

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the Effect of Aqua and Land Based Closed Kinetic Chain Exercises on Pain, Function, Knee Instability, Proprioception, Kinesiofobia, and Quality of Life in Women with Osteoarthritis and Knee Instability.

#### Protocol summary

##### Study aim

Determining the effect of eight weeks of closed range of motion exercises in the water environment on pain, performance, in women with knee osteoarthritis.

##### Design

This study was a blind one-way clinical trial (the evaluator does not know who is in which group) with parallel groups with a pre-test-post-test design in which 32 patients with knee osteoarthritis with instability were studied in two groups. Phase 3 will be studied.

##### Settings and conduct

The place of conducting the evaluations and tests of the study will be the corrective movements and sports rehabilitation laboratory of the Faculty of Sports Sciences of Razi University.

##### Participants/Inclusion and exclusion criteria

- Age over 40 years. - Having the clinical criteria of knee osteoarthritis of the American College Rheumatology. Having a score of  $\leq 11$  in the Kellgren and Lawrence criteria. -pain score of at least 4 on the visual analogue pain scale. - Reduction of joint space or osteophyte in radiography. Exclusion criteria: - uncontrolled diabetes, (BMI>40kg/m<sup>2</sup>), patients with extreme obesity. Physiotherapy or knee surgery (during the last 12 months). Lower limb arthroplasty. Intra-articular steroid injections (during the last 6 months). arthroplasty.

##### Intervention groups

Closed Kinetic Chain exercises In this study, the subjects are randomly allocated in water-based and land-based closed movement chain training intervention groups. The exercises will be performed for eight weeks, three sessions a week and 60 minutes each week.

##### Main outcome variables

Assessment of pain intensity by VAS visual scale; Performance (UGT test, 40 meter walking test and going up and down 8 standard stairs); Knee instability;

#### General information

##### Reason for update

In the system, there was an expected date of patient recruitment, but the actual date of the researchers' patient recruitment was different. So, it should be corrected.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230409057863N1**

Registration date: **2023-12-20, 1402/09/29**

Registration timing: **prospective**

Last update: **2025-07-11, 1404/04/20**

Update count: **1**

##### Registration date

2023-12-20, 1402/09/29

##### Registrant information

##### Name

Mahshid Mohammadi

##### Name of organization / entity

The University of Razi

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 4838 1418

##### Email address

mahshid.mohammadi1188@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-05, 1402/02/15

##### Expected recruitment end date

2023-06-05, 1402/03/15

**Actual recruitment start date**

2024-01-01, 1402/10/11

**Actual recruitment end date**

2024-04-12, 1403/01/24

**Trial completion date**

2024-04-12, 1403/01/24

**Scientific title**

Comparing the Effect of Aqua and Land Based Closed Kinetic Chain Exercises on Pain, Function, Knee Instability, Proprioception, Kinesiofobia, and Quality of Life in Women with Osteoarthritis and Knee Instability.

**Public title**

Comparing the Effect of Aqua and Land Based Closed Kinetic Chain Exercises on in Women with Osteoarthritis and Knee Instability.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

"Age over 40 years" "Having the clinical criteria of knee osteoarthritis of the American College of Rheumatology"

"Having a score of  $\leq 11$  in the Kellgren and Lawrence criteria" "Chronic knee pain most days, for at least 3 months, a pain score of at least 4 on the analogue scale visual pain" "reduction of joint space or osteophyte in radiography"

**Exclusion criteria:**

history of knee or spine surgery Awaiting arthroplasty Uncontrolled diabetes History of joint injections or other complementary treatments during the last three months Use of walking aids Lack of balance

**Age**

From **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **32**

Actual sample size reached: **29**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Subjects will be randomized based on the Random Number Generator software, and then based on the concealment of allocation by the SNOSE method, they will be divided into groups of water-based closed motion chain exercises (n=16) and land-based closed motion chain exercises (n=16). n) will be allocated. The random distribution list will be extracted from the software by a person not involved in data collection and will be provided to the laboratory expert. After evaluating each subject, by removing one of the sealed envelopes, the subject and the evaluator will be informed of the assigned group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, since the evaluator and the subjects will be informed about the intervention groups after the evaluation of the primary and secondary outcomes, the researcher will not have any information about the exercises and interventions assigned to the groups. However, it is not possible to blind the subjects from the study interventions. It will also be possible to inform the person who will analyze the data about the groups and exercises assigned to them.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Vice President of Education, Research and Technology of the Red Crescent Society

**Street address**

Block 20, Plot 416, Phase 2, Elkhebal St., Imam Reza Town,

**City**

Kermanshah-Sahne city

**Province**

Kermanshah

**Postal code**

6746189180

**Approval date**

2023-07-16, 1402/04/25

**Ethics committee reference number**

IR.RAZI.REC.1402.037

**Health conditions studied****1****Description of health condition studied**

Knee osteoarthritis

**ICD-10 code**

M19.0

**ICD-10 code description**

Primary osteoarthritis of other joints

**Primary outcomes****1****Description**

"Assessment of pain intensity"

**Timepoint**

Before and eight weeks after the intervention

**Method of measurement**

"VAS visual scale"

## 2

### **Description**

Function

### **Timepoint**

"Before and eight weeks after the intervention"

### **Method of measurement**

"UGT test, 40 meters walking test and going up and down 8 standard stairs"

## 3

### **Description**

"Knee instability"

### **Timepoint**

"Before and eight weeks after the intervention"

### **Method of measurement**

"Felson Questionnaire"

## **Secondary outcomes**

## 1

### **Description**

Kinesiophobia

### **Timepoint**

"Before and eight weeks after the intervention"

### **Method of measurement**

Tampa scale

## 2

### **Description**

Knee proprioception

### **Timepoint**

"Before and eight weeks after the intervention"

### **Method of measurement**

"Inclinometer"

## 3

### **Description**

"Quality of life (OAKHQoL)"

### **Timepoint**

"Before and eight weeks after the intervention"

### **Method of measurement**

"OAKHQoL questionnaire"

## 4

### **Description**

"Distribution of plantar pressure"

### **Timepoint**

"Before and eight weeks after the intervention"

### **Method of measurement**

"PET-Scan machine"

## 5

### **Description**

"Strength of the muscles acting on the knee"

## **Timepoint**

"Before and eight weeks after the intervention"

## **Method of measurement**

"Pull-Push dynamometer"

## **Intervention groups**

## 1

### **Description**

Intervention group: Water-based Closed Kinetic Chain exercises: The exercises will be applied by an expert certified in the field of corrective exercises and sports rehabilitation. The exercises will also be approved by a physiotherapist specializing in exercise therapy. The exercises will be performed for eight weeks, three sessions a week, and 60 minutes each week. In each session, 10 minutes of warm-up exercises (forward walking, backward walking, lateral walking, and stretching movements), 10 minutes of cooling down exercises (stretching movements) and the main exercise will last 40 minutes. The temperature of the pool for water-based closed kinetic chain exercises will be 32 degrees in a shallow environment with dimensions of 152 x 86 cm and a depth of 95 cm. Tools such as chairs, steps, weights, stretch bands, pilates balls, etc. will also be used in the implementation of study training protocols. The main program of closed kinetic chain exercises includes exercises such as mini squats, front and side step-ups, front and side step-downs, wall sliding, heel rising, lunge exercises from the front and sides, quadriceps setting exercises, and single leg mini squats.

### **Category**

Rehabilitation

## 2

### **Description**

Control group: Land-based-Closed Kinetic Chain exercises: The exercises of both groups will be applied by an expert certified in the field of corrective exercises and sports rehabilitation. The exercises will also be approved by a physiotherapist specializing in exercise therapy. The exercises will be performed for eight weeks, three sessions a week, and 60 minutes each week. In each session, 10 minutes of warm-up exercises (forward walking, backward walking, lateral walking, and stretching movements), 10 minutes of cooling down exercises (stretching movements), and the main exercise protocol will last 40 minutes. Tools such as chairs, steps, weights, stretch bands, pilates balls, etc. will also be used in the implementation of study training protocols. The main program of closed kinetic chain exercises includes exercises such as mini squats, front and side step-up, front and side step-downs, wall sliding, heel rising, lunge exercises from the front and sides, quadriceps setting exercises, and single leg mini squats.

### **Category**

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shahid Fatahi Clinic

**Full name of responsible person**

Mahshid Mohammadi Darvishani

**Street address**

Plot 416, Block 20, Phase 2, Elkhebal St., Imam Reza Town,

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**Email**

mahshid.mohammadi1188@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Razi university

**Full name of responsible person**

Mahshid Mohammadi Darvishani

**Street address**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Red Crescent

**Proportion provided by this source**

50

**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**

Razi University-Faculty of Sports Sciences

**Full name of responsible person**

Mahshid Mohammadi Darvishani

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Sports pathology and corrective exercises

**Street address**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Razi University-Faculty of Sports Sciences

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**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**

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**

Not applicable

**Title and more details about the data/document**

Based on the opinion of the colleagues, after the work is done, a decision will be made for publication, and the data can be provided to the readers in order to publish the articles by emailing the responsible author.

**When the data will become available and for how long**

If the corresponding author is emailed, the data will be made available after the articles are published.

**To whom data/document is available**

Authors of scientific articles and editors of journals.

**Under which criteria data/document could be used**

To check the validity of the results of the study, the data will be presented.

**From where data/document is obtainable**

To the corresponding author.

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

by Email.

**Comments**