Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of addition of lumbar support belt to core and knee exercises on pain, performance and balance in recreational endurance runners with patellofemoral pain

Protocol summary

Study aim

The effect of addition of lumbar support belt to core and knee exercises in recreational endurance runners with patellofemoral pain

Design

This study is a assessor, and data analyst-blind, parallel group randomized clinical trial. 32 patients will be randomly assigned to one of two groups of the study with Block Randomization method.

Settings and conduct

Both groups are treated for four weeks. Control groups get 10 sessions exercises on knee and core. Intervention group use lumbar belt(everytime they run) plus same control group exercise Outcome measures will be assessed pre- and post-interventions,and 4 weeks post-intervention in both groups.

Participants/Inclusion and exclusion criteria

Age between 18 and 40 years Anterior knee pain while running and at least 3 activities: going up and down stairs, running, squatting, kneeling, squatting, and sitting for long periods of time At least 3 months pain in anterior of the knee Running at least 3 times a week for a minimum of 30 and a maximum of 55 minutes Pain behind the patella Pain intensity between 3 and 7 on VAS and 50 to 80 score on the Kojala questionnaire No use of painkillers, two weeks before the start of the study Exclusion criteria for participants: Knee, lower limb and trunk surgery Structural disorders of the knee Presence of pathology in knee meniscus, ligaments and tendons A history of patellar dislocation or subluxation The existence of muscle tears, Osgoodschlatter syndrome, Johansson and Plica syndrome Systemic diseases Cardiopulmonary diseases Diseases of the visual system Alcoholism and smoking back pain pregnancy lumbar belt intolerance

Intervention groups

Intervention group: 10 sessions of therapeutic exercises plus using lumbar belt(everytime they run) during 4 weeks. Control group:10 sessions of therapeutic exercises over 4 weeks.

Main outcome variables

Pain intensity, performance level, agility, speed and balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140408017177N3**
Registration date: **2024-07-25, 1403/05/04**
Registration timing: **prospective**

Last update: **2024-07-25, 1403/05/04**
Update count: **0**

Registration date

2024-07-25, 1403/05/04

Registrant information

Name

Iman Rezaei

Name of organization / entity

School of Rehabilitation

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-22, 1403/06/01

Expected recruitment end date
2025-02-18, 1403/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of addition of lumbar support belt to core and knee exercises on pain, performance and balance in recreational endurance runners with patellofemoral pain

Public title
The effect of addition of lumbar support belt to core and knee exercises in recreational endurance runners with patellofemoral pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The age of the runner between 18 and 40 years Pain in the front of the knee when running and during at least three activities: going up and down stairs, running, squatting, kneeling and sitting for long periods of time. At least three months of pain in the front of the knee Pain intensity between 3 and 7 on the visual analog scale and a score of 50 to 80 on the Kojala questionnaire in the last month before the intervention Running at least 3 days a week for at least 30 and at most 55 minutes a day People with patellofemoral pain if their pain originates from behind the patella (i.e. pain behind the patella) No use of painkillers, two weeks before the start of the study
Exclusion criteria:
Knee, lower limb and trunk surgery Structural disorders of the knee Presence of pathology in knee meniscus, ligaments and tendons A history of patellar dislocation or subluxation The presence of muscle tears, Osgoodschlatter syndrome, Johanson syndrome and Plica syndrome Systemic diseases such as diabetes, rheumatological disorders, etc Cardiopulmonary diseases Diseases of the visual system Alcoholism and smoking back pain pregnancy lumbar belt intolerance
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples will be randomly assigned to one of the two study groups using the block randomization method using the online randomisation sealedenvelope.com in 8 blocks of 4.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the evaluator, and the person who analyzes the data will be unaware of which group each participant is in.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz School of Rehabilitation Sciences
Street address
Amirul Mominin (AS) Burn Accident Hospital, Shahid Doran Campus, School of Rehabilitation Sciences, Sadra City Road, Shiraz, Fars, Iran
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Shiraz
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Postal code
7198754361
Approval date
2024-05-25, 1403/03/05
Ethics committee reference number
IR.SUMS.REHAB.REC.1403.003

Health conditions studied

1

Description of health condition studied
Patellofemoral pain in in recreational endurance runners
ICD-10 code
M22.2
ICD-10 code description
Patellofemoral disorders

Primary outcomes

1

Description
Intensity of pain
Timepoint
pre-intervention, post-intervention, 4 weeks post-intervention
Method of measurement
Visual analog scale

2

Description
performance level
Timepoint
pre-intervention, post-intervention, 4 weeks post-intervention
Method of measurement
Step down performance test and Kujala questionnaire

Secondary outcomes

1

Description
Dynamic balance
Timepoint
Pre-intervention, Post-intervention, 4 weeks post-intervention
Method of measurement
Modified SEBT balance test

2

Description
Speed
Timepoint
Pre-intervention, Post-intervention, 4 weeks post-intervention
Method of measurement
50 meters test

3

Description
Agility
Timepoint
Pre-intervention, Post-intervention, 4 weeks post-intervention
Method of measurement
T test

Intervention groups

1

Description
Intervention group, doing same control exercises in 10 sessions plus lumbar belt (everytime they run) for 4 weeks.
Category
Rehabilitation

2

Description
Control group:Exercises in both groups are performed for 4 weeks, in 10 sessions (once every 3 days), for about 19-25 minutes at home using checklists. These checklists are given to them to confirm the exercises and according to the exercise program,exercises will change on the 3rd and 6th sessions. 3 initial sessions (about 19 minutes) 1. Stretching of the hamstrings, iliotibial band and gastrocnemius muscles (hold for 30 seconds, repeat 5 times) 2. Sting of the quadriceps muscle (hold for 10 seconds, repeat 10 times) 3. Bridge while a ball is placed between the legs (3 repetitions, hold for 10 seconds) 4. Lying on the side and abduction of the hip joint (6 repetitions, holding for 10 seconds) 3 secondary sessions (about 21 minutes) 1. Straight leg lifting (3 sets) , 10 repetitions, hold for 10 seconds) 2. Step-up movement from the front (3 sets, 10 repetitions) 3. Raising the leg while lying on the side (3 sets, 10 repetitions) 4. Sitting down while a ball be between the legs (repeat 5 times, hold for 10 seconds). The last 4 sessions (about 25 minutes) 1. Squatting at 30 degree knee flexion (3 sets, hold for 10 seconds) 2. Step-up from the side (3 sets, hold for 10 seconds) 3. Contraction of the hip abduction muscles in standing position Isometrically (15 repetitions, hold for 5 seconds) 4. Alternately move the shoulder forward and backward while standing on the involved limb (15 repetitions, hold for 5 seconds) 5. While standing on the involved leg, trunk to the healthy side rotate while the hip joint is in internal rotation (15 repetitions, hold for 5 seconds) 6. Sit down while a ball is between the legs and the knees are straight (6 repetitions, hold for 10 seconds) 7. Sit down from the side while that the ball is between the legs and the knee is flat (hold 6 times for 10 seconds).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz University of Medical Sciences, School of Rehabilitation Sciences
Full name of responsible person
Dr. Iman Rezaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Iman Rezaei

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Assistant Professor

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Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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Other areas of specialty/work
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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