Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of water-based resistance training with blood flow restriction on functional capacity,heart rate variability, electrical activity of quadriceps muscles and knee joint kinematic while walking in postmenopausal women with knee osteoarthritis.

Protocol summary

Study aim
Determining the effect of resistance training with blood flow restriction in water on functional capacity, heart rate variability, electrical activity of quadriceps muscles and knee joint kinematics during walking in postmenopausal women with knee osteoarthritis

Design
A clinical trial with a control group, with parallel groups (resistance in water, resistance with blood flow restriction), Restricted randomization with a stratified method, on 45 patients with 2nd and 3rd degree arthritis, postmenopausal women, Gpower software was used for the sample size in three groups.

Settings and conduct
Training sessions will be conducted in the culture pool of Qaen city under the supervision of the physiotherapist and the research team. The desired tests will be conducted in the Physiology Laboratory of Birjand University.

Participants/Inclusion and exclusion criteria
Postmenopausal women with grade 2 and 3 arthritis; No history of cardiovascular disease; non-smokers; Not suffering from skin and contagious diseases that can be transmitted by water; not taking non-steroidal and anti-inflammatory drugs in the last 3 months; No injection of corticosteroids in the last 6 months; No surgery or other invasive procedure on the knee in the last 6 months

Intervention groups
The Progressive resistance group in the water by tying weights to the ankles and performing hydrotherapy movements for knee strengthening, The Progressive resistance group with blood flow restriction in the water by tying a cuff around the thigh and tying weights to the ankles and performing hydrotherapy movements for knee strengthening, The Control group did not receive any activities under the supervision of the research group and did their normal life activities

Main outcome variables
Heart rate variability; Knee kinematic condition while walking; Electrical activity of the quadriceps muscle; Functional capacity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240911063005N1**
Registration date: **2024-09-22, 1403/07/01**
Registration timing: **prospective**

Last update: **2024-09-22, 1403/07/01**
Update count: **0**

Registration date
2024-09-22, 1403/07/01

Registrant information

Name
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Name of organization / entity
University Of Birjand

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

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

Effect of water-based resistance training with blood flow restriction on functional capacity,heart rate variability, electrical activity of quadriceps muscles and knee joint kinematic while walking in postmenopausal women with knee osteoarthritis.

Public title

Comparison of resistance exercises in water with and without blood flow restriction on people with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Postmenopausal women with grade 2 and 3 arthritis No history of cardiovascular disease Non-smokers Absence of skin and contagious diseases that can be transmitted by water Not taking non-steroidal and anti-inflammatory drugs in the last 3 months No injection of corticosteroids in the last 6 months No surgery or other invasive procedure on the knee in the last 6 months

Exclusion criteria:

Menopause of people Arthrosis degree lower than 2 and higher than 3 History of cardiovascular disease

Age

From **45 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Limited randomization and stratified method considering homogeneity in anthropometric characteristics (weight, Age of menopause and body mass index in three groups)

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Birjand University Research

Street address

Birjand University Campus., University Blvd., at the end of Shahid Avini Boulevard

City

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Province

South Khorasan

Postal code

9717434765

Approval date

2024-02-21, 1402/12/02

Ethics committee reference number

IR.BIRJAND.REC.1402.016

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Functional capacity

Timepoint

Measurement of functional capacity 48 hours before the start and 48 hours after the end of the study

Method of measurement

Chair stand test, walking speed, timed walking test, 2-minute walk and rise test (TUG) and dynamic balance

2

Description

Heart rate variability

Timepoint

Measurement of heart rate variability 48 hours before the start and 48 hours after the end of the study

Method of measurement

Polar heart rate monitor

3

Description

Electrical activity of quadriceps muscles

Timepoint

Measurement of electrical activity of quadriceps muscles 48 hours before the start and 48 hours after the end of the study

Method of measurement

Electromyography device(EMG)

4

Description

Knee joint kinematics while walking

Timepoint

Measurement of knee joint kinematics while walking 48 hours before the start and 48 hours after the end of the study

Method of measurement

Inertial measurement unit device(IMU)

Secondary outcomes

1

Description

Pain

Timepoint

48 hours before the start and after the end of the study

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index Questionnaire

Intervention groups

1

Description

Intervention group: Water resistance for 8 weeks and 3 sessions per week with progressive weights and knee therapy exercises

Category

Treatment - Other

2

Description

Intervention group: resistance along with blood flow restriction in water for 8 weeks and 3 sessions every week for 45 minutes, therapeutic knee exercises in water with a cuff around the thigh and weight on the ankle during the main exercises.

Category

Treatment - Other

3

Description

Control group: They do not receive any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology specialist doctor's office

Full name of responsible person

Dr. Zeinab Sarmi

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Shafa doctors building, Taleghani 20

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Sponsors / Funding sources

1

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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

The University of Birjand

Proportion provided by this source

100

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
The University of Birjand
Full name of responsible person
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Position
assistant professor
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available