# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effect of aquatic exercise on Functional Movement Assessments and Elements of Sensorimotor Function in Athletes with Chronic Ankle Instability

## Protocol summary

**Study aim**
The effect of a aquatic exercise course on ankle dorsiflexion range of motion, lower limb motor performance screening, ankle self-report scores, sensorimotor performance elements, functional tests in athletes with chronic ankle instability.

**Design**
40 male athletes (20 in each group) participated in this study. They were selected purposefully based on the entry and exit criteria and were randomly divided into two groups (control group and experimental group).

**Settings and conduct**
The experimental group does aquatic exercise for 8 weeks, the place of exercises (protocol) is in the pool They did three sessions a week for (1/5) an hour and a half with specific methods of warming up, the main exercise, the number of sets, rests and the number of movements. The control group did not do any intervention and continued their exercises.

**Participants/Inclusion and exclusion criteria**
Admission: history of sprained ankles in the last two years, feeling of empty ankles twice in the last six months, obtaining the specified score in all four questionnaires, having the age range (18-30) years, voluntary consent of the subjects to participate in the research. Failure to enter: not having a history of ankle sprains in the last two years, not having the feeling of emptying the ankle twice in the last six months, not obtaining the specified score in all four questionnaires, not having the age range (18-30) years.

**Intervention groups**
People in two groups (experimental group did daily exercises and a specialized and specified water sports intervention for 8 weeks, which is designed to be effective for athletes with chronic ankle instability), (interventional control group) did not do and followed up their daily exercises) were divided.

**Main outcome variables**
Functional Movement, Sensorimotor Function

## General information

**Reason for update**
**Acronym**
AQE-CAI
**IRCT registration information**
IRCT registration number: **IRCT20230709058724N1**
Registration date: **2024-06-29, 1403/04/09**
Registration timing: **retrospective**

Last update: **2024-06-29, 1403/04/09**
Update count: **0**
**Registration date**
2024-06-29, 1403/04/09

**Registrant information**
**Name**
Saeed Zarei
**Name of organization / entity**
The University of Shahrekord
**Country**
Iran (Islamic Republic of)
**Phone**
+98 25 3885 4864
**Email address**
saeidzareei1999@gmail.com

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2023-07-17, 1402/04/26
**Expected recruitment end date**
2023-07-28, 1402/05/06
**Actual recruitment start date**

2023-06-27, 1402/04/06

**Actual recruitment end date**

2023-07-23, 1402/05/01

**Trial completion date**

2023-10-02, 1402/07/10

**Scientific title**

The effect of aquatic exercise on Functional Movement Assessments and Elements of Sensorimotor Function in Athletes with Chronic Ankle Instability

**Public title**

The effect of aquatic exercise on Athletes with Chronic Ankle Instability

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Athletes (basketball, handball, volleyball, futsal) History of ankle sprains in the last two years Twice feeling empty ankles in six months Obtaining the determined score in four questionnaires Male athletes (18-30) with chronic ankle instability Three years of sports experience with three sessions a week No history of spine or lower limb surgery No hearing problems Not having balance problems

**Exclusion criteria:**

Acute Ankle Sprain (less than 6 weeks old) Severe Lower Limb Injuries like fractures, ligament tears requiring surgery uncontrolled medical conditions like heart disease, high blood pressure, or neurological disorders

**Age**

From **18 years** old to **30 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants will randomly assign to either the aquatic exercise group or the control group using a computer-generated random sequence with a 1:1 allocation ratio. This randomization sequence will be generated by an independent statistician not involved in participant recruitment or data collection. Allocation concealment was achieved using sequentially numbered, opaque envelopes. These envelopes contained pre-printed group assignments and were opened only after obtaining informed consent and completing baseline assessments for each participant.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study will employ a single-blind randomized controlled trial design. Participants will be aware of their group assignment (aquatic exercise group or control group) throughout the study duration. However, all data collection procedures will be standardized to minimize potential bias from assessors. Data analysts will be blinded to group assignment until after all data collection complete and the primary analyses conduct. A single, un-blinded researcher not involve in data collection or participant interaction will maintain the randomization sequence and ensured proper allocation concealment.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

two control and experimental groups. The experimental group performs the water sports protocol along with the sports exercises, and the control group performs their own sports exercises.

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shahrekord University

**Street address**

Rahbar Boulevard, Shahrekord University

**City**

Chaharmahal va Bakhtiari

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

۸۸۱۸۶۳۴۱۴۱

**Approval date**

2023-11-11, 1402/08/20

**Ethics committee reference number**

IR.SKU.REC.1402.036

## Health conditions studied

**1**

**Description of health condition studied**

Chronic ankle instability

**ICD-10 code**

M25.37

**ICD-10 code description**

Other instability, ankle and foot

## Primary outcomes

**1**

**Description**

Motor performance and sensory-motor performance elements

**Timepoint**
Before the start of the intervention and after the end of the intervention
**Method of measurement**
8 specialized tests(1-Knee to wall dorsiflexion ankle test 2-Stroke balance test 3-Y balance test 4-Functional movement screen 5-Side–hop test 6-Figure-of-8-Hop Test 7-Triple hop for distance 8-Assessment of sensory-motor function

## Secondary outcomes

### 1

**Description**
After the implementation of the water exercise protocol on chronic ankle instability in the study, the secondary outcome variable can be "quality score of ankle questionnaires and self-report" and "lower limb motor performance screening scores" and "static and dynamic balance test and range of motion" ankle dorsiflexion and elements of sensory-motor and functional function.
**Timepoint**
Before the start of the intervention and after the end of the intervention
**Method of measurement**
پرسشنامه (1-پرسشنامه بی ثباتی مچ پای کامبرلند 2- پرسشنامه تشخیص بی ثباتی عملکردی مچ پا 3-مقایس سنجش توانایی پا و مچ پا 4- مقیاس سنجش توانایی پا و مچ پل در فعالیت ورزشی) 8 تست تخصصی(1-آزمون رساندن زانو به دیوار 2-آزمون تعادل ایستا لک لک 3-آزمون تعادل پویا 4-آزمون غربالگری حرکات عملکردی 5-آزمون جهش جانبی 6-آزمون جهش هشت لاین 7-آزمون سه لی برای مسافت 8-ارزیابی عملکرد حسی-حرکتی

## Intervention groups

### 1

**Description**
Intervention Group: Aquatic exercises that focus on the ankle joint start from the first week with the least resistance and gradually intensify until the eighth week and reach the maximum pressure. These exercises include the following: increasing the load (resistance exercises), improving agility and jumping (after reaching the necessary preparation). And tools such as: water noodle, swimming board, rope, ladder have been used.
**Category**
Rehabilitation

### 2

**Description**
Control group:Participants in the control group will continue their daily activities and routine work (team or individual exercises three times a week).
**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahrekord University
**Full name of responsible person**
Saeed Zarei
**Street address**
Leader Blvd
**City**
Shahrekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
۸۸۱۸۶۳۴۱۴۱
**Phone**
+98 38 3232 4401
**Email**
saeidzareei1999@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Department of Sports and Youth
**Full name of responsible person**
Saeed Zarei
**Street address**
Imam Hossein Square
**City**
Sharekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
۷۳۴۷۵ – ۸۸۱۶۴
**Phone**
+98 38 1225 1000
**Email**
saeidzareei1999@gmail.com
**Web page address**
https://chb.msy.gov.ir
**Grant name**
Finance and research plan
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Department of Sports and Youth
**Proportion provided by this source**
10
**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**
Other

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Shahrekord University
**Full name of responsible person**
saeedzarei
**Position**
Student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Sports pathology and corrective movements
**Street address**
Leader Blvd
**City**
Sharekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
۷۳۴۷۵ – ۸۸۱۶۴
**Phone**
+98 38 1225 1000
**Email**
saeidzareei1999@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Sharekord University
**Full name of responsible person**
sajad bagherian dehkordi
**Position**
Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Sports pathology and corrective movements
**Street address**
Leader Blvd
**City**
Sharekord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
۷۳۴۷۵ – ۸۸۱۶۴
**Phone**
+98 38 1220 1000
**Email**
sajjadbagherian@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
ShahreKord University
**Full name of responsible person**
Saeed Zarei
**Position**
Student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Sports pathology and corrective movements
**Street address**
Leader Blvd
**City**
ShahreKord
**Province**
Chahar-Mahal-va-Bakhtiari
**Postal code**
۷۳۴۷۵ – ۸۸۱۶۴
**Phone**
+98 38 1220 1000
**Email**
saeidzareei1999@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**
Data can be shared.6
**When the data will become available and for how long**
The access period starts one year after the results are published
**To whom data/document is available**
Academic and scientific researchers
**Under which criteria data/document could be used**
For use in future research
**From where data/document is obtainable**
saeidzareei1999@gmail.com
**What processes are involved for a request to access data/document**
One year after the statistical analysis and summarization of all the results and all the mentioned documents will be provided to you.
**Comments**