Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Effect of Instrument-Assisted Soft Tissue Mobilization on Gait and Sit to Stand Task Biomechanics in Individuals with Knee Osteoarthritis

Protocol summary

Study aim
The aim of this study is to investigate the effect of instrument-assisted soft tissue mobilization on the gait biomechanics of different preferential and high walking speeds and sit to stand task as well as performance and quality of life 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
The intervention group will be treated with instrument-assisted soft tissue mobilization along with stretching and strengthening exercises, and the control group will receive the instrument as a placebo. The intervention will be performed for both groups in four sessions over two weeks

Main outcome variables
Kinetic and kinematic variables of gait and sit to stand task; pain; strength; Function; Range of motion

General information

Reason for update
Adding review of another functional activity

Acronym

IRCT registration information
IRCT registration number: **IRCT20201128049511N2**
Registration date: **2021-12-25, 1400/10/04**
Registration timing: **prospective**

Last update: **2023-01-09, 1401/10/19**
Update count: **1**

Registration date
2021-12-25, 1400/10/04

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
2022-01-05, 1400/10/15

Expected recruitment end date
2022-08-21, 1401/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Instrument-Assisted Soft Tissue Mobilization on Gait and Sit to Stand Task Biomechanics in Individuals with Knee Osteoarthritis

Public title
Effects of Instrument-Assisted Soft Tissue Release on Walking and Sit to Stand in Individuals 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 Joint injection in the last six months The difference in the length of the lower limbs is more than one and a half centimeters Medium to high intensity involvement of both knees Genovarum with a knee angle greater than 10 degrees A body mass index greater than 30

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**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly divided into two groups: treatment and placebo. In this way, four blocks are identified, of which two blocks belong to the placebo group and two blocks belong to the treatment group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants are unaware of the allocation of study groups. The treatment in the two groups is quite similar, and the only difference in the use of tools in the placebo group is that they are exactly the same instruments used in the treatment group, but the intensity of pressure and the type of movement of the tool are different. The intensity of pressure and type of movement are two subjects that patients do not have and will not notice if they are in the placebo or treatment group. The outcome assessor is also unaware of the grouping of individuals.

Placebo
Used

Assignment
Parallel

Other design features
People are randomly divided into two groups. The intervention group receives the instrument along with exercise therapy. The control group will receive the instrument as a placebo along with exercise therapy

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tarbiat Modares University

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

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1411713116

Approval date
2021-10-23, 1400/08/01

Ethics committee reference number
IR.MODARES.REC.1400.202

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
Gait and sit to stand task kinematic and kinetic variables

Timepoint
Before and after the Intervention

Method of measurement
Inverse dynamics and force plate

2

Description

Pain

Timepoint

Before and after the Intervention

Method of measurement

Visual analogue scale

3

Description

Strength

Timepoint

Before and after the Intervention

Method of measurement

Dynamometer

4

Description

Musculoskelatal performance

Timepoint

Before and after the Intervention

Method of measurement

Functional tests

5

Description

Range of motion

Timepoint

Before and after the Intervention

Method of measurement

Goniameter

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and after the Intervention

Method of measurement

Questionnaire

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

Full name of responsible person

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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

Name of organization / entity
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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