

# 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 ( $\geq 48$  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**  
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**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,

#### **City**

Semnan

#### **Province**

Semnan

#### **Postal code**

3519698375

#### **Phone**

+98 23 3332 8502

#### **Email**

bhrjfri@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Allameh Tabataba'i University

**Full name of responsible person**

Dr. Mandana Tishehyar

**Street address**

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

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**Phone**

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**Email**

mandana.tishehyar@gmail.com

**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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## Person responsible for scientific inquiries

#### Contact

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Allameh Tabataba'i University

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

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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