

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of movement system impairment-based classification treatment compared to routine physiotherapy on pain, disability, and alignment and movement impairments in individuals with tibiofemoral rotation syndrome: A randomized controlled trial

Protocol summary

Study aim

Comparison of the effect of two treatment methods based on the movement system impairment classification and routine physiotherapy among people between 18 to 40 years old with tibiofemoral rotation syndrome

Design

Clinical trial with two groups, Parallel groups, single-blinded, randomized, on the 40 patients, block randomization with blocks of 4 by using the Randomization website

Settings and conduct

This study will be performed in the IUMS School of Rehabilitation Science. participants after performing the examinations, during the block randomization process, are placed in one of two treatment groups, including treatment based on a MSI and routine physiotherapy. Primary and secondary outcomes will be recorded before and immediately after the measurement sessions and the resulting data will be recorded for statistical analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages of 18 to 40 years, Diagnosis of acquired TFRval/var, Pain in any structures of the knee with gradual onset for at least one month and with Intensity greater than 3 and less than 6, Pain during activities that include loading on a flexed knee. Exclusion criteria: Musculoskeletal injuries other than patellofemoral pain; such as: meniscus & ligamentous injury, history of patellar dislocation, severe osteoporosis, progressive neurological disorders, lumbosacral radiculopathies, History of any traumatic injury in the last 6 months, History of any lower limb surgery in the last 6 months Any specific deformity in the spine and lower extremities, Complaints of pain in the other joints of the lower limbs, Constant severe pain that interferes with the testing process

Intervention groups

group1: Movement System Impairment based treatment
group2: routine physiotherapy treatment

Main outcome variables

Pain intensity, Disability/ limitation of function

General information

Reason for update

Change in the secondary outcome and the number of study samples due to research conditions

Acronym

IRCT registration information

IRCT registration number: **IRCT20210505051181N3**
Registration date: **2022-05-28, 1401/03/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-09, 1402/09/18**

Update count: **1**

Registration date

2022-05-28, 1401/03/07

Registrant information

Name

Mehrnaz Kajbafvala

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

2022-01-10, 1400/10/20

Actual recruitment end date

2023-07-23, 1402/05/01

Trial completion date

2023-07-23, 1402/05/01

Scientific title

The effect of movement system impairment-based classification treatment compared to routine physiotherapy on pain, disability, and alignment and movement impairments in individuals with tibiofemoral rotation syndrome: A randomized controlled trial

Public title

Movement System Impairment classification approach at knee pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

age between 18 and 40 years history of sudden or gradual pain at the knee complex or surrounding tissues a pain intensity of at least 3 points measured using a 0- to 10-point visual analog scale Pain during activities that include loading on a flexed knee; Such as: running, jumping, squatting, climbing and descending stairs Literacy for reading and writing Ability to understand Persian language

Exclusion criteria:

Musculoskeletal injuries other than patellofemoral pain; such as: meniscus injury, ligamentous injury, history of patellar dislocation, severe osteoporosis, progressive neurological disorders, lumbosacral radiculopathies History of any traumatic injury in the last 6 months History of any lower limb surgery in the last 6 months Any specific deformity in the spine and lower extremities; such as: scoliosis, kyphosis, femoral anteversion, tibial torsion Complaints of pain in the other joints of the lower limbs Constant severe pain that interferes with the testing process Taking the analgesic and anti-inflammatory drugs during the study The history of malignancy, cardiovascular disease Pregnancy

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

After initial evaluations, peoples that have inclusion criteria and do not have exclusion criteria will be divided into two groups of intervention (based on movement disorder) and active control (routine physiotherapy) through block randomization method and creating random blocks of 4. Creating a random sequence will be done using the Randomization website. The person who creates the random sequence is not involved in any other stage of the investigation.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, which included a comparison of two different treatment approaches (intervention group based on the movement system impairment classification approach and active control group including routine physiotherapy); Participants are blind to being in an active intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

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Iran University of Medical Sciences, Shahid Hemmat Highway

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-07-17, 1400/04/26

Ethics committee reference number

IR.IUMS.REC.1400.336

Health conditions studied**1****Description of health condition studied**

Knee osteoarthritis

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Patellofemoral pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

pain intensity

Timepoint

over the previous 24 hours and 1 week ago and
immediately after the intervention

Method of measurement

Visual Analog Scale

2

Description

Disability

Timepoint

Before and immediately after the intervention

Method of measurement

Kujala Questionnaire

Secondary outcomes

1

Description

Alignment and movement impairments

Timepoint

Before and immediately after the intervention

Method of measurement

alignment and movement impairments data form

Intervention groups

1

Description

Intervention group: Movement System Impairment based
treatment

Category

Rehabilitation

2

Description

Active control group: routine physiotherapy treatment

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of rehabilitation, Iran University of Medical
Sciences

Full name of responsible person

Dr. Mehrnaz Kajbafvala

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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

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Seyyedeh Forouzan Mousavi

Position
Student
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Bachelor
Other areas of specialty/work
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data or results of the present study will be
presentation in an article or some articles that will be
published, also will be available through correspondence
with the corresponding author

When the data will become available and for how long

After completing the present study and publishing the
resulting article or articles

To whom data/document is available

All researchers in the field of the present study

Under which criteria data/document could be used

With the same goal as the present study and with
mention of the present study as the reference. All
intellectual property rights of the present study belongs
to the Iran University of Medical Sciences

From where data/document is obtainable

The corresponding author of the article or articles
derived from the study

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

Written request from the author responsible for the
present review after the publication of the article or
articles

Comments

