degrees Joint injection in the last six months Medium to high intensity involvement of both knees

Age

From **45 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **34**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are admitted to the study depending on criteria for inclusion and exclusion. The stratified block randomization approach will be used for this study's randomization. People with moderate osteoarthritis are classified into two subgroups based on the amount of pain (three and four) or (five and six). In each subgroup, randomization is performed by four blocks (two in the treatment group and two in the placebo group). For random allocation, code 1 for treatment and code 0 for placebo are placed in sealed envelopes. In this way, the people of each subgroup take one of the sealed envelope and are assigned in the treatment or placebo group according to the code.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will be randomly divided into two groups of treatment and placebo. In the treatment group, the master therapist uses soft tools to treat soft tissue by selecting pressure, direction, type of stroke, distance, duration, speed and type of tool. But in the placebo group, the use of the tool is dramatic and has no therapeutic properties. Both groups receive the same strengthening and stretching exercises so people do not notice this difference. The evaluator is also blind.

Placebo

Used

Assignment

Parallel

Other design features

Individuals are randomly divided into two groups. Therapeutic exercise is common in both groups. The intervention group receives the instrument but the control group receives the instrument as a placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Tarbiat Modares University, Nasr Bridge, Jalal Al Ahmad Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2021-10-27, 1400/08/05

Ethics committee reference number

IR.MODARES.REC.1400.201

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
Muscles activity around the knee joint during walking and sit to stand task
Timepoint
Before and after the Intervention
Method of measurement
Surface electromyography device

Secondary outcomes

1

Description
Quality of life
Timepoint
Before and after the Intervention
Method of measurement
36 item short form quality of life questionnaire and lequesne algofunctional index Questionnaire

2

Description
Pain
Timepoint
Before and after the Intervention
Method of measurement
Pain Visual Analogue Scale

3

Description
Strength
Timepoint
Before and after the Intervention
Method of measurement
Dynamometer

Intervention groups

1

Description
Intervention group: A series of lightweight steel instruments are gently applied to the muscles around the knee. The movement of the instrument in specific therapeutic directions is applied to the skin based on the initial assessment, and an emollient is used to move the instrument more easily. The treatment time with this tool is approximately five minutes. Then stretching and strengthening exercises are performed.
Category
Treatment - Other

2

Description
Control group: Steel instruments are gently applied to the muscles around the knee in this group. Using an emollient, the instrument is applied as a placebo with the least amount of pressure on the skin in all directions. The tool is moved on the patient's skin in different directions without considering the initial assessment. The direction and pressure applied by the instrument have no therapeutic properties. The treatment time is approximately five minutes. Then stretching and strengthening exercises are performed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Research-therapeutic center of movement disordes, Tarbiat Modares University
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Sponsors / Funding sources

1

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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
Tarbiat Modares 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
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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared after people are not identified

When the data will become available and for how long

After the results are published, the access phase started six months later

To whom data/document is available

Researchers in academic and research organizations will also have access to the data

Under which criteria data/document could be used

to do scientific research

From where data/document is obtainable

Sahar Boozari, Jalal Al Ahmad Highway, Tarbiat Modares University s.boozari@modares.ac.ir, 00982182885053

What processes are involved for a request to access data/document

Send the project plan, and if approved, it will be sent following a complete evaluation of the persons and organizations involved in the project

Comments