

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of combined bodyweight strength training on dynamic balance, muscle strength, functional movement stability, and fall risk in older adults in

Protocol summary

Study aim

To evaluate the effects of a combined bodyweight strength training program on dynamic balance, muscle strength, functional movement stability, and fall risk in older adults.

Design

A randomized controlled clinical trial with parallel groups, single-blind (assessor-blinded), conducted in 40 participants

Settings and conduct

The study is conducted at Semnan University of Medical Sciences. After recruitment and screening, participants are randomly allocated to intervention and control groups. Baseline and post-intervention assessments are performed at the university setting. The exercise intervention is implemented over 8 weeks. Outcome assessments are conducted by a trained assessor blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 60 years and older; residence in Semnan city; ability to walk independently (with or without assistive devices); no severe medical conditions limiting physical activity; no cognitive impairment affecting understanding or performing exercise instructions; no participation in any regular or structured exercise program during the past six months; provision of written informed consent. Exclusion criteria: Any medical contraindication to physical activity; history of lower-limb or spinal orthopedic surgery affecting balance or gait.

Intervention groups

Intervention group: Combined bodyweight strength training for 8 weeks, 2 sessions per week (≥ 48 hours between sessions), 60 minutes per session, supervised by the researcher; including 5–10 min warm-up, lower-limb and core strength exercises with progressive overload, and 5–10 min cool-down. Control group: No

structured exercise intervention; continuation of usual daily activities throughout the study period.

Main outcome variables

Static balance (force plate); dynamic balance (10-m walk); knee muscle strength (peak torque, Biodex); gait stability (gait parameters).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251214068338N1**

Registration date: **2026-02-06, 1404/11/17**

Registration timing: **retrospective**

Last update: **2026-02-06, 1404/11/17**

Update count: **0**

Registration date

2026-02-06, 1404/11/17

Registrant information

Name

Bahar Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 999 181 5566

Email address

bhrjfri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-06, 1404/10/16

Expected recruitment end date

2026-01-10, 1404/10/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of combined bodyweight strength training on dynamic balance, muscle strength, functional movement stability, and fall risk in older adults in

Public title
Bodyweight exercise for fall prevention in older adults

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age \geq 60 years Ability to walk independently (with or without assistive devices) No history of acute cardiovascular disease, neurological, neuromuscular, or orthopedic conditions that would preclude participation in physical activity No severe cognitive impairment that would interfere with understanding or performing exercise instructions No participation in any regular or structured exercise program within the past six months
Exclusion criteria:
Any medical contraindication to physical activity or lack of medical clearance to participate. History of lower-limb or spinal orthopedic surgery affecting balance or gait.

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The unit of randomization in this study is the individual. After initial screening, confirmation of eligibility, and obtaining written informed consent, participants are randomly allocated to the intervention and control groups. Participants are assigned to the intervention and control groups using block randomization with a fixed block size of 4 and a 1:1 allocation ratio. The random allocation sequence is generated by an independent researcher using SPSS software (version 26). To ensure allocation concealment, the allocation sequence is placed in sequentially numbered, opaque, sealed envelopes. After final enrollment of each participant, the corresponding envelope is opened in numerical order and the group assignment is revealed. Random sequence generation and group allocation are performed by a researcher independent of the intervention delivery and outcome assessment.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be conducted as a single-blind trial, in which the outcome assessors will be blinded to group allocation. Due to the nature of the exercise intervention, blinding of participants and intervention providers is not feasible.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Allameh Tabataba'i University

Street address
Allameh Tabataba'i University (Central Campus), Dehkadeh Olympic Blvd., Shahid Hemmat Expressway Intersection Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1489683991

Approval date
2025-12-13, 1404/09/22

Ethics committee reference number
IR.ATU.REC.1404.144

Health conditions studied

1

Description of health condition studied
Balance impairment and functional mobility limitation in older adults

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Static balance

Timepoint
Outcome measures are assessed at two time points: 1. Baseline (pre-intervention) 2. Post-intervention (after completion of the 8-week training program)

Method of measurement

Static balance is measured using the Single-Leg Stance Test, assessed with a Force Plate.

2

Description

Dynamic balance

Timepoint

Outcome measures are assessed at two time points: 1. Baseline (pre-intervention) 2. Post-intervention (after completion of the 8-week training program)

Method of measurement

Dynamic balance is evaluated using the 10-Meter Walk Test, assessed with a Force Plate.

3

Description

lower-limb muscle strength

Timepoint

Outcome measures are assessed at two time points: 1. Baseline (pre-intervention) 2. Post-intervention (after completion of the 8-week training program)

Method of measurement

Muscle strength of the knee flexor and extensor muscles is measured using a Biodex System 3 isokinetic dynamometer.

4

Description

functional movement stability

Timepoint

Outcome measures are assessed at two time points: 1. Baseline (pre-intervention) 2. Post-intervention (after completion of the 8-week training program)

Method of measurement

.Functional movement stability is assessed using a motion analysis system during the performance of the 10-Meter Walk Test

Secondary outcomes

1

Description

Fall risk

Timepoint

Outcome measures are assessed at two time points: 1. Baseline (pre-intervention) 2. Post-intervention (after completion of the 8-week training program)

Method of measurement

Falls Efficacy Scale-International (FES-I)

Intervention groups

1

Description

Intervention group: Participants in the intervention group will take part in a combined bodyweight strength training program. The program will be conducted for 8 weeks,

with two sessions per week, and each session will last approximately 60 minutes. The training intervention focuses on strengthening the lower limb and core muscles and is designed to improve functional abilities related to balance and movement stability. Each training session consists of three components: 1. Warm-up (approximately 10 minutes), including light activities and stretching exercises; 2. Main training phase (approximately 40 minutes), consisting of bodyweight strength exercises targeting the lower limbs and core muscles, as well as functional balance-related exercises; 3. Cool-down (approximately 10 minutes), including gentle stretching exercises. Training sessions are delivered according to a structured exercise program and are performed in a group-based format. Exercise intensity and difficulty are progressively adjusted according to participants' abilities. All exercises are conducted with careful consideration of older adults' safety, and all training sessions are carried out under the direct supervision of the researcher or a trained instructor.

Category

Rehabilitation

2

Description

Control group: Participants in the control group do not receive any structured exercise intervention during the study period and continue their usual daily activities. No specific exercise program or physical activity recommendations are provided, and participants are instructed to maintain their habitual level of physical activity throughout the study

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation research center

Full name of responsible person

Bahar Jafari

Street address

Neuromuscular rehabilitation research center; Ghods Boulevard,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Allameh Tabataba'i University

Full name of responsible person

Dr. Mandana Tishehyar

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Allameh Tabataba'i University (Central Campus),
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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

Allameh Tabataba'i University

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

Allameh Tabataba'i University

Full name of responsible person

Bahar Jafari

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Geriatrics

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Position

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Other areas of specialty/work

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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

Due to the limited sample size and the nature of functional and performance-related data in older adults, there is a potential risk of indirect participant identification. Therefore, to ensure data confidentiality and comply with ethical considerations, there is no plan

to share individual participant data (IPD).

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