Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ≤II in the Kellgern 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/m2), 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)
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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 ≤II in the Kellgern and Lawerence 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Razi university
Full name of responsible person
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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
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Person responsible for updating data

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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