Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of stabilization exercises with and without education on pain, function, and psychological factors in individuals with patellofemoral pain

Protocol summary

Study aim

Comparison of education intervention plus stabilization exercises with stabilization exercises in improving pain, function and, psychological outcomes in patients with patellofemoral pain

Design

Two arm parallel groups randomised trial with blinded outcome assessment

Settings and conduct

Assessments are in baseline, after 8-week intervention, and 3 months follow-up by a blind assessor. Participants are asked to report their pain and fill out questionnaires for function, pain catastrophizing, and kinesiophobia before the intervention. Muscle strength is evaluated at the laboratory of biomechanics at the university. Education sessions will be held online and exercises will be provided in the health center of the University. Outcome assessor will be blinded to the randomization and group assignment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male and female between 18 and 40, complaint of patellofemoral pain during daily activates, diagnosed by an orthopedic physician; exclusion criteria: Surgery and /or intra-articular pathology in any lower limb, joint knee joint effusion, having physiotherapy treatment knee pain up to 3 months before participating.

Intervention groups

Experimental group: 2 education sessions for each patient and aims to provide information about the nature of pain to reduce kinesiophobia and avoid behavior, and thus improve self-efficacy. Also, 24 sessions of stabilization training during 8 weeks includes warming up, training and cooling down. Exercises improve the motor control of the trunk and hip muscles, increase the strength of the trunk and hip muscles and making the exercises more difficult. Control group: Only perform stabilization exercises with the same number of sessions, and aims as experimental groupو without education sessions.

Main outcome variables

Pain, function, Pain Catastrophizing, Kinesiophobia, and lower limbs Muscle strength

General information

Reason for update

Adding the start and end dates of the actual subject recruitment and the date of study ending.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210701051754N2**
Registration date: **2021-08-21, 1400/05/30**
Registration timing: **prospective**

Last update: **2023-10-01, 1402/07/09**
Update count: **2**

Registration date

2021-08-21, 1400/05/30

Registrant information

Name
Pouya Rabiei
Name of organization / entity
Kharazmi University
Country
Iran (Islamic Republic of)
Phone
+98 86 3403 1371
Email address
pouya.rabiei.pr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

2021-08-28, 1400/06/06

Actual recruitment end date

2021-12-25, 1400/10/04

Trial completion date

2022-09-24, 1401/07/02

Scientific title

Investigating the effect of stabilization exercises with and without education on pain, function, and psychological factors in individuals with patellofemoral pain

Public title

Effect of education on improving patellofemoral pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Persian native male and female between 18 and 40 years Primary complaint of the anterior knee pain and the symptoms of patellofemoral pain during daily functional activates which is diagnosed by an orthopedic physician

Exclusion criteria:

Surgery and /or intra-articular pathology in any lower limb joint knee joint effusion Having physiotherapy treatment for knee pain up to 3 months before participating

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Following the baseline examination, by using the method on the website http://randomizer.org/ (Social Psychology Network, Connecticut, USA), participants are randomly assigned into the experimental group (education plus stabilization exercises) and control group (stabilization exercises). This method was used based on similar previous study. On this website, we will enter the number of sets you want (two sets of numbers are required; 1. Experimental group and 2. Control group). The numbers that Research Randomizer needs to generate in each set will be specified (two sets of 30 numbers are required for each group). The lowest and highest value of the numbers that need will specify (range of 1 up to 60). Concealed allocation is performed using a computer-generated block randomized table of numbers (4 Blocks, 2 allocations for experimental group and 2 allocations for control group) created before the start of data collection by a researcher who is not involved in the recruitment or treatment of patients. Then, the random numerical sequence is placed in sealed opaque envelopes. Another researcher, blind to the baseline examination, opens an envelope and processed with treatment according to the group assignment. A blinded outcome assessor who does not know the hypothesis and study methods, measures outcome at baseline, 8 weeks post-intervention, and 3 months follow-up.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor was blind to the process of randomization and assignment of individuals into experimental and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sport Sciences Research Institute

Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2021-06-21, 1400/03/31

Ethics committee reference number

IR.SSRC.REC.1400.058

Health conditions studied

1

Description of health condition studied

patellofemoral pain

ICD-10 code

M22.2

ICD-10 code description

Patellofemoral disorders

Primary outcomes

1

Description
Pain intensity
Timepoint
Baseline, 8 weeks after intervention, and 3 months follow up
Method of measurement
How to measure a variable is using Visual Analogue Scale.

Secondary outcomes

1

Description
Function
Timepoint
Baseline, 8 weeks after intervention, and 3 months follow up
Method of measurement
Knee outcome survey activities for daily living.

2

Description
Pain Catastrophizing
Timepoint
Baseline, 8 weeks after intervention, and 3 months follow up
Method of measurement
Pain Catastrophizing Scale.

3

Description
Kinesiophobia
Timepoint
Baseline, 8 weeks after intervention, and 3 months follow up
Method of measurement
Tampa Scale for Kinesiophobia.

4

Description
Muscle strength
Timepoint
Baseline, 8 weeks after intervention, and 3 months follow up
Method of measurement
Handheld dynamometer.

Intervention groups

1

Description
Intervention group: Patient in this group receive 2 supervised sessions for education before stabilization exercises. Each session is provided one-by-one between a patient and allocated physical therapist and lasts approximately between 30 and 45 minutes for each patient. As kinesiophobia and pain catastrophizing are important in patellofemoral pain, each session aims to provide information about the nature of pain to reduce kinesiophobia and avoidance behavior, and consequently to promote self-efficacy. Using explanation and showing pictures, the discussed subjects in each session included: (1) the cause and the reasons behind PFP happening (e.g., main passive and active structures of the knee joint, important roles of the hip joint alignment and musculature); (2) the ways to manage pain (e.g., how to move better during daily activities, preventing knee malalignment [knee valgus] during standing, walking, taking stairs, from sitting to standing, and other activities). For stabilization exercises, exercises are designed for 8 weeks, 3 sessions for each week, and 45 to 60 minutes for each session (the initial 10 minutes for warm-up, and the final 10 minutes for cooldown). Eight weeks of exercise are divided into 3 parts with specific aims. In the first 2 weeks (1st part) the emphasis is on improving motor control of the trunk and hip muscles. In the following 3 weeks (2nd part) the aim is to increase the strength of the trunk and hip muscles and to continue improving motor control using weight-bearing activities. In the last 3 weeks (3rd part) the load is increased, and the exercises became more difficult.
Category
Rehabilitation

2

Description
Control group: This group receives only stabilization exercises. exercises are designed for 8 weeks, 3 sessions for each week, and 45 to 60 minutes for each session (the initial 10 minutes for warm-up, and the final 10 minutes for cooldown). Eight weeks of exercise are divided into 3 parts with specific aims. In the first 2 weeks (1st part) the emphasis is on improving motor control of the trunk and hip muscles. In the following 3 weeks (2nd part) the aim is to increase the strength of the trunk and hip muscles and to continue improving motor control using weight-bearing activities. In the last 3 weeks (3rd part) the load is increased, and the exercises became more difficult.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Kharazmi University Health Center
Full name of responsible person
Pouya Rabiei
Street address
No. 38, Shokofeh street, Mehrshahr
City
Karaj
Province
Alborz

Postal code
3186689314
Phone
+98 86 3403 1371
Email
Pouya.rabiei.pr@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kharazmi University
Full name of responsible person
Amir Letafatkar
Street address
Center for Human Movement Sciences Kharazmi University Mirdamad, South Razan Street, Hesari Street, Keshvari Sport complex
City
Tehran
Province
Tehran
Postal code
15719-14911
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
No governmental fund has been received for this study, and it is conducted by researchers.
Proportion provided by this source
100
Public or private sector
Private
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
Kharazmi University
Full name of responsible person
Amir Letafatkar
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Sports science
Street address
Center for Human Movement Sciences Kharazmi University Mirdamad, South Razan Street, Hesari Street, Keshvari Sport complex
City
Tehran
Province
Tehran
Postal code
15719-14911
Phone
+98 21 2222 8001
Email
letafatkaramir@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kharazmi University
Full name of responsible person
Amir Letafatkar
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
sports science
Street address
Center for Human Movement Sciences Kharazmi University Mirdamad, South Razan Street, Hesari Street, Keshvari Sport complex
City
Karaj
Province
Alborz
Postal code
15719-14911
Phone
+98 21 2222 8001
Email
letafatkaramir@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kharazmi University
Full name of responsible person
Amir Letafatkar
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
sports science
Street address
Center for Human Movement Sciences Kharazmi University Mirdamad, South Razan Street, Hesari Street, Keshvari Sport complex

City
Tehran
Province
Tehran
Postal code
15719-14911
Phone
+98 21 2222 8001
Email
letafatkaramir@yahoo.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
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
Title and more details about the data/document
Only data related to demographic and outcomes information is shared.
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 at the reasonable request of the Iranian Clinical Trial Registration Center, journals and university individuals / researchers who are conducting research and scientific activities in this field.
Under which criteria data/document could be used
Data analysis and use of documents can only be done provided that their results are presented in systematic review articles conducted by researchers and academic researchers. Necessary conditions for sending data and documents include: 1. Sending an email (preferably with valid university addresses) to one of the researchers of the study 2. A brief and logical explanation of how to use the data or documents 3. Ensuring the registration of the protocol Systematic review studies that have requested access to data or documentation.
From where data/document is obtainable
Through requesting from Pouya Rabiei: Pouya.rabiei.pr@gmail.com Amir letafatkar: letafatkaramir@yahoo.com Bahram Sheikhi: sheikhibahram@gmail.com
What processes are involved for a request to access data/document
The applicant can request details from the researchers within 7 to 10 days using the message sent by email.
Comments

Trial results

Please tick if results have been published
Yes
Summary result posting date
2023-10-01, 1402/07/09
Table of baseline comparison

Table 2. Demographic and baseline characteristics of the study's patients.

Characteristic	Total sample (n = 60)	Experimental group (n=30)	Control group (n=30)
Age, y	31.36±5.79	30.60±6.04	32.12±5.52
Body mass, kg	72.51±10.78	73.42±10.72	71.60±10.96
Body height, cm	171.30±8.53	170.23±7.84	172.37±9.17
Body mass index, kg/m2	24.71±3.35	25.34±3.47	24.08±3.17
Sex, n (%)			
Female	24 (40)	13 (43.3)	11 (36.7)
Male	36 (60)	17 (56.7)	19 (63.3)
Symptoms, n (%)			
Unilateral	12 (20)	7 (23.3)	5 (16.7)
Bilateral	48 (80)	23 (76.7)	25 (83.3)
Pain rating (0-10)	5.90±1.43	6.10 ±1.52	5.70±1.34
Pain duration, (months)	58.75±29.68	60.27 ±30.66	57.23±29.10

Smoking status, n (%)			
Never smoked	46 (76.7)	21 (70)	25 (83.3)
Current	7 (11.7)	5 (16.7)	2 (6.7)
Past	7 (11.7)	4 (13.3)	3 (10)
Education level, n (%)			
High school or less	21 (35)	13 (43.3)	8 (26.7)
Bachelor’s degree	26 (43.3)	11 (36.7)	15 (50)
Master’s degree or higher	13 (21.7)	6 (20)	7 (23.3)
Marital status, n (%)			
Married/cohabitating	38 (63.3)	19 (63.3)	19 (63.3)
Single	12 (20)	8 (26.7)	4 (13.3)
Separated/divorced/widowed	10 (16.7)	3 (10)	7 (23.3)

Abbreviations: Continuous variables were expressed as mean ± standard deviation and categorical variables as number (n) and percentage (%). Experimental group, education followed by trunk and hip exercises; Control group, trunk and hip exercises.

Participant flow diagram

https://doi.org/10.1016/j.apmr.2023.08.030

Table of variable outcomes' results

Table 3. Outcomes of linear mixed model for primary and secondary results of each group. Treatment effects measured at 8-weeks post-intervention and 3-months follow-up.

Characteristic	**Experimental group**	**Change relative to baseline (%)**	**Control group**	**Change relative to baseline (%)**	**Group Difference, Mean (95% CI)**	**Effect Size†**	**Main Effect of Time**		**Interaction Effect**		**Bonferroni post-hoc tests**	
	Mean ± SDa		**Mean ± SDa**				***F**1,58*	***P*-value**	***F**1,58*	***P*-value**	**Time**	**Group**
Primary Outcome Measure												
Pain (VAS)												
Baseline	6.10±1.52	NA	5.70±1.34	NA	0.40 (-0.229 to 0.788)	NA						
Post-intervention	3.41±1.47	44.10 ↓	3.93±1.26	31.05 ↓	-0.51 (-0.890 to 0.131)	0.38	94.60	<0.001	7.82	0.001	Baseline > 8 wk, 3 mo (*p*<0.001b,c)	3 mo(*p*=0.032)
Follow-up	2.29±1.14	62.46 ↓	2.91±0.97	48.95 ↓	-0.60 (-1.103 to -0.069)	0.59						
Secondary Outcome Measures												
Function (KOS-ADL)												
Baseline	64.90±8.918	NA	66.57±7.48	NA	-1.75 (-0.710 to 0.304)	NA						
Post-intervention	76.35±6.56	17.64 ↑	74.49±6.03	11.90 ↑	1.85 (-0.214 to 0.804)	0.30	72.99	<0.001	7.65	0.005	Baseline < 8 wk, 3 mo (*p*<0.001b,c)	3 mo(*p* =0.036)
Follow-up	0.55±5.66	24.11 ↑	77.41±5.76	16.28 ↑	3.20 (0.034 to 1.065)	0.55						
Pain catastrophizing (PCS)												
Baseline	20.10±4.77	NA	18.80±4.87	NA	1.32 (-0.239 to 0.778)	NA						
Post-intervention	12.96±4.04	35.52 ↓	15.29±4.52	18.67 ↓	-2.32 (-1.059 to -0.028)	0.54	281.68	<0.001	47.34	<0.001	Baseline > 8 wk, 3 mo (*p*<0.001b,c)	8 wk (*p*=0.007); 3 mo (*p*=0.043)

Follow-up	9.21±3.69	54.18 ↓	12.04±4	35.96 ↓	-2.82 (-1.258 to -0.213)	0.74						
Kinesiophobia (TSK)												
Baseline	42.47±7.20	NA	39.93±7.11	NA	2.71 (-0.155 to 0.865)	NA						
Post-intervention	32.07±7.05	24.49 ↓	35.79±6.44	10.37 ↓	-3.56 (-1.067 to -0.035)	0.55	157.42	<0.001	52.61	<0.001	Baseline > 8 wk, 3 mo (p<0.001b,c)	8 wk (p=0.045); 3 mo (p=0.002)
Follow-up	27.89±4.99	34.33 ↓	32.56±5.90	18.46 ↓	-4.54 (-1.383 to -0.326)	0.85¥						
Muscles strength (BW)												
Hip abductors												
Baseline	16.19±5.08	NA	17.24±4.30	NA	-1.05 (-0.731 to 0.285)	NA						
Post-intervention	21.41±4.94	32.24 ↑	20.76±3.85	20.42 ↑	0.64 (-0.36 to 0.654)	0.15	387.33	<0.001	0.042	0.84	Baseline < 8 wk, 3 mo (p<0.001b,c)	N.S
Follow-up	23.73±4.71	46.57 ↑	22.65±3.64	31.38 ↑	1.07 (-0.252 to 0.765)	0.26						
Hip external rotators												
Baseline	12.07±3.62	NA	13.54±3.78	NA	-1.41 (-0.908 to 0.114)	NA						
Post-intervention	18.04±4.02	49.46 ↑	17.54±3.77	29.54 ↑	0.51 (-0.378 to 0.635)	0.13	196.15	<0.001	0.001	0.97	Baseline < 8 wk, 3 mo (p<0.001b, c)	N.S
Follow-up	21.12±4.08	74.98 ↑	20.25±3.96	49.56 ↑	0.90 (-0.291 to 0.724)	0.22						
Hip extensors												
Baseline	18.64±4.27	NA	19.46±3.93	NA	-0.77 (-0.707 to 0.308)	NA						
Post-intervention	23.38±4.27	25.43 ↑	22.84±3.87	17.37 ↑	0.57 (-0.374 to 0.639)	0.13	359.82	<0.001	0.039	0.84	Baseline < 8 wk, 3 mo (p<0.001b, c)	N.S
Follow-up	25.56±4.08	37.12 ↑	24.68±3.68	26.82 ↑	0.89 (-0.281 to 0.742)	0.23						
Knee extensors												
Baseline	25.18±4.78	NA	26.51±4.63	NA	-1.3 (-0.791 to 0.226)	NA						
Post-intervention	32.03±4.51	27.20 ↑	31.05±4.32	17.13 ↑	0.95 (-0.286 to 0.730)	0.22	435.27	<0.001	0.024	0.88	Baseline < 8 wk, 3 mo (p<0.001b, c)	N.S
Follow-up	34.17±4.70	35.70 ↑	33.29±4.24	25.58 ↑	0.87 (-0.311 to 0.704)	0.20						

Abbreviations: †, Effect size (Cohen's *d*); ¥, Large effect size (*d* >0.80) based on the study of Cohen (1988); ↓, Decrease; ↑, Increase; a, Values are expressed as means ± standard deviations; b, Results of Bonferroni Post Hoc tests in the experimental group; c, Results of Bonferroni Post Hoc tests in the control group; ADL, Knee outcome survey activities for daily living; BW, Body weight; CI, Confidence Interval; Control group, trunk and hip exercises; Experimental group, education followed by trunk and hip exercises; KOS- PCS, Pain Catastrophizing Scale; NA, Not applicable; N.S, Not significant; TSK, Tampa Scale for Kinesiophobia; VAS, Visual Analogue Scale.

Table of adverse events

- No adverse events occurred in either intervention group.

First publication date

2023-09-15, 1402/06/24

Abstract of published paper

Abstract Objective: To investigate the effect of adding education to trunk and hip exercises in patients with patellofemoral pain (PFP). Design: A randomised controlled trial. Setting: Research laboratory. Participants: Sixty patients with PFP were randomly assigned to either an experimental group (education followed by trunk and hip exercises, n= 30) or a control group (trunk and hip exercises, n= 30). Interventions: Both groups received 8 weeks of trunk and hip exercises, while patients in the experimental group participated in 3 prior education sessions. Main Outcome Measures: The primary outcome was pain; secondary outcomes were pain catastrophizing, kinesiophobia, function, and muscle strength. Outcomes were assessed at baseline, after 8 weeks (post-intervention), and 3 months post-intervention (follow-up). Results: No significant between-group differences were observed for pain outcome post-intervention. The

experimental group showed superiority over the control group in the improvement of pain catastrophizing (mean difference: -2.32; 95% confidence interval [CI] -1.059 to 0.028) and kinesiophobia (mean difference: -3.56; 95% CI -1.067 to -0.035) at post-intervention. In the experimental group, improvements were maintained at follow-up assessment for all outcomes, except muscle strength. Conclusion: Adding education to trunk and hip exercises was associated with greater improvements in psychological outcomes than trunk and hip exercises alone after the intervention. Education can be incorporated when designing trunk and hip exercises for patients with PFP.