

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 the 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

Country

Iran (Islamic Republic of)

Phone

+98 24 3352 2824

Email address

mohsenmoradi90@gmail.com

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	Not used
Scientific title	Assignment
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	Parallel
Public title	Other design features
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	Secondary Ids
Purpose	empty
Treatment	Ethics committees
Inclusion/Exclusion criteria	1
Inclusion criteria:	Ethics committee
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.	Name of ethics committee
Exclusion criteria:	Shahid Beheshti University
Failure to participate in two consecutive and three non-consecutive training sessions. Progression of symptoms and pain. The patient's unwillingness to continue treatment.	Street address
Age	Shahid Beheshti University, Daneshjo Blvd., Velenjak
From 55 years old to 65 years old	City
Gender	Tehran
Female	Province
Phase	Tehran
N/A	Postal code
Groups that have been masked	1983969411
• Outcome assessor	Approval date
Sample size	2021-03-13, 1399/12/23
Target sample size: 56	Ethics committee reference number
Randomization (investigator's opinion)	IR.SBU.REC.1400.126
Randomized	Health conditions studied
Randomization description	1
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.	Description of health condition studied
Blinding (investigator's opinion)	Osteoarthritis of knee
Single blinded	ICD-10 code
Blinding description	M17
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.	ICD-10 code description
Placebo	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

Full name of responsible person

Lida Mokhtari

Street address

Shahid Beheshti University, Daneshjo Blvd., Velenjak

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 919 345 0353

Email

ahbarati20@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti university

Full name of responsible person

Amir Hossein Barati

Street address

Shahid Beheshti University, Daneshjo Blvd., Velenjak

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 919 345 0353

Email

ahbarati20@gmail.com

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

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

Street address

Kharazmi University, Faculty of Physical Education and Sport Sciences, Mirdamad Boulevard, tehran

City

Tehran

Province

Tehran

Postal code

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Phone

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Email

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Web page address

Kharazmi university

Full name of responsible person

Mohsen Moradi

Position

Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Sport injury and corrective exercise

Street address

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Tehran

Province

Tehran

Postal code

4519174555

Phone

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Email

Mohsenmoradi90@gmail.com

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

Person responsible for scientific 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

Street address

Faculty of Physical Education and Sports Sciences, Mirdamad Boulevard

City

Tehran

Province

Tehran

Postal code

4519174555

Phone

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Email

Mohsenmoradi90@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

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