Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation the effect of valgus unloading knee brace on gait harmonic ratio in patients with medial compartment knee osteoarthritis

Protocol summary

Study aim

Investigate the effect of unloading knee valgus brace on improving harmonic ratio as well as balance (star balance test), pain and disability (KOOS questionnaire) and walking speed in patients with unilateral knee osteoarthritis

Design

This study is a clinical trial and parallel and the subjects will randomly divide into control and intervention groups (Brace). This is a single-blinded study.

Settings and conduct

The study will be conducted in Shiraz university of Rehabilitation Sciences and the study population (n = 20) will be randomly divided into control and intervention groups (Brace). The intervention group will wear brace for 4 weeks and both groups will perform similar exercises during this period.This is a single-blinded study and the evaluator will be unaware of the nature of the individuals in each group

Participants/Inclusion and exclusion criteria

People with unilateral symptomatic knee osteoarthritis aged 45-75 years who are able to walk at least 15 meters without auxiliary equipment, have K&L grade ≥2 and PI-NRS ≥2 ؛ but dont have lower limb fractures ، history of spine and lower limb surgery In the past 6 months and obvious ligament injuries of the lower limbs and chronic low back pain and any soft tissue, neurological or vascular problems and high obesity (over 20% ideal body weight)and systemic or metabolic diseases , stroke, Parkinson's and rheumatologic conditions other than knee osteoarthritis, enter the study

Intervention groups

Intervention group will wear unloading valgus knee brace on the affected side for 4 weeks, 4 hours daily while standing and during daily activities. Both experimental and control groups will perform similar exercises at home during the study period (one month).

Main outcome variables

KOOS questionnaire؛ Harmonic ratio؛ Balance (star test)؛ Walking speed and isometric quadriceps strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131225015932N15**
Registration date: **2019-11-23, 1398/09/02**
Registration timing: **prospective**

Last update: **2021-11-21, 1400/08/30**
Update count: **1**

Registration date

2019-11-23, 1398/09/02

Registrant information

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Alireza Motealleh

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-24, 1398/09/03

Expected recruitment end date

2020-02-22, 1398/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigation the effect of valgus unloading knee brace on gait harmonic ratio in patients with medial compartment knee osteoarthritis

Public title
Investigation the effect of valgus unloading knee brace on gait harmonic ratio in patients with medial compartment knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Symptomatic unilateral knee osteoarthritis Knee medial compartment involvement Age 45-75 years Ability to walk at least 15 meters without auxiliary equipment K&L grade ≥2 (based on knee x-ray most related to one last year) PI-NRS ≥ 2

Exclusion criteria:
Articular and lower extremity fractures History of knee and spine and lower extremity surgery in the past 6 months knee and hip replacement tibial osteotomy Any soft, neurological or vascular tissue problems where wearing a brace is harmful for the long term, including varicose veins and skin problems Obesity enough to make wearing a brace uncomfortable and uneffective (weighing more than 20% of ideal body weight) Systemic or metabolic diseases including diabetes Any condition or diseases other than osteoarthritis that affects walking, including stroke and Parkinson's chronic low back pain Ligamentous injuries of the lower extremities Other rheumatologic diseases except knee osteoarthritis

Age
From **45 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects will be divided equally between the intervention and control groups according to the randomized block allocation method. How to allocate randomly by variable block method: Considering that there are two treatment modalities (Brace A and Control B) in this study, there will be six different conditions considering quadri blocks: 1-AABB 2-BBAA 3-ABAB 4-BABA 5-ABBA 6-BAAB Then we create random numbers using the computer. For numbers between 0 to 1/6 compound 1, numbers between 1/6 to 2/6 compound 2, numbers between 2/6 to 3/6 compound 3 and ... will be considered.

Blinding (investigator's opinion)
Single blinded

Blinding description
After selecting the samples, one person (x) performs the evaluations on all subjects . After performing the measurements, another person (y) divides the patients into two groups, and then another person (z) applies the interventions to the patients. At the end of the study period (1 month), patients will be referred one week later and the person who performed the measurement (x) will repeat the measurements on all subjects. It is noteworthy that the measurements will be made without brace. So the person making the measurements will not be aware of the nature of the grouping of people.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Rehabilitation school of Shiraz University of Medical Sciences, Abivardi Ave., Chamran Boulevard

City
shiraz

Province
Fars

Postal code
71345-1733

Approval date
2019-10-09, 1398/07/17

Ethics committee reference number
IR.SUMS.REHAB.REC.1398.029

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
Harmonic ratio measured with accelerometer

Timepoint
Baseline (before intervention) and one week after intervention (one month intervention)
Method of measurement
Based on studies to calculate the harmonic gait ratio, accelerometer (Biomethrics) will be fitted to the lower lumbar vertebrae(l4-l5) at the lower back. Gait analysis will be performed using an accelerometer in the laboratory environment as individuals walk a 15-meter-long, horizontal path at their usual speed; a heel switch will be connected in the heel area of right foot to define the start of the walking cycle ; the linear acceleration of the trunk will be sampled along the anterior-posterior, medial-lateral, and vertical axes at a frequency of 200 Hz. Signal processing will be performed using matlab software. To calculate the harmonic ratio using fourier transformation, the contents of the in phase accelerated signals (even harmonics) are compared to the contents of out-of-phase signals (odd harmonics)

Secondary outcomes

1

Description
Pain and disability measered with KOOS quationniare
Timepoint
Baseline (before intervention) and one week after intervention (one month intervention)
Method of measurement
KOOS Questionnaire: Knee Injury and Osteoarthritis Outcome Score This questionnaire contains 42 items that assess the patient's opinion on the five dimensions related to the knee and its problems, including: pain (9 questions), other specialized symptoms of illness (7 Questions), daily life performance (17 questions), recreational and sports performance (5 questions), and knee-related quality of life (4 questions).

2

Description
Balance
Timepoint
Baseline (before intervention) and one week after intervention (one month intervention)
Method of measurement
Star Equilibrium Test: To do this test, 8 strip strips with a 45 degree angle are attached to the ground. Evaluation will be done with the bare foot, and the patient will be asked to stand in the center of the star with the leg that is stance positioned and center the arch, while maintaining the balance on the leg in the center, and with the other foot touch the longest distance on any tape

3

Description
Pain meassured with PI-NRS (Pain intensity numeric range scale)
Timepoint
Baseline (before intervention) and one week after intervention (one month intervention)
Method of measurement
An 11-point scale that reports the patient's pain level. The patient is asked to choose a number between 0 and 10 that is most proportional to their pain intensity

4

Description
Isometric strength of quadriceps
Timepoint
Baseline (before intervention) and one week after intervention (one month intervention)
Method of measurement
Isometric quadriceps muscle strength will be measured using a handheld dynamometer

Intervention groups

1

Description
Intervention group: Intervention group wear knee unloading valgus brace for 4 weeks, daily and 4 hours daily while standing and during daily activities and perform exercises which similar to control group. Patients are asked to record hours of use of the brace
Category
Rehabilitation

2

Description
Control group: During the intervention, the control group performs similar exercises to the intervention group
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapy clinic of rehabilitation school of Shiraz univercity of medical sciences
Full name of responsible person
Mahnaz Daman
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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
Shiraz 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
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Position
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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
Study participants' personal data will be shared after unidentifiable individuals

When the data will become available and for how long
The access period begins 6 months after the results are published

To whom data/document is available
All academics as well as the public can access this data

Under which criteria data/document could be used
The data will be made publicly available for further analysis with a citation

From where data/document is obtainable
Dr. Alireza Motaleh, Rehabilitation Sciences school, Shiraz University of Medical Sciences, Chamran Boulevard, Abivardi Ave., Phone 00987136271551, Email Motealleh@sums.ac.ir

What processes are involved for a request to access data/document
6 months after the results are published, people will be notified by email or phone

Comments