Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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

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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

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
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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