

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the effectiveness of aquatic and land HIIT on knee function and quality of life in young male soccer players with patellofemoral pain syndrome

Protocol summary

Study aim

Studying the effect of two types of activities in water and on land on knee pain syndrome

Design

The present study is a pre-test-post-test randomized clinical trial with a control group (without blinding). 40 subjects were randomly (simple randomization) divided into four groups: aquatic exercise group (10 people), land exercise group (10 people), combined group (10 people), and control group (10 people).

Settings and conduct

This study will be conducted in the sports club and swimming pool in the Khanagah. The aquatic group (performed 4 resistance movements in 8 sets, each set consisting of 2 minutes of intense interval training and 2 minutes of active rest between each set), the land group (performed 10 repetitions of 60 seconds of pedaling on an ergometer bike with 60 seconds of rest between repetitions), the combined group (one week of aquatic exercise and one week of land exercise), and the control group (no regular exercise). The experimental groups performed the exercises 3 sessions per week, each session lasting 40 min, for 2 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men with knee pain syndrome for at least six months in both legs, Absence of any other symptoms, No tobacco or alcohol addiction, Exclusion criteria: history of trauma, injury or surgery in the past three months, use of intra-articular injections in the past three months

Intervention groups

The subjects were randomly divided into four groups (10 people each), including a control group, a land exercise group, a water exercise group, and a combined exercise group (water and land exercise every other week). The control group will not have any exercise program during this period.

Main outcome variables

Dependent variables: Dynamic balance, lower limb function, lower limb strength, pain reduction, and quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240702062312N2**

Registration date: **2026-01-23, 1404/11/03**

Registration timing: **retrospective**

Last update: **2026-01-23, 1404/11/03**

Update count: **0**

Registration date

2026-01-23, 1404/11/03

Registrant information

Name

Naser Rostamzadeh

Name of organization / entity

The University of Farhangian

Country

Iran (Islamic Republic of)

Phone

+98 87 3371 1530

Email address

naserrostamzadeh806@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-10, 1404/10/20

Expected recruitment end date

2026-01-15, 1404/10/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of aquatic and land HIIT on knee function and quality of life in young male soccer players with patellofemoral pain syndrome

Public title

effectiveness of aquatic and land HIIT on knee function and quality of life in soccer players with patellofemoral pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men with knee pain syndrome for at least six months in both legs
Absence of any other symptoms of illness
No history of trauma, injury, or surgery in the past three months
Age between 20 and 40 years
No addiction to tobacco or alcohol, no use of intra-articular injections in the past three months
No use of painkillers or dietary supplements in the past three months and no history of joint-threatening diseases

Exclusion criteria:

Failure to attend training sessions regularly and becoming ill
Any spinal problems
Recent surgery, any musculoskeletal problems (such as fractures, bursitis)

Age

From **20 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is designed as a randomized controlled clinical trial with an individual-level unit of randomization. A total of 40 eligible participants, after careful verification of the inclusion and exclusion criteria, completion of baseline assessments, and provision of written informed consent, will be randomly allocated to one of four study groups: control, aquatic exercise, land-based exercise, and combined exercise. Participants will be assigned to the study groups using a simple randomization method, with an equal allocation ratio of 1:1:1:1. Each participant will therefore have an equal and independent probability of being allocated to any of the four groups. The random allocation sequence will be generated using a computer-based random number generation procedure implemented in SPSS statistical software (version 26). The generation of the randomization sequence will be performed by an independent researcher who is not

involved in participant recruitment, baseline assessment, intervention delivery, or data analysis. To minimize the risk of selection bias and to preserve internal validity, strict allocation concealment will be maintained until the point of final group assignment. The randomization results will be placed in sequentially numbered, opaque, sealed, and light-impermeable envelopes prepared by the independent researcher. These envelopes will be securely stored and opened strictly in the order of participant enrollment. The investigator responsible for participant recruitment and baseline assessments will remain blinded to the allocation sequence and group assignments until the envelope corresponding to the enrolled participant is opened. Each envelope will be opened only after eligibility confirmation, completion of baseline measurements, and signing of the informed consent form. This procedure ensures that neither the investigators nor the participants can predict or influence group assignment. Due to the nature of the exercise interventions, blinding of participants and intervention providers is not feasible. However, where possible, outcome assessments will be conducted by an independent assessor who is blinded to group allocation in order to minimize detection bias. All procedures related to randomization, allocation concealment, and group assignment will be fully documented and made available for review by the Ethics Committee or relevant regulatory authorities upon request.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah Razi University

Street address

university street

City

Kermanshah

Province

Kermanshah

Postal code

6714414971

Approval date

2024-03-06, 1402/12/16

Ethics committee reference number

IR.RAZI.REC.1403.003

Health conditions studied

1

Description of health condition studied

Patellofemoral Pain Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

knee pain

Timepoint

Before starting the protocol and again after 2 months training

Method of measurement

VAS Questionnaire

Secondary outcomes

1

Description

functional performance

Timepoint

Before starting the protocol and again after 2 months training

Method of measurement

hop test

2

Description

lower strength

Timepoint

Before starting the protocol and again after 2 months training

Method of measurement

one repetition maximum (leg press)

3

Description

upper strength

Timepoint

Before starting the protocol and again after 2 months training

Method of measurement

one repetition maximum (chest press)

4

Description

speed

Timepoint

Before starting the protocol and again after 2 months training

Method of measurement

20m test

5

Description

dynamic balance

Timepoint

Before starting the protocol and again after 2 months training

Method of measurement

Y test

6

Description

quality of life

Timepoint

Before starting the protocol and again after 2 months training

Method of measurement

SF-36 Questionnaire

Intervention groups

1

Description

Intervention group: aquatic training group performed 8 weeks of high-intensity interval training in water, including 4 movements (stationary running, cross-country skiing, jumping jacks, and frontal kicks) in 8 sets, with 2 minutes of high-intensity interval training per set and 2 minutes of active rest between each set.

Category

Lifestyle

2

Description

Intervention group: Land-based HIIT (ergometer cycling at 85–95% HRmax), 8 weeks of training on a stationary bike on land

Category

Lifestyle

3

Description

Intervention group: Combined group, one week of training in water and one week of training on land, aquatic training 4 weeks of high-intensity interval training in water, including 4 movements (stationary running, cross-country skiing, jumping jacks, and frontal kicks) in 8 sets, with 2 minutes of high-intensity interval training per set and 2 minutes of active rest between each set and 4 weeks of land training -based HIIT (ergometer cycling at 85–95% HRmax)

Category

Lifestyle

4

Description

Control group: This group does not receive any intervention and only participates in measurements

Category
Lifestyle

Country of origin
Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi university
Full name of responsible person
Naser Rostamzadeh
Street address
No.1, Zibashahr Ave., Baharan Town
City
Sanandaj
Province
Kurdistan
Postal code
6617881554
Phone
+98 918 992 8216
Email
naserrostamzadeh806@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Razi university
Full name of responsible person
Manochehr Haidary
Street address
Faculty of Agriculture Campus, Asatid Complex, Block 3, Unit 4
City
Kermanshah
Province
Kermanshah
Postal code
6715685420
Phone
+98 912 538 2491
Email
mhaidary2000@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Razi university

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
university of kurdistan
Full name of responsible person
Naser Rostamzadeh
Position
University lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
No.1,Zibashahr Ave., Baharan Town
City
Sanandaj
Province
Kurdistan
Postal code
6617881554
Phone
+98 87 3371 1530
Email
naserrostamzadeh806@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
university of kurdistan
Full name of responsible person
Naser Rostamzadeh
Position
University lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
No.1,Zibashahr Ave., Baharan Town
City
Sanandaj
Province
Kurdistan
Postal code
6617881554
Phone
+98 87 3371 1530
Email
naserrostamzadeh806@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
university of kurdistan

Full name of responsible person

Naser Rostamzadeh

Position

University lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

No.1,Zibashahr Ave., Baharan Town

City

Sanandaj

Province

Kurdistan

Postal code

6617881554

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+98 87 3371 1530

Email

naserrostamzadeh806@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

En Part of the data, such as average age, gender,the average of the body mass index and results of the outcome have the possibility of sharing

When the data will become available and for how long

6 months after the print results

To whom data/document is available

Researcher people in Academic and scientific institutions

Under which criteria data/document could be used

Just to compare with similar research using the documentation permitted

From where data/document is obtainable

By email to Nasser Rostamzadeh
naserrostamzadeh806@gmail.com

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

After you send the request via e-mail, lasts for 2 months

Comments