Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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 AABB, 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 leteralis 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 Shakibaee
Street address
Imam Hossein University, Lashgarak Bridge, Shahid Babaei Highway
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Postal code
1698715861
Phone
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shakibaee.abolfazl@yahoo.com
Web page address
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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
PhD candidate of physiotherapy
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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