Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of the effect of Real-time Feedback and Electromyography Biofeedback compared with Exercise therapy on Fear of movement, Clinical prediction rules and Stair-descent Kinematics in Subjects with Patellofemoral Pain Syndrome

Protocol summary

Study aim
Comparison of the effect of Real-time Feedback and Electromyography Biofeedback compared with Exercise therapy on Fear of movement, Clinical prediction rules and Stair-descent Kinematics in Subjects with Patellofemoral Pain Syndrome

Design
Clinical trial with parallel groups, Double-blind and randomized.

Settings and conduct
Ninety-three patients with patellofemoral pain syndrome who were included in the study were randomly divided into three groups. All three groups will do their specific exercises three days a week for eight weeks. The total duration of the training session will be 60 minutes, which is the initial 10 to 15 minutes of warm-up and stretching movements to prevent possible injuries to the The musculoskeletal system will be allocated. The main exercises will be performed for 30 to 40 minutes. During these exercises, each subject will rest for one minute between each set and one to two minutes between each movement.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Retropatellar knee pain present for at least 2 mo during at least 2 of the following activities : Ascending / descending stairs Hopping / jogging Prolonged sitting with flexed knees Kneeling Squatting.Pain rated as at least 3 cm within the week before participation on the 10-cm visual analogue pain scale. Clark test is positive. Exclusion criteria: History of knee surgery. History of low back, hip, or ankle injury within the 6 mo before participation. Anterior knee pain of secondary origin.

Intervention groups
Real-time Feedback with Exercise therapy group, Electroencephalographic Biofeedback with Exercise therapy group - Control group

Main outcome variables
Fear of movement, Predictive rules (Pain, Performance, Strength of the Knee extensor muscles and Hip muscles, Endurance of the Trunk muscles), Kinematics of the lower limbs

General information

Reason for update

Acronym
PFPS

IRCT registration information
IRCT registration number: **IRCT20200628047946N1**
Registration date: **2020-07-16, 1399/04/26**
Registration timing: **prospective**

Last update: **2020-07-16, 1399/04/26**
Update count: **0**

Registration date
2020-07-16, 1399/04/26

Registrant information

Name
saeedeh musavi

Name of organization / entity
Kharazmi

Country
Iran (Islamic Republic of)

Phone
+98 21 2612 1726

Email address
std_musavimoghadam@khu.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01
Expected recruitment end date
2020-09-30, 1399/07/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Real-time Feedback and Electromyography Biofeedback compared with Exercise therapy on Fear of movement, Clinical prediction rules and Stair-descent Kinematics in Subjects with Patellofemoral Pain Syndrome

Public title
Comparison of the effect of Real-time Feedback and Electromyography Biofeedback compared with Exercise therapy on Fear of movement, Clinical prediction rules and Stair-descent Kinematics in Subjects with Patellofemoral Pain Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Retropatellar knee pain present for at least 2 mo during at least 2 of the following activities : Ascending / descending stairs Hopping / jogging Prolonged sitting with flexed knees Kneeling Squatting Pain on palpation of 1 of the following , medial or lateral patellar facets, Anterior portion of the medial or lateral femoral condyle Patellar tendon Pain rated as at least 3 cm within the week before participation on the 10-cm visual analogue pain scale Clark test is positive
Exclusion criteria:
History of knee surgery Severe abnormalities in the lower limbs Any neurologic injury or disease that would influence gait or balance History of low back, hip, or ankle injury within the 6 mo before participation Insidious onset of knee pain not related to trauma Currently involved in physical therapy or has undergone physical therapy for a lower extremity injury within the 6 mo before participation Anterior knee pain of secondary origin
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **93**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples will be randomly divided into three homogeneous groups including two intervention groups and a control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, Researchers, Outcome evaluators and data analyzer are kept blind.
Placebo
Not used
Assignment
Parallel
Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kharazmi University
Street address
Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street, Keshvarei Sport complex Tehran, Iran
City
Tehran
Province
Tehran
Postal code
-
Approval date
2020-01-12, 1398/10/22
Ethics committee reference number
IR.KHU.REC.1398.042

Health conditions studied

1

Description of health condition studied
patellofemoral pain syndrom
ICD-10 code
M22.2X
ICD-10 code description
Patellofemoral disorders

Primary outcomes

1

Description
Fear of movement
Timepoint
Before and after the intervention

Method of measurement
Fear of movement questionnaire

2

Description
Pain
Timepoint
Before and after the intervention
Method of measurement
VAS

3

Description
Function
Timepoint
Before and after the intervention
Method of measurement
WOMAC Functional Questionnaire

4

Description
Strength of Knee extensor muscles and Hip muscles
Timepoint
Before and after the intervention
Method of measurement
Manual dynamometer

5

Description
Endurance of Trunk muscles
Timepoint
Before and after the intervention
Method of measurement
Planck test

6

Description
Lower limb kinematics
Timepoint
Before and after the intervention
Method of measurement
3D motion analysis system

Secondary outcomes

empty

Intervention groups

1

Description
Control group: 45 minutes of therapeutic exercises including strengthening the central muscles of the trunk and thigh and knee muscles in each session.
Category
Rehabilitation

2

Description
Intervention group: 45 minutes of therapeutic exercises including strengthening the central muscles of the trunk and thigh and knee muscles with Real-time feedback in each session.
Category
Rehabilitation

3

Description
Intervention group: 45 minutes of therapeutic exercises including strength training of the central muscles of the trunk and muscles of the thighs and knees with biofeedback electromyography in each session.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Kharzmi University Health and Wellness Center
Full name of responsible person
Seyedeh Saeedeh Mousavi Moghaddam Qaleh Zoo
Street address
Center for Human Movement Sciences Kharazmi university Mirdamad, Sout Razan Street, Hesari Street, Keshvarei Sport complex Tehran, Iran
City
Tehran
Province
Tehran
Postal code
-
Phone
+98 21 2222 8001
Email
letafatkaramir@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi University
Full name of responsible person
Amir Letafatkar
Street address
-
City
Tehran
Province
Tehran
Postal code
-
Phone

+98 21 2222 8001

Email

letafatkaramir@yahoo.com

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kharazmi University

Proportion provided by this source

20

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

Center for Human Movement Sciences Kharazmi University

Full name of responsible person

Seyedeh Saeedeh Mousavi Moghaddam Qaleh Zoo

Position

Master student of corrective exercise and sport injury prevention

Latest degree

Master

Other areas of specialty/work

Corrective exercise and sports injury prevention

Street address

Center for Human Movement Sciences Kharazmi university Mirdamad, Sout Razan Street, Hesari Street, Keshvarei Sport complex Tehran, Iran

City

Tehran

Province

Tehran

Postal code

-

Phone

+98 21 2222 8001

Email

smusavi73@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Center for Human Movement Sciences Kharazmi University

Full name of responsible person

Seyedeh Saeedeh Mousavi Moghaddam Qaleh Zoo

Position

Master student of corrective exercise and sport injury prevention

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Province

Tehran

Postal code

-

Phone

+98 21 2222 8001

Email

smusavi73@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Physical Education, Kharazmi University

Full name of responsible person

Seyedh Saeedeh Musavi Moghadam Qole Zoo

Position

Master student of corrective exercise and sport injury prevention

Latest degree

Master

Other areas of specialty/work

Corrective Exercise and Sport injury prevention

Street address

Center for Human Movement Sciences Kharazmi university Mirdamad, Sout Razan Street, Hesari Street, Keshvarei Sport complex Tehran, Iran

City

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Province

Tehran

Postal code

-

Phone

+98 21 2222 8001

Email

smusavi73@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

Only part of the data, such as dependent variables, the average of all samples, can be shared in scientific article.

When the data will become available and for how long

The date of access is November 2020.

To whom data/document is available

Personal information is confidential and general outcomes in paper form available to everyone.

Under which criteria data/document could be used

Information is not available to anyone. Only the results are presented as a scientific article.

From where data/document is obtainable

Seyedeh Saeedeh Mousavi Moghadam Qaleh Zoo- Phone 09010965165- Email smusavi73@gmail.com

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

-

Comments

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