

Effect of functional training in water on lower limb function in patients with anterior cruciate ligament reconstruction

Submission date 18/07/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/07/2025	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/07/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Anterior cruciate ligament (ACL) reconstruction is an internationally recognized surgical method for the treatment of ACL rupture, but it is difficult for patients to recover their proprioception after surgery, which significantly affects the functional performance of the lower limbs, especially the knee joint. Functional proprioception training in water is a kind of rehabilitation training that utilizes the resistance, buoyancy, massage relaxation and constant temperature in the water environment to enhance the proprioception and functional performance of the lower limbs, which is mostly used in the rehabilitation training of lower limb sports injuries, and it can effectively enhance the proprioception and limb function, but few studies evaluate the effect of its restoration of the proprioception after the ACL reconstruction. This study aims to investigate the effectiveness of functional proprioceptive training in water in enhancing lower limb motor function performance after ACL reconstruction in male patients returning to sports.

Who can participate?

Male patients aged 18-55 years following first-time ACL reconstruction surgery

What does the study involve?

Using a study design in which participants are randomly assigned to groups, but the participants do not know which group they are in. Patients who met the criteria for first-time unilateral ACL reconstruction were recruited at Wuhan Institute of Physical Education. The patients were divided into an in-water functional proprioceptive training group and a land-based functional proprioceptive training group according to a randomized numeric table method, and underwent 6 weeks of in-water and land-based functional proprioceptive training, respectively, for 12 weeks (3 months) after the operation (3 times/week, 60 min/session. 1 time/day) of functional proprioceptive training in water and on land, respectively. Primary measures of functional performance tests were measured before and after 6 weeks of training, and secondary outcome measures included: muscle strength, balance, overall knee function, and a psychosocial assessment of ACL reconstruction reintegration.

What are the possible benefits and risks of participating?
To improve lower extremity performance and return to sport in patients undergoing ACL reconstruction. Hypersensitivity to the water environment cannot be ruled out in some patients.

Where is the study run from?
Wuhan Sports Institute, China

When is the study starting and how long is it expected to run for?
April 2023 to June 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Hai-Ou Wu, who1692841980@163.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Improving the ability of postoperative patients to return to exercise: the effect of functional proprioceptive training in water on the lower limb motor function performance of male patients after anterior cruciate ligament reconstruction

Study objectives

This study aimed to investigate the effect of functional proprioceptive training in water on return-to-exercise lower limb functional performance and related knee function in male patients more than 12 weeks (3 months) after ACL reconstruction. The study hypothesizes that functional proprioceptive training in water would provide better recovery for male ACL reconstruction patients returning to sports.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 17/04/2023, Medical Ethics Committee of Wuhan Institute of Physical Education (No. 461, Luoyu Road, Hongshan District, Wuhan, Hubei Province, 430079, China; +86 027 8719 1933; wtkyc-collector@whsu.edu.cn), ref: 2023021

Study design

Single-center prospective single-blind randomized controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

A rehabilitation program to improve lower extremity functional performance in male patients after anterior cruciate ligament reconstruction.

Interventions

Seventeen patients who met the criteria for ACL reconstruction were divided into an in-water functional proprioceptive training group (n=9) and a land functional proprioceptive training group (n=8) according to the randomized numerical table method, and underwent in-water and on-land functional proprioceptive training for 6 weeks (3 times/week, 60 min/trip, 1 time/day), respectively, at 12 weeks (3 months) postoperatively. The principle of gradual progression was used, and the training intensity was increased every two weeks. All patients underwent an 8-minute pre-training warm-up, which consisted of regular head, shoulder, waist, hip, knee, and ankle warm-up activities or aquatic warm-up activities (aquatic slow walking, aquatic lateral walking, aquatic backwards walking, aquatic high leg jumps, and aquatic open and close jumps). The 30-minute formal functional proprioceptive training was divided into three phases (i.e., the first two weeks, the middle two weeks, and the last two weeks).

Intervention Type

Behavioural

Primary outcome(s)

The level of functional performance of the subjects' lower limbs was measured using the one-legged one-hop test, the one-legged three-hop test, and the 6-meter one-legged hop test before and after the test

Key secondary outcome(s)

The secondary outcome measures were assessed before and after the test:

1. Knee muscle strength was measured using a Hoggan handheld dynamometer and the IseMed isometric force measurement system
2. Balance function was measured using a Y balance tester
3. Overall knee function was measured using the Lysholm Rating Scale
4. Postoperative return to sport ability of the subjects was measured by using the Anterior Cruciate Ligament Return to Sport After Injury Scale

Completion date

10/06/2024

Eligibility

Key inclusion criteria

1. Males aged 18-55 years old
2. First time ACL reconstruction surgery
3. Autologous tendon graft was used
4. Patients more than 12 weeks (3 months) after surgery
5. Knee mobility: flexion greater than 100°, full extension (0°)
6. Unilateral anterior cruciate ligament with or without meniscus injury, no other ligament tear except medial collateral ligament
7. Receive water training and be unafraid of water

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

55 years

Sex

Male

Total final enrolment

17

Key exclusion criteria

1. History of neurological diseases (stroke, degenerative diseases of the central nervous system or peripheral nervous system, vestibular or visual disorders)
2. Other back, hip, and ankle problems
3. Taking psychotropic or antihypertensive medications

4. Contraindications to water activities (especially skin)
5. Recent lower extremity sprains less than 3 months old may affect postural control
6. Being enrolled in another physical therapy or training program

Date of first enrolment

10/04/2023

Date of final enrolment

10/04/2024

Locations

Countries of recruitment

China

Study participating centre

Sports Rehabilitation Center, School of Sports Medicine, Wuhan Institute of Physical Education

No. 461, Luoyu Road, Hongshan District

Wuhan, Hubei Province

China

430079

Study participating centre

Aquatic Rehabilitation and Fitness Research Center, Wuhan Institute of Physical Education

No. 461, Luoyu Road, Hongshan District

Wuhan, Hubei Province

China

430079

Study participating centre

Wuhan Sports Institute Fitness Center

No. 461, Luoyu Road, Hongshan District

Wuhan, Hubei Province

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430079

Sponsor information

Organisation

Wuhan Sports Institute

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Wu Hai-Ou, who1692841980@163.com.

1. Data type: unconditional sharing
2. Data for this study are expected to be available from the corresponding author in October 2025 upon reasonable request
3. Participant consent has been obtained
4. No data anonymization is required
5. This trial has been approved by the Human Experimentation Ethics Review Board

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Including consent form		23/07/2025	No	Yes