Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effectiveness of aquatic and land HIIT on knee function and quality of life in young male soccer players with patellofemural 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 Khanaqin. 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

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Naser Rostamzadeh
Name of organization / entity
The University of farhangian
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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 patellofemural pain syndrome

Public title
effectiveness of aquatic and land HIIT on knee function and quality of life in soccer players with patellofemural 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: Lanland-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

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi university
Full name of responsible person
Naser Rostamzadeh
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Postal code
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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
Country of origin
Type of organization providing the funding
Academic

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
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Other areas of specialty/work
Physiology
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Person responsible for updating data

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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