Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of 12 week corrective exercises on radiological indices of lower limb alignment, Proprioception and Balance in Patients with Osteoarthritis with Varus Knee Deformity

Protocol summary

Study aim
Investigating the effect of 12 weeks of corrective exercises on the radiological indicators of the lower limbs, proprioception and balance in patients with osteoarthritis with varus knee.

Design
The current study has two intervention groups: 1- experimental intervention group that will perform corrective exercises 2- control intervention group with specific quadriceps and hamstring exercises, a clinical trial study type with a control group, with parallel groups

Settings and conduct
The first step: selection of students based on the entry criteria Second step: grouping The third stage: pre-test The fourth stage: three months of training Fifth step: pre-test The place of testing was in the laboratory of Faculty of Physical Education and Sports Sciences of Shahid Beheshti University of Tehran and Alborz Sports Complex.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having knee pain for 6 months or more; Having knee varus deformity (the distance between the knees is more than 2.5 cm); Having limited Range of Motion and Functional score II and III based on clinical and radiological signs. Exclusion criteria: Failure to participate in two consecutive and three non-consecutive training sessions; Progression of symptoms and pain and ihe patient's unwillingness to continue treatment.

Intervention groups
Experimental group (corrective exercises). Control group: the control group continued their daily activities during the implementation of the project.

Main outcome variables
Radiological indicators of lower limb alignment, proprioception and balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180414039299N2**
Registration date: **2025-01-04, 1403/10/15**
Registration timing: **retrospective**

Last update: **2025-01-04, 1403/10/15**
Update count: **0**

Registration date
2025-01-04, 1403/10/15

Registrant information

Name
Mohsen Moradi
Name of organization / entity
The University of Kharazmi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-22, 1403/08/01

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 12 week corrective exercises on radiological indices of lower limb alignment, Proprioception and Balance in Patients with Osteoarthritis with Varus Knee Deformity

Public title
The Effect of 12 week corrective exercises on radiological indices of lower limb alignment, Proprioception and Balance in Patients with Osteoarthritis with Varus Knee Deformity

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having knee pain for 6 months or more. Having knee varus deformity (the distance between the knees is more than 2.5 cm). Having limited Range of Motion. Functional score II and III based on clinical and radiological signs.

Exclusion criteria:
Failure to participate in two consecutive and three non-consecutive training sessions. Progression of symptoms and pain. The patient's unwillingness to continue treatment.

Age
From **55 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Using randomized permuted block randomization (7 blocks of size 8), the two treatment combinations are independently assigned to participants in a 1:1 ratio (after the initial assessment). Randomized sequence listing is done by computer (Pocock SJ. Clinical Trials: A Practical Approach. Wiley; 1983) and also by website (https://www.randomizer.org). This step will be ensured by a blind evaluator.

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome assessors will be blinded to group allocation. Participants will not be blinded to study and grouping, but will be blinded to the intervention they are receiving (there is an unavoidable risk of bias in this study that the intervention cannot be blinded to interventionists, patients). Before the evaluation, the necessary training will be given to the outcome evaluator in relation to how to evaluate the variables in order to prevent any questions and answers between the evaluator and the subjects.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University

Street address
Shahid Beheshti University, Daneshjo Blvd., Velenjak

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Province
Tehran

Postal code
1983969411

Approval date
2021-03-13, 1399/12/23

Ethics committee reference number
IR.SBU.REC.1400.126

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

2

Description of health condition studied
Knee varus

ICD-10 code
M21.16

ICD-10 code description
Varus deformity, not elsewhere classified, knee

Primary outcomes

1

Description
Radiological indicators of lower limb alignment

Timepoint
The First of all, Measuring the parameters of radiological indices of the lower limb in the post-test, and then after twelve weeks, measuring the parameter of radiological indices of the lower limb in the pre-test

Method of measurement
Radiographs were taken in the standard position and

bearing weight of the entire length of the lower limb.

2

Description
Proprioception
Timepoint
First, Measuring the parameter proprioception in the post-test, and then after eight weeks, Measuring the parameter of proprioception in the pre-test
Method of measurement
Knee joint position sense was measured by goniometer.

3

Description
Balance
Timepoint
First, Measuring the parameter Balance in the post-test, and then after eight weeks, Measuring the parameter of balance in the pre-test
Method of measurement
Stork test was used to measure static balance and Y test was used to measure dynamic balance.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, the combination of theraband and strength exercises was used for the training group. In this research, the use of the Theraband exercise protocol approved by the Medical College of Georgia, University of Nursing, Augusta, Georgia, USA for people with knee osteoarthritis, adapted to Joost Decker's 2014 recommendation and based on special recommendations The American College of Sports Medicine (ACSM) was implemented based on the principles of exercise science, each training session consisted of 10 minutes of warm-up, the main part of the exercises was 30-50 minutes, and 5 minutes of cooling down. There was a 2-minute rest between each exercise. The exercises were performed for 12 weeks and in the form of 3 sessions per week. Yellow, red, and green tapes were used to perform the theraband exercises, and the repetition of each exercise was 8 to 12 times per leg. Also, in the strength training program, attention was paid to the ability of the participants, and each session added repetitions or movement time.
Category
Rehabilitation

2

Description
The control group continued their daily activities during the implementation of the project.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid beheshti university
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Lida Mokhtari
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti university
Proportion provided by this source
50
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
Kharazmi University

Full name of responsible person
Mohsen Moradi

Position
Ph.D

Latest degree
Ph.D.

Other areas of specialty/work
Corrective Exercise

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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
The information related to the variables of the radiological indicators of the lower limbs, proprioception and balance are recorded in the pre-test and after twelve weeks of training, the information of the mentioned variables are recorded in the post-test and the results of the changes are recorded.

When the data will become available and for how long
After publishing the article/articles extracted from the study

To whom data/document is available
The data can be displayed and shared upon the reasonable request of Iran's Clinical Trial Registration Center, journals and academic people/researchers who are conducting research and scientific activities in this field.

Under which criteria data/document could be used
Data analysis and the use of documentation can only be done under the condition that their results are reported in scientific articles by academic researchers and authors. The necessary conditions for sending data and documents include: 1. Sending an email (preferably with

valid university addresses) to one of the researchers of the study. 2. A brief and logical explanation related to the use of data or documents.

From where data/document is obtainable

Through request from researcher Mohsen Moradi Mohsenmoradi90@gmail.com

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

The applicant can request details from the researchers using the message sent by email within 7 to 10 days

Comments