

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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, Osgood-schlatter 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)

##### Phone

+98 71 1627 1551

##### Email address

irezaei@sums.ac.ir

##### 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, Osgood-schlatter 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

**City**

Shiraz

**Province**

Fars

**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 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

##### **Street address**

Amirul Mominin (AS) Burn Accident Hospital, Shahid Doran Campus, School of Rehabilitation Sciences, Sadra City Road, Shiraz, Fars, Iran

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

7198754361

##### **Phone**

+98 71 3212 2600

##### **Email**

irezaei@sums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr. Mohammad Hashem Hashempour

**Street address**

Shiraz University Of Medical Sciences Building, Zand Street, Shiraz, Fars, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Phone**

+98 71 3235 7282

**Email**

hashempurm@sums.ac.ir

**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

**Street address**

Amirul Mominin (AS) Burn Accident Hospital, Shahid Doran Campus, School of Rehabilitation Sciences, Sadra City Road, Shiraz, Fars, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7198754361

**Phone**

+98 71 3212 2600

**Email**

irezaei@sums.ac.ir

## Person responsible for scientific 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

**Street address**

Amirul Mominin (AS) Burn Accident Hospital, Shahid Doran Campus, School of Rehabilitation Sciences, Sadra City Road, Shiraz, Fars, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7198754361

**Phone**

+98 71 3212 2600

**Email**

irezaei@sums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Sara Jafari

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

Amirul Mominin (AS) Burn Accident Hospital, Shahid Doran Campus, School of Rehabilitation Sciences, Sadra City Road, Shiraz, Fars, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7198754361

**Phone**

+98 71 3212 2600

**Email**

sarajafari@sums.ac.ir

## 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