

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The effect of neuromuscular training of gastrocnemius and Gluteus maximus compared to quadriceps muscles by biofeedback method on pain, function and changes in electromyography findings in subjects with knee osteoarthritis, during gait: A randomized single blind clinical trial intervention

Protocol summary

Study aim

Comparing the increase in activity in the stance phase of walking in the direction of biomechanics and pattern changes (gluteus maximus and gastrocnemius) in comparison with the increase in activities against the changed pattern (quadriceps) and bringing people with KOA closer to healthy people on the symptoms and Electromyography findings of subjects with moderate KOA before, after the first session, after the end of the session and three months later

Design

Both groups: ten sessions of routine rehabilitation One group received neuromuscular training of the gastrocnemius and gluteus maximus by biofeedback method during walking at desired speed and the second group received neuromuscular training of the quadriceps by biofeedback method during walking at desired speed in addition to routine treatment for ten sessions.

Settings and conduct

All pre- and post-assessment stages, including EMG tests, pain and function tests, will be performed in the biomechanics laboratory and treatment sessions will be performed in the physiotherapy clinic of the rehabilitation faculty of Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria

unilateral and moderate osteoarthritis of the knee (40 to 75 years) with VAS >3 in the last month and the ability to walk for 15 to 30 minutes without a history of previous knee and hip surgery; hip and ankle arthrosis; Arthritis of the joints and a history of joint injection; steroid use and physiotherapy in the last six months; and BMI > 35 Kg/m²

Intervention groups

-Routine treatment: including TENS, Pulsed US, stretching exercises and joint and soft tissue mobilization
-Neuromuscular training of gastrocnemius and gluteus maximus / & Quadriceps neuromuscular training by biofeedback method during walking task at desired speed

Main outcome variables

Pain; Function; EMG findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231024059846N1**

Registration date: **2023-11-30, 1402/09/09**

Registration timing: **prospective**

Last update: **2023-11-30, 1402/09/09**

Update count: **0**

Registration date

2023-11-30, 1402/09/09

Registrant information

Name

Soheila Ganjeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-21, 1402/09/30

Expected recruitment end date

2024-11-20, 1403/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of neuromuscular training of gastrocnemius and Gluteus maximus compared to quadriceps muscles by biofeedback method on pain, function and changes in electromyography findings in subjects with knee osteoarthritis, during gait: A randomized single blind clinical trial intervention

Public title

Physiotherapy and exercise therapy by biofeedback method in people with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People with moderate knee osteoarthritis in the age range of 40 to 75 years With pain number more than 3 on the VAS scale have unilateral KOA (in bilateral cases, the side where the pain and symptoms predominate is considered the studied side The subjects have experienced pain in most of the days of the last month Have the ability to walk normally for 15 to 30 minutes.

Exclusion criteria:

Have a previous history of hip or knee joint replacement. have hip or ankle osteoarthritis at the same time. have rheumatoid arthritis of the joints at the same time. Have a BMI > 35 Kg/m² In the past six months, she/he has received treatments such as oral or injectable corticosteroids, any knee surgery such as osteotomy, conservative treatments such as physical therapy, manual therapy, acupuncture, and exercise therapy. Any neuromuscular-skeletal disease that made walking "difficult" for the patient

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple non-random sampling method is available and the sample allocation in the groups will be random The

grouping is also done by a random method of sequential type and one by one in chronological order of the referring people (Patients from among the people referred to the orthopedic clinic of Akhtar Hospital (non-randomized) who have grade 3 knee arthritis and then are randomly assigned to treatment group 1 or 2 (randomization)

Blinding (investigator's opinion)

Single blinded

Blinding description

The therapist and the data evaluator are two different people and the evaluator has no information about the group therapy of the patients

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak

City

Tehran

Province

Tehran

Postal code

ندارد

Approval date

2023-10-22, 1402/07/30

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.375

Health conditions studied

1

Description of health condition studied

moderate knee osteoarthritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

VAS: Before and after the first session, after the tenth session, after three months/ KOOS: Before first session,

after the tenth session, after three months

Method of measurement

visual analog scale- KOOS

2

Description

Function

Timepoint

KOOS: Before the first session, after the tenth session, after three months/ 10 M Fast walking: Before and after the first session, after the tenth session, after three months

Method of measurement

KOOS, 10 M Fast walking

3

Description

Amplitude of muscle action

Timepoint

Before and after the first session, after the tenth session, after three months

Method of measurement

Surface electromyography and force plate

4

Description

Muscle contraction duration

Timepoint

Before and after the first session, after the tenth session, after three months

Method of measurement

Surface electromyography and force plate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Neuromuscular training by biofeedback method for the quadriceps muscle during walking In addition to routine physiotherapy treatment

Category

Rehabilitation

2

Description

Intervention group: Neuromuscular training by biofeedback method for gastrocnemius and gluteus maximus muscles during walking In addition to routine physiotherapy treatment

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Orthopedic Specialist Hospital

Full name of responsible person

Dr Hamidreza Aslani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Research Organization of Shahid Beheshti University of Medical Sciences

Street address

Velenjak

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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

Shahid Beheshti 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

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Email

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soheila Ganjeh

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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