Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Eight weeks Aquatic Therapy on Knee Proprioception and Gait Speed among Female Older Adults with Knee Osteoarthritis

Protocol summary

Study aim
This study will be aimed to evaluate the effects of an eight-week aquatic therapy on gait speed and knee proprioception in this population.

Design
a randomized controlled trial (RCT) with a single-blind, pre-test and post-test design.

Settings and conduct
A total of 34 female participants diagnosed with KOA will be recruited from a clinic in Ardabil, Iran, and randomlywill be assigned to either an aquatic therapy group or a control group. The interventionwill be involved structured aquatic therapy sessions conducted over eight weeks. Pre- and post-intervention assessments will be conducted to evaluate knee proprioception using a digital goniometer and gait speed using the 10-Meter Walk Test (10MWT) under simple walking and cognitive task conditions.

Participants/Inclusion and exclusion criteria
Participants will be recruited from a clinic in Ardabil. Patients will be examined by a rheumatologist. Additionally, participants were required to have completed the Kellgren-Lawrence (KL) grading scale within the last six months. The KL scale is a widely used method for assessing the severity of knee osteoarthritis. Participants will be only included in the study if they had a KL grade of 1 or higher, indicating the presence of some degree of osteoarthritis

Intervention groups
Aquatic Therapy Group

Main outcome variables
knee proprioception , 10-Meter Walk Test (10MWT) under simple walking and cognitive task conditions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190908044722N7**
Registration date: **2024-11-26, 1403/09/06**
Registration timing: **retrospective**

Last update: **2024-11-26, 1403/09/06**
Update count: **0**

Registration date
2024-11-26, 1403/09/06

Registrant information

Name
Razieh Khanmohamadi

Name of organization / entity
The university of Urmia

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2024-11-21, 1403/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Eight weeks Aquatic Therapy on Knee Proprioception and Gait Speed among Female Older Adults with Knee Osteoarthritis

Public title
Effects of Eight weeks Aquatic Training on Knee Proprioception and Gait Speed among Female Older Adults with Knee Osteoarthritis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
• Women aged 63 to 70 years • Diagnosed with KOA by a certified rheumatologist through both clinical assessment and X-ray examination • Inactive individuals, engaging in less than one hour of physical activity per week • Free from severe medical conditions such as diabetes, asthma, cardiovascular diseases, neurological conditions (e.g., seizures, brain surgeries, or chronic headaches), and skin diseases • Body mass index (BMI) below 40 kg/m² • Not participating in any other clinical study at the time of recruitment
Exclusion criteria:
• History of knee surgeries or other joint diseases • Cortisone injection in the knee joint within the past month • Severe respiratory, neurological, or musculoskeletal disorders, or left ventricular dysfunction
Age
From **63 years** old to **70 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **34**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were randomly allocated to either the aquatic therapy exercise group or the control group using a simple randomization method. The unit of randomization was the individual participant. The randomization was carried out using Random Allocation Software version 1.0.0. To ensure proper allocation concealment, a single individual, blinded to the group allocation, handled the enrollment and group assignment process. This individual generated the random sequence using the software and assigned participants to groups without revealing the allocation to either the participants or the researchers conducting the intervention. This procedure maintained the integrity of the randomization process.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be blinded, so the evaluators will not know which patients are in the intervention group and which are in the control group.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University
Street address
Urmia University, Kilometer 11 of Cypress Road - West Azarbaijan Province -Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5756151818
Approval date
2024-01-06, 1402/10/16
Ethics committee reference number
IR.URMIA.REC.1402.027

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M15.0
ICD-10 code description
Primary generalized (osteo)arthritis

Primary outcomes

1

Description
knee proprioception
Timepoint
before and after intervention
Method of measurement
In order to evaluate and test the sense of the knee joint position, a digital goniometer with an accuracy of 0.1 degrees will be used

2

Description
Gait Speed
Timepoint
before and after intervention
Method of measurement
using the 10-Meter Walk Test

3

Description
Cognitive Task Condition
Timepoint
before and after intervention
Method of measurement
Participants will be asked to perform a dual-task, walking the 10-meter distance while simultaneously engaging in a visuospatial N-back task

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Aquatic Therapy :Participants in the aquatic therapy group will complete an 8-week program, consisting of 2 sessions per week, held at Ardabil's Jam swimming pool. Each session will last 60 minutes, including a 10-minute warm-up, 45 minutes of water exercises like : Heel Raises: ,Mini Squats, Hip Abduction ,Hip Extension ,Hip Flexion Step-Ups Arm Movements: , and a 5-minute cool-down
Category
Rehabilitation

2

Description
Control group: The control group will not receive any active intervention but continued with their usual care
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
a clinic in Ardabil
Full name of responsible person
Razieh Khanmohammadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University
Full name of responsible person
Abbas Banj Shafiei
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Urmia University, Kilometer 11 of Cypress Road - West Azarbaijan Province -Urmia
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urmia University
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Urmia University
Full name of responsible person
Razieh Khanmohammadi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
motor behavior
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Ethical Considerations: The ethical review board overseeing this study recommended against the release of IPD due to concerns about potential misuse or misinterpretation of the data outside of its intended context.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The analysis of information obtained from the results of the interventions on Knee Proprioception and Gait Speed can be published

When the data will become available and for how long
From the time the article was published until a year later

To whom data/document is available
All researchers

Under which criteria data/document could be used
در صورتی که فردی بخواهد طرح تحقیقاتی مشابه انجام دهد

From where data/document is obtainable
r.khanmohamadi65@yahoo.com

What processes are involved for a request to access data/document
Send request by email

Comments