

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### The Effect of an 8-week Exercise Program Focused on Anticipatory postural Adjustments on Static and Dynamic balance in pre-fatigue and post-fatigue Elderly women

#### Protocol summary

##### Study aim

Investigating the Effect of Balance Exercises Focused on Anticipatory Postural Adjustments on Motor Performance, Quality of Life, and Balance Confidence in Older Women, Before and After Fatigue

##### Design

This study is a quasi-experimental pretest-posttest design with a control group. Participants were recruited through voluntary convenience sampling and, after baseline assessments, were allocated to intervention and control groups using matched-pair randomization generated by Random Allocation Software.

##### Settings and conduct

This study will be conducted on older women over 60 years of age residing in Isfahan, Iran. Participants will be recruited through voluntary convenience sampling from the elderly female population of Isfahan. After baseline assessments, participants will be allocated into intervention and control groups using matched-pair randomization. All outcomes were assessed in both groups before and after fatigue.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include age  $\geq 60$  years, completion of informed consent, and absence of medical or ethical contraindications to participate in exercise. Exclusion criteria include failure to complete the assessments, absence from more than one-third of the 8-week training sessions (more than 8 sessions), or presence of lower limb length discrepancy.

##### Intervention groups

Intervention group: Older women  $>60$  years performing 8 weeks of balance training focused on anticipatory postural adjustments. Control group: Older women ( $>60$  years) receiving no intervention during the study period.

##### Main outcome variables

The primary outcome is the change in static balance (Functional Reach Test), dynamic balance (Timed Up and

Go test), and quality of life (SF-36 questionnaire) in older women before and after the training intervention and under pre- and post-fatigue conditions.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20251121068066N10**

Registration date: **2026-05-04, 1405/02/14**

Registration timing: **prospective**

Last update: **2026-05-04, 1405/02/14**

Update count: **0**

##### Registration date

2026-05-04, 1405/02/14

##### Registrant information

##### Name

Atiyeh Hesari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 915 718 4680

##### Email address

articlelab2025ir@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2026-05-31, 1405/03/10

##### Expected recruitment end date

2026-07-23, 1405/05/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of an 8-week Exercise Program Focused on Anticipatory postural Adjustments on Static and Dynamic balance in pri-fatigue and post-fatigue Elderly women

**Public title**

The Effect of an 8-week Exercise Program Focused on Anticipatory postural Adjustments on Static and Dynamic balance in pri-fatigue and post-fatigue Elderly women

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

No medical or ethical contraindications for participating in the exercises (including visual, auditory, cardiopulmonary, communicative, etc.) Minimum age of 60 years Completion of the informed consent form

**Exclusion criteria:**

Absence of leg length discrepancy Failure to complete the tests and participate in the training sessions (The training program is designed for an 8-week period with 3 sessions per week, totaling 24 one-hour sessions. Participants who miss more than one-third of the sessions—i.e., 8 sessions—for any reason will be excluded from the study.)

**Age**

From **60 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The participants were first matched based on weight and height. Each matched pair was then randomly allocated to one of the two groups using block randomization and random sequences generated by the Random Allocation Software. The allocation process was conducted by an independent individual to minimize allocation bias.

**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**

Research Ethics Committee, Islamic Azad University, Isfahan Branch (Khorasgan)

**Street address**

Jey Sharqi Street, Arghavanieh, Daneshgah Boulevard, Islamic Azad University, Isfahan Branch (Khorasgan), Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

39998-81551

**Approval date**

2024-08-27, 1403/06/06

**Ethics committee reference number**

IR.IAU.KHUISF.REC.1403.318

**Health conditions studied**

**1**

**Description of health condition studied**

Age-related balance impairment in older women

**ICD-10 code**

**ICD-10 code description**

Age-related balance impairment in older women

**Primary outcomes**

**1**

**Description**

Static Balance: The ability to maintain static balance in older women.

**Timepoint**

Before the start of the intervention and after the 8-week intervention period, assessed under both pre-fatigue and post-fatigue conditions.

**Method of measurement**

Assessed using the Functional Reach Test. The maximum forward reach distance without stepping is measured, and the difference between the initial and maximal reach positions is recorded in centimeters.

**2**

**Description**

Dynamic Balance:The ability to maintain balance during movement and mobility.

**Timepoint**

Before the intervention and after completion of the intervention, under both pre-fatigue and post-fatigue conditions.

**Method of measurement**

Assessed using the Timed Up and Go (TUG) test. The time required to stand up from a chair, walk 3 meters,

turn, walk back, and sit down is recorded in seconds.

### 3

#### **Description**

Quality of Life: Health-related quality of life in older women.

#### **Timepoint**

Before the intervention and after the completion of the 8-week intervention.

#### **Method of measurement**

Assessed using the validated SF-36 questionnaire, which evaluates multiple domains of quality of life and provides a score ranging from 0 to 100.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control group: Older women (>60 years) receiving no intervention during the study period.

#### **Category**

Treatment - Other

### 2

#### **Description**

Intervention group: Elderly women aged over 60 years participated in an 8-week exercise program focusing on enhancing the anticipatory postural adjustment mechanism of balance control. Training was performed three sessions per week, with each session lasting 60 minutes (10 minutes warm-up, 40 minutes main exercises, and 10 minutes cool-down). The main exercises consisted of ball throwing and catching tasks with progressive manipulation of variables such as throwing distance, direction, type of throw, ball weight, and body posture (changes in base of support). The program was progressively designed to challenge anticipatory balance mechanisms and improve motor function and balance control in older adults.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Novin Clinic

##### **Full name of responsible person**

Sarah Bayat

##### **Street address**

4th Floor, Omits Building, Bozorgmehr St., between Rokn-od-Dowleh St. and Hasht Behesht Crossroad, Isfahan, Iran

#### **City**

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#### **Province**

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#### **Postal code**

8158867791

#### **Phone**

+98 31 3268 7420

#### **Email**

sarabayathealth031@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University, Isfahan Branch (Khorasgan)

##### **Full name of responsible person**

Gholamreza Talebi

##### **Street address**

Jey Sharqi Street, Arghavanieh, Daneshgah Boulevard, Islamic Azad University, Isfahan Branch (Khorasgan), Isfahan

##### **City**

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##### **Phone**

+98 31 3500 2364

##### **Email**

khosrojalali@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Islamic Azad University, Isfahan Branch (Khorasgan)

#### **Proportion provided by this source**

50

#### **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**

Islamic Azad University, Isfahan Branch (Khorasgan)

##### **Full name of responsible person**

Hamed Arghavani

##### **Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Corrective movements

**Street address**

Jey Sharqi Street, Arghavanieh, Daneshgah  
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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University, Isfahan Branch (Khorasgan)

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Hamed Arghavani

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Islamic Azad University, Isfahan Branch (Khorasgan)

**Full name of responsible person**

Hamed Arghavani

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available