Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Handpolo Exercise on Occupational Stress, Motor Fitness, and Perceived Self-Efficacy in Employed Middle-Aged Women with Metabolic Syndrome: A Three-Arm Randomized Controlled Trial

Protocol summary

Study aim

to compare the effects of aquatic handpolo exercise and simple aquatic therapy on occupational stress, motor fitness, and perceived self-efficacy in middle-aged women with metabolic syndrome, relative to a control group.

Design

Randomized controlled trial with a control group, three parallel groups, single-blind, conducted on 60 participants. Randomization was performed using the Random Allocation Software.

Settings and conduct

The study will be conducted in city pools offering aquatic handpolo programs. Employed women aged 30–40 years with clinical signs of metabolic syndrome will be recruited through health centers, sports facilities, and workplace wellness programs. All participants will undergo clinical and laboratory screening, including physical examination and blood tests, to confirm eligibility and readiness for aquatic exercise. Physical fitness will be assessed using functional tests and the PAR-Q+ questionnaire. After informed consent, Participants will be randomly assigned to one of three groups (aquatic handpolo, Aqua aerobic , or control). Outcome assessors will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Participants of this study will include employed women aged 30 to 40 years who will have clinical symptoms of metabolic syndrome and will be able to participate in the aquatic handpolo exercise program. The main inclusion criteria will be active employment, being within the specified age range, and confirmation of metabolic syndrome criteria through clinical and laboratory assessments. Exclusion criteria will include the presence of serious cardiovascular or respiratory diseases, medical limitations preventing participation in aquatic exercise, pregnancy,

Intervention groups

Aquatic handpolo exercise group, Aqua aerobic exercise

Main outcome variables

1. Dynamic Balance, Perceived Self-Efficacy, Motor Performance ,Occupational Stress

General information

Reason for update

The date of admission was before the clinical code was recorded, so it was corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190908044722N11**
Registration date: **2025-09-29, 1404/07/07**
Registration timing: **prospective**

Last update: **2026-06-08, 1405/03/18**
Update count: **2**

Registration date

2025-09-29, 1404/07/07

Registrant information

Name
Razieh Khanmohamadi
Name of organization / entity
The university of Urmia
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-02, 1404/07/10

Expected recruitment end date

2025-10-26, 1404/08/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Handpolo Exercise on Occupational Stress, Motor Fitness, and Perceived Self-Efficacy in Employed Middle-Aged Women with Metabolic Syndrome: A Three-Arm Randomized Controlled Trial

Public title

The Effect of Handpolo Exercise on Occupational Stress, Motor Fitness, and Perceived Self-Efficacy in Employed Middle-Aged Women with Metabolic Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Full-time or part-time employment for at least the past six months. Presence of at least three out of five diagnostic criteria for metabolic syndrome according to the NCEP ATP III guidelines Waist circumference ≥ 88 cm. Fasting blood glucose ≥ 100 mg/dL or receiving treatment for elevated blood glucose. Serum triglycerides ≥ 150 mg/dL or under treatment. HDL cholesterol < 50 mg/dL or under treatment. Blood pressure ≥ 130/85 mmHg or taking antihypertensive medication. Enrollment in a center that offers aquatic Handpolo activities. Ability and willingness to participate in moderate-intensity aquatic physical activity.

Exclusion criteria:

Pregnancy or intention to become pregnant during the study period. History of cardiovascular, renal, or severe musculoskeletal disorders that contraindicated exercise. Engagement in a structured exercise program more than twice per week within the past three months Use of medications significantly affecting lipid metabolism or cortisol levels, beyond standard treatment for metabolic syndrome Presence of psychiatric or neurological disorders interfering with adherence to the intervention protocol Inability to attend at least 80% of the scheduled intervention sessions.

Age

From **30 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After completion of the screening process and provision of written informed consent, eligible participants will be randomly assigned in a 1:1:1 ratio to one of three groups: aquatic handpolo exercise, aquatic therapy, or control. To ensure balanced group sizes and minimize allocation bias, randomization will be performed using a block randomization method with variable block sizes (6 and 9). The allocation sequence within each block will be generated in a fully random manner using the Random Allocation Software.

Blinding (investigator's opinion)

Single blinded

Blinding description

To reduce the risk of assessment bias, outcome assessors were blinded to group allocation. All measurements related to balance, motor fitness, and occupational stress were conducted by a trained evaluator who was unaware of participants' group assignments.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sport Sciences Research Institute

Street address

No. 3, Fifth Alley, Miramad Street, Tehran

City

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Province

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Postal code

1587958711

Approval date

2025-08-20, 1404/05/29

Ethics committee reference number

IR.SSRC.REC.1404.069

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description
Dynamic Balance
Timepoint
Before and after intervention
Method of measurement
Dynamic balance will be assessed using the Y-Balance Test, a simplified version of the Star Excursion Balance Test (SEBT). This test evaluates participants' ability to maintain postural control during functional lower-limb movements. The Y-Balance Test has demonstrated high validity and sensitivity for detecting functional asymmetries and predicting lower-limb injury risk. Intra- and inter-rater reliability has been reported with ICC values between 0.85 and 0.91

2

Description
Perceived Self-Efficacy
Timepoint
Before and after intervention
Method of measurement
Participants' perceived self-efficacy will be measured using the General Self-Efficacy Scale (GSES), a 10-item questionnaire rated on a 4-point Likert scale. Higher scores indicate greater self-efficacy. The validated Persian version (Nejati et al., 2005) has acceptable reliability ($\alpha = 0.81$). The scale will be administered pre- and post-intervention in both groups.

3

Description
Motor Performance
Timepoint
Before and after intervention
Method of measurement
Core muscle endurance will be assessed using the McGill protocol, including tests for trunk flexors, extensors, and right and left lateral flexors. Each test will be performed once with a 3-minute rest interval. The maximum time participants can maintain each position will be recorded in seconds. Equipment will include a bench, 60° inclined surface, stopwatch, and straps.

4

Description
Occupational Stress
Timepoint
Before and after intervention
Method of measurement
Occupational stress will be measured using the HSE Stress Questionnaire, which includes 35 items across 7 domains. The tool has demonstrated acceptable reliability (Cronbach's $\alpha = 0.78$)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Aquatic Handpolo was implemented over 8 weeks in a total of 16 sessions (2 sessions per week) in an indoor pool with a constant depth of 1.2–1.5 m, water temperature maintained at 34–36°C, and air temperature at approximately 24°C. Each session consisted of a 10-minute warm-up, 45 minutes of Handpolo practice, and a 5-minute cool-down. Exercise intensity was progressively adjusted according to participants' fitness levels using the Borg Rating of Perceived Exertion scale (RPE = 12–14). Activities were carried out in teams (4 players from each team in the water simultaneously) and included passing, dribbling, moving toward the goal, and scoring. All sessions were supervised by a trained Handpolo coach and a certified lifeguard, with blood pressure and physical condition monitored prior to each session to ensure participants' safety.
Category
Rehabilitation

2

Description
Intervention group 2: Participants in the aquatic exercise group completed an 8-week water-based aerobic training program conducted twice per week, with each 60-minute session consisting of a 10-minute warm-up, 40-minute main exercise, and 10-minute cool-down. The protocol was adapted from the aquatic aerobic program of Yoo et al. (2021) (12) and modified to match the duration and frequency of the present study. The warm-up involved light whole-body movements in water, followed by the main exercise, which included multi-directional dynamic activities such as water jogging, bouncing, jumping jacks, scissors, kicks, rocking horse, leaping, frog jumps, leg curls, twisting heel-toe motions, and ankle mobility drills.
Category
Rehabilitation

3

Description
Control Group (Usual Care with Standard Medications):Participants in the control group will continue their usual daily activities without receiving any structured intervention. They may continue their regular medications for metabolic syndrome as prescribed by their physician, but will not receive any new exercise or aquatic program. All assessments and monitoring (occupational stress, motor fitness, and perceived self-efficacy) will be conducted similarly to the intervention groups to ensure comparable conditions and participant safety.
Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
indoor swimming pool of Urmia Municipality Sports Complex.

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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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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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
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
Provided Someone wants to do a similar research project

From where data/document is obtainable
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What processes are involved for a request to access data/document
Send request by email

Comments