Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the Effectiveness of Knee and Hip_ Knee muscle Strengthening Exercises on Single Leg Squat and Step Decent Kinematics in Individuals with Patellofemoral Pain

Protocol summary

Study aim
To determine the effect of knee and hip muscle strengthening on lower limb kinematics in Females with Patellofemoral Pain

Design
This is a double-blinded RCT with parallel design in which 50 females with PFP will randomly be assigned to 2 groups of the case (1) and control (2). Balanced randomization technique and sealed envelope will be used for group assignment.

Settings and conduct
Group 1 and 2 will perform the knee plus knee, and the knee strengthening and stretching exercises, respectively. Patients will receive 4 weeks of treatment, 3 times a week. A motion analysis system will record kinematic data while patients perform a single-legged squat and stair descent. A dynamometer will measure the maximal isometric strength of knee and hip muscles. Joint kinematics and muscle strength will be assessed 2-3 days before and after interventions. The assessor and data analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria
Females with a history of anterior/retro patellar pain with a severity of at least 30 on a 100 mm Visual Analogue Scale in two daily activities of ascending and descending stairs, kneeling, squatting, and long sitting in the last 2 months will be entered to the study Females with a history of patellar dislocation, patellofemoral joint surgery, meniscal and ligament injury, Osgood-Schlatter Syndrome, Positive Apprehension Test, knee tendinitis will be excluded.

Intervention groups
Participants will randomly be allocated to the hip and knee strengthening (group 1) and knee strengthening groups (group 2 or control group). Group 1 and 2 will receive 12 sessions of physiotherapy focusing on hip plus knee muscles (group 1), and knee muscles (group 2) strengthening exercises.

Main outcome variables
The hip, knee joint flexion, abduction, and internal rotation. The hip and knee muscles strength.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140705018362N4**
Registration date: **2018-11-09, 1397/08/18**
Registration timing: **retrospective**

Last update: **2018-11-09, 1397/08/18**
Update count: **0**

Registration date
2018-11-09, 1397/08/18

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date

2018-10-21, 1397/07/29

Actual recruitment start date

2018-07-22, 1397/04/31

Actual recruitment end date

2018-10-11, 1397/07/19

Trial completion date

2019-02-03, 1397/11/14

Scientific title

Comparison of the Effectiveness of Knee and Hip_ Knee muscle Strengthening Exercises on Single Leg Squat and Step Decent Kinematics in Individuals with Patellofemoral Pain

Public title

Effects of Muscle strengthening on Motion Characteristics in Patellofemoral Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Females with PFP in the age range of 18-45 Reporting Anterior Knee Pain a minimum pain intensity of 30 based on a 100-mm visual analogue scale A history of Knee Pain in the last 2 months Anterior Knee pain in at least 2 daily activities of ascending and descending stairs, squatting, kneeling, long sitting pain on palpation of the medial and/or lateral facet of patella

Exclusion criteria:

Ligament instability Signs or symptoms of meniscal injury or any intra-articular disorder more than trace knee effusion Neural system involvmen that leading to walking disorer Osgood's_ Schlatter syndrome positive Apprehension Test excessive foot pronation, excessive knee valgus/varus Hip pain, sacroiliac pain, back pain patella, iliotibial band and pes anserinus tendonitist A history of Patellar dislocation

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced- Randomization technique will be used to allocate patients to the intervention groups. A person who has no role in the study will allocate the participants to the treatment groups. The Taves technique will be used to balance the groups with respect to demographic variables.

Blinding (investigator's opinion)

Double blinded

Blinding description

The assessor and data analyst will be blinded to group allocation of the participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Central Office, University Campus, Golestan

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Province

Khouzestan

Postal code

۶۱۳۵۷-۱۵۷۹۴

Approval date

2018-06-09, 1397/03/19

Ethics committee reference number

IR . AJUMS . REC . ۱۳۹۷. ۳۸

Health conditions studied

1

Description of health condition studied

Patellofemoral Pain

ICD-10 code

M22.4

ICD-10 code description

Chondromalacia patellae

Primary outcomes

1

Description

Maximal Isometric strength of Quadriceps muscles

Timepoint

Before and after treatment

Method of measurement

A fixed dynamometer

2

Description

Maximal Isometric strength of hamstring muscles

Timepoint

Before and after treatment

Method of measurement

a fixed dynamometer

3

Description
Maximal isometric strength of Hip external rotators and Abductor Muscles
Timepoint
Before and after treatment
Method of measurement
a fixed dynamometer

4

Description
Knee flexion angle
Timepoint
Before and after treatment
Method of measurement
Motion Analysis System

5

Description
Hip flexion angle
Timepoint
before and after treatment
Method of measurement
Motion Analysis system

6

Description
Hip internal/external rotation angle
Timepoint
before and after treatment
Method of measurement
Motion analysis system

7

Description
Hip Abduction/adduction angle
Timepoint
before and after treatment
Method of measurement
Motion analysis system

8

Description
Knee abduction/adduction angle
Timepoint
before and after treatment
Method of measurement
Motion analysis system

Secondary outcomes

1

Description
Pain intensity
Timepoint
Before and after treatment
Method of measurement
Visual Analog scale

2

Description
Function
Timepoint
Before and after treatment
Method of measurement
Kujala Questionnaire and the step-down test

Intervention groups

1

Description
Group 1: Individuals in this group will perform the hip abductor and external rotator muscle strengthening exercises in addition to knee muscles strengthening and stretching. Each individual will receive 12 sessions of treatment with the frequency of 3 sessions per week for 45 minutes in each session. Each week, the amount of resistive load will be adjusted to 70% of the 1-repetition maximum. For exercise with the elastic band, the resistance will be adjusted to the maximum resistance each individual can use to complete 10 repetitions of the exercise with no pain. ťretching for the muscles interest consists of three trials of a 30-second stretch, assisted by the therapist.
Category
Rehabilitation

2

Description
Treatment for group 1 includes the knee muscles strengthening and stretching exercises. Each individual will receive 12 sessions of treatment with the frequency of 3 sessions per week for 45 minutes in each session. Each week, the amount of resistive load will be adjusted to 70% of the 1-repetition maximum. For exercise with the elastic band, the resistance will be adjusted to the maximum resistance each individual can use to complete 10 repetitions of the exercise with no pain. ťretching for the muscles interest consists of three trials of a 30-second stretch, assisted by the therapist.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
IR . AJUMS . REC
Grant code / Reference number
1397.380
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available