Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing The Effects Of Selected Training With And Without Water Inertia Load On Motor Performance, Gait Kinematic Parameters, Postural sway, And Fear Of Falling In Elderly People With A History Of Falls

Protocol summary

Study aim

This study aims to compare the effects of selected exercises with and without water inertial loading on motor performance, gait kinematic parameters, postural oscillation, motor control, and fear of falling in elderly people with a history of falls. It also examines which type of exercise is more effective in improving these variables

Design

This randomized (blocked) single-blind clinical trial will equally divide 45 elderly people with a history of falls into three groups (unstable load training, fixed load training, and control). The aim of this initial phase study is to investigate the effectiveness of these exercises on balance and motor function with assessors unaware of the grouping

Settings and conduct

This quasi-experimental study compares the effects of aquatic (water bag) and dumbbell exercises on motor function, balance, and fear of falling in 45 elderly people aged 60-75 years with a history of falls. In this 8-week study with 3 groups (aquatic, dumbbell, control) and 2-month follow-up, the assessors and data analysts will be blinded

Participants/Inclusion and exclusion criteria

Physical activity level, general health Ability to walk 6 meters, ability to perform exercises MMSE greater than 24. Musculoskeletal disorders Use of medications that affect the nervous system Neurological, cardiovascular diseases Unstable medical conditions Significant visual, hearing, cognitive disorders

Intervention groups

Training using an unstable load (using a water bag) resulting from the inertia of water. Training using a stable load (dumbbells)

Main outcome variables

Improved core motor function (strength and endurance) Enhanced gait kinematic parameters (e.g., speed, cadence, stability ratio, stride length, step width, double support time) Increased postural sway and motor control (balance, postural control) Reduced fear of falling Decreased overall fall risk

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260516069421N1**
Registration date: **2026-06-03, 1405/03/13**
Registration timing: **prospective**

Last update: **2026-06-03, 1405/03/13**
Update count: **0**

Registration date

2026-06-03, 1405/03/13

Registrant information

Name

Nahid Jalil Piran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3224 9599

Email address

nahid@webmail.gulan.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-10, 1405/03/20

Expected recruitment end date

2026-08-11, 1405/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing The Effects Of Selected Training With And Without Water Inertia Load On Motor Performance, Gait Kinematic Parameters, Postural sway, And Fear Of Falling In Elderly People With A History Of Falls

Public title

"The Effect of Exercises with Unstable and Stable Loads on Balance and Motor Function in Older Adults with a History of Falls"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Has a history of falling Age 60 to 75 years

Exclusion criteria:

Having a cognitive disorder

Age

From **60 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to three groups: control, water-unstable load training, and constant load training in a 1:1:1 ratio. Randomization will be performed in a block-wise manner with block sizes of 3 and 6 using Random Allocation Software (version 2.0). To conceal allocation, opaque, sealed, and numbered envelopes will be used, prepared by an individual independent of the study team, and opened as participants arrive

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is designed as a single-blind (assessor-blinded) trial. Given the nature of the exercise interventions, blinding of participants and exercise instructors is not feasible. However, all outcome assessors (those measuring motor function) remain fully blinded to participant group assignments to prevent assessment bias. Furthermore, the data analyst will also remain blinded to participant group assignments until the completion of the analysis.

Placebo

Not used

Assignment

Parallel

Other design features

"The present study follows a standard design, and its design specifications have been described in detail in previous sections. There are no unique features that require separate explanation."

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University

Street address

8th kilometer of Qazvin Road, Faculty of Physical Education, Rasht.

City

Rasht

Province

Guilan

Postal code

4199843653

Approval date

2026-04-13, 1405/01/24

Ethics committee reference number

IR.GUILAN.REC.1405.006

Health conditions studied

1

Description of health condition studied

Comparing The Effects Of Selected Training With And Without Water Inertia Load On Motor Performance, Gait Kinematic Parameters, Postural sway, And Fear Of Falling In Elderly People With A History Of Falls

ICD-10 code

M63

ICD-10 code description

Disorders of muscle in diseases classified elsewhere

Primary outcomes

1

Description

Motor Performance

Timepoint

One day before, 60 and 120 days later

Method of measurement

Using the Sorenson-Magill test and the Madison ball throw

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: "The training protocol used in this research was designed and implemented based on the neuromotor training model with unstable loads [56]. This approach specifically utilizes the dynamic and inertial properties of water within aqua bags to create controlled perturbations and enhance balance capabilities in older adults. Its primary mechanism involves continuous stimulation of the sensorimotor systems to maintain postural stability when faced with shifts in the center of gravity caused by water movement.For the implementation of neuromotor training with unstable water inertia loads and a two-month follow-up, participants will attend the training hall for 8 weeks (three sessions per week) from 9 to 10 AM. (The first experimental group attends on odd days from 9 to 10 AM). Each training session will last for 60 minutes, consisting of 10 minutes of warm-up (including dynamic stretching), 40 minutes of the training protocol, and 10 minutes of cool-down (including static stretching and walking).The structure of this protocol is divided into two sequential phases to ensure that the principles of progressive overload are applied with priority given to safety and movement quality control. The phases of the protocol and their respective overload levels will be finalized in a pilot test.Phase 1: Adaptation, Baseline Stability, and Safety (Weeks 1-4)The first phase is the foundational stage of the protocol, focusing on adaptation to the equipment and exercises.Primary Goal of Phase 1: Complete body adaptation to the variable weight and dynamics of the aqua bag, improve postural control in standing, strengthen hip movement foundations, and enhance core stability within a limited range of motion.Loading in Phase 1: At the beginning of the phase, the suggested load for most exercises will be considered empty (0 kg) so that the body solely focuses on stabilizing the aqua bag.Safety and Exercise Exclusion: Exercises requiring strong single-leg hip function, such as single-leg stands and overhead presses with the aqua bag, as well as single-leg hip hinges, are excluded in this phase to minimize the risk of injury.Phase 2: Controlled Progression and Overload Application (Weeks 5-8)Transition to Phase 2 will occur after the successful completion of Phase 1 and stabilization of movement quality without any falls or loss of balance.Primary Goal of Phase 2: Gradually and controlledly apply progressive overload, slightly increase the range of motion in foundational movements, and gradually incorporate more complex exercises excluded from Phase 1.Overload Strategy: Progression in Phase 2 includes increasing the following parameters:Increased Duration: Extending the execution time for endurance exercises, such as walking, up to 3 consecutive minutes.Increased Weight: Gradually adding weight to the aqua bag (0.5 kg per week) to core movements after ensuring complete stability.Increased Range/Repetitions: Improving the depth of movements like hip hinges and increasing repetitions.Critical Safety Requirements Throughout the Period:The execution of the protocol is contingent upon constant supervision by a qualified professional. Immediate cessation is required in case of dizziness or severe pain, and regular breathing must be maintained. Changes in training difficulty should be applied to only one parameter per week, and movement quality always takes precedence over increasing weight or repetitions.

Category

Rehabilitation

2

Description

Intervention group2: Intervention group 2: The training protocol used in this study includes a period of training using a stable load (dumbbells) and a two-month follow-up for 8 weeks (three sessions per week, 60 minutes each session). This protocol relies on applying a constant and predictable external load and there are no movements due to environmental instability. In order to perform exercises with a stable load, the subjects participate in training sessions for 8 weeks (three sessions per week). Each session is 60 minutes long, including 10 minutes of warm-up, 40 minutes of performing the training protocol, and 10 minutes of cooling down. The training sessions of the second experimental group are held on even-numbered days from 9 to 10 am in the training hall.

Category

Rehabilitation

3

Description

Control group: The control group does not receive any intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Guilan univercity

Full name of responsible person
Nahid JalilPiran

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Guilan univercity
Full name of responsible person
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Postal code
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Phone
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Email
nahid_jalil@yahoo.com
Web page address
https://www.guilan.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Guilan univercity
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
Guilan univercity
Full name of responsible person
Nahid Jalil Piran
Position
Phd student
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Guilan university

Full name of responsible person
Nahid Jalil Piran

Position
Phd student

Latest degree
Master

Other areas of specialty/work
Sports injuries and corrective exercises

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

Title and more details about the data/document
“De-identified individual participant data will be shared in full. Supporting study documents, such as the study protocol and statistical analysis plan, will also be available upon request.”

When the data will become available and for how long
The 6-month access period begins after the results are published.

To whom data/document is available
Access to the data and documents will be open to all academic and industry researchers interested in using them. Applicants can request access by submitting a formal application, which will be reviewed for eligibility before granting access.

Under which criteria data/document could be used
Use of the data and documents is permitted solely for research and academic purposes, and any commercial use or republication without written permission is prohibited. Applicants must commit to preserving individual anonymity and using the data only in accordance with approved ethical protocols.

From where data/document is obtainable
Applicants can send their requests to nahid_jalil@yahoo.com. After reviewing the request, the necessary information will be sent back through the same channel.

What processes are involved for a request to access data/document
After sending the email, your request will be reviewed and approved within 3 to 5 business days. Once the review process is complete, the data or documents will be sent to you via the same email address.

Comments
No additional information is available.