

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of comprehensive rehabilitation treatment on pain, muscle force, physical function and quality of life in officer students with dynamic valgus of the lower limb

Protocol summary

Study aim

Effect of rehabilitation treatment on pain, muscle force, physical function and quality of life in officer students with dynamic valgus of lower limb

Design

Clinical trial with an intervention group and a control group, with parallel groups, single blinded, randomly constructed, on 40 people in each group

Settings and conduct

In this study, eligible individuals among the officer students of Imam Hossein University who refer to the university clinic, will enter the study and be randomly assigned to two intervention and control groups. The researcher will conduct therapeutic interventions for each group within six weeks. Data collection, outcome assessment, and data analysis will be done by another colleague and the researcher will be blind to this process. The data collection tools includes lower limb functioning questionnaire, quality of life questionnaire, numerical pain scale, and manual dynamo meter.

Participants/Inclusion and exclusion criteria

Inclusion criteria: knee rotation syndrome with valgus, pain at least 3 on the numerical pain scale, knee pain when running, jumping, sitting and standing up Exclusion criteria: trauma, injury to anterior cruciate ligament

Intervention groups

Intervention group: knee strengthening exercises (specific strengthening of Vastus medialis oblique muscle), hip strengthening exercises (specific strengthening of hip abductor and external rotator muscles), taping and biofeedback correction of wrong biomechanical patterns of the lower limbs in daily functions. Control group: knee strengthening exercises (general strengthening of the quadriceps muscle), hip strengthening exercises (general strengthening of the muscles around the hip). In both groups, the interventions will be conducted for six weeks and three

sessions per week.

Main outcome variables

Pain intensity; maximum muscle isometric contraction force; physical performance; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048523N1**

Registration date: **2022-11-17, 1401/08/26**

Registration timing: **prospective**

Last update: **2022-11-17, 1401/08/26**

Update count: **0**

Registration date

2022-11-17, 1401/08/26

Registrant information

Name

Saeed Mikaili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8879 5422

Email address

saeed.mikaely@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of comprehensive rehabilitation treatment on pain, muscle force, physical function and quality of life in officer students with dynamic valgus of the lower limb

Public title
Effect of rehabilitation treatment in dynamic valgus of lower limb

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 People with knee rotation syndrome along with valgus
 Pain at least 3 score based on the numerical pain scale
 Knee pain when running, jumping sitting, and standing up
Exclusion criteria:
 Trauma to knee Injury to anterior cruciate ligament

Age
From **18 years** old to **30 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
 The random allocation method in this study will be performed as block randomization method. This method is implemented considering blocks of 4, so that the total number of possible permutations of four is 6, including: ABAB, ABBA, BAAB, BABA AAB, BBAA. Eligible people are placed in one of the following groups based on quadruple blocks, A: intervention group, B: control group. To create a random sequence, we will number the possible blocks (6 blocks) from 1 to 6, we will select the block numbers from the random number table, and based on these numbers, we will determine the sequence of blocks in each group. We need 20 blocks to select 80 people. In this study, the unit of randomization is the individual. Allocation concealment will be done by using sequentially numbered, sealed opaque envelopes in a random sequence.

Blinding (investigator's opinion)
Single blinded

Blinding description
 The main researcher will be blinded to the selection and randomization of the participants. The treatment in the intervention and control groups will be done by the main researcher. Data collection before and after the

intervention will be done by another colleague who is blinded like the main researcher. The outcomes evaluation and data statistical analysis will be done by the statistical consultant of the project and the main researcher will be also blinded in these fields.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Research Ethics Committees of Baqiyatallah Hospital
Street address
 Baqiyatallah University of Medical Sciences., South Sheikh Bahai., Mollasadea St., Vanak Sq
City
 Tehran
Province
 Tehran
Postal code
 1435916471

Approval date
2022-10-03, 1401/07/11

Ethics committee reference number
IR.BMSU.BAQ.REC.1401.062

Health conditions studied

1

Description of health condition studied
Genu Valgum (Knock knee)

ICD-10 code
M21.06

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

Primary outcomes

1

Description
Pain intensity

Timepoint
Measurement of pain intensity at the beginning of the study (before the intervention) and at the end of the study (6 weeks after the intervention).

Method of measurement
Numerical pain rating scale

2

Description

Maximum muscle isometric contraction force

Timepoint

Measurement of maximum muscle isometric contraction force at the beginning of the study (before the intervention) and at the end of the study (6 weeks after the intervention).

Method of measurement

Hand dynamo-meter

3

Description

Physical performance level

Timepoint

Measurement of physical performance level at the beginning of the study (before the intervention) and at the end of the study (6 weeks after the intervention).

Method of measurement

Lower extremity functional scale

4

Description

Quality of life

Timepoint

Measurement of level of quality of life at the beginning of the study (before the intervention) and at the end of the study (6 weeks after the intervention).

Method of measurement

36-question quality of life questionnaire

Secondary outcomes

1

Description

Thickness and angle fibers of vastus medialis and lateralis oblique muscles

Timepoint

Measurement of thickness and angle of muscle fibers at the beginning of the study (before the intervention) and at the end of the study (6 weeks after the intervention).

Method of measurement

Ultrasonography

2

Description

Joint distance of knee

Timepoint

Measurement of joint distance at the beginning of the study (before the intervention) and at the end of the study (6 weeks after the intervention).

Method of measurement

Ultrasonography

Intervention groups

1

Description

Intervention group: knee strengthening exercises (specific strengthening of vastus medialis oblique muscle), hip strengthening exercises (specific strengthening of hip abductor and external rotator muscles), taping and biofeedback correction of wrong biomechanical patterns of lower limbs in daily functions. The interventions will be conducted for six weeks and three sessions per week.

Category

Rehabilitation

2

Description

Control group: knee strengthening exercises (general strengthening of the quadriceps muscle), hip strengthening exercises (general strengthening of the muscles around the hip). The interventions will be conducted for six weeks and three sessions per week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein University

Full name of responsible person

Abolfazl Shakibaei

Street address

Imam Hossein University, Lashgarak Bridge, Shahid Babaei Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

AbbasAli Imani Fooladi

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Baqiyatallah University of Medical Sciences., South Sheikh Bahai., Mollasadea St., Vanak Sq

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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
Bagheiat-allah 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
Saeed Mikaili
Position
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Latest degree
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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

All above will be published in the article.

When the data will become available and for how long

After the article publication

To whom data/document is available

Researchers and students in academic centers

Under which criteria data/document could be used

Other researchers and therapists in the rehabilitation and medical field can use this use the data of this study after the article publication.

From where data/document is obtainable

After the article publication, people can find the article by searching in internet and access the data.

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

After the article publication, people can find the article by searching in internet and access the data.

Comments