

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of perturbation training on kinetic factor, EMG, functional movement tests, quality of life and fear of falling in elderly people

#### Protocol summary

##### Study aim

The purpose is to provide a special balance training program for improving balance and fall prevention in elderly.

##### Design

In this experimental study, 60 elderly men with a history of falls were randomly assigned to 3 groups of anticipatory postural adjustment training, current balance training, and the control group, and the training groups were trained for 8 weeks. three arm parallel group randomized trial.

##### Settings and conduct

In this study, after grouping the samples randomly, two training groups individually performed their exercises under the supervision of the instructor at the sports club.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria were included the men aged between 65 to 80 years, having the ability to walk without help, having the normal or corrected vision and hearing and positive response to the whole question of Physical Activity Readiness Questionnaire (PARQ). Exclusion criteria were included having abnormalities in the foot, score of less than 24 out of 30 on Mini-Mental State Examination.

##### Intervention groups

First intervention group: Apply a anticipatory postural adjustment focused training program. Second intervention group: Applying the current balance training program for the elderly Control group: no intervention

##### Main outcome variables

static balance, dynamic balance, center of pressure displacement, onset muscle contraction, balance confidence and quality of life in the elderly.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180618040132N1**

Registration date: **2018-09-01, 1397/06/10**

Registration timing: **retrospective**

Last update: **2018-09-01, 1397/06/10**

Update count: **0**

##### Registration date

2018-09-01, 1397/06/10

##### Registrant information

###### Name

Hamed Arghavani

###### Name of organization / entity

University of isfahan

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3529 1225

###### Email address

h.arghavani@spr.ui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-22, 1396/11/02

##### Expected recruitment end date

2018-02-24, 1396/12/05

##### Actual recruitment start date

2018-01-22, 1396/11/02

##### Actual recruitment end date

2018-02-24, 1396/12/05

##### Trial completion date

empty

##### Scientific title

Effect of perturbation training on kinetic factor, EMG, functional movement tests, quality of life and fear of falling in elderly people

**Public title**

The Effect of balance Exercises Training on Preventing Falling in the Elderly

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

men aged between 60 to 80 years, having the ability to walk without help having the normal or corrected vision and hearing positive response to the whole question of Physical Activity Readiness Questionnaire

**Exclusion criteria:**

having abnormalities in the foot score of less than 24 out of 30 on Mini-Mental State Examination

**Age**

From **60 years** old to **80 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After considering the criteria of the research, the samples were randomly assigned with the help of a random number table.

**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**

Institutional Review Board of Isfahan University of Medical Sciences

**Street address**

University of Medical Sciences, Hezarjerib street, Isfahan

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**Approval date**

2018-03-07, 1396/12/16

**Ethics committee reference number**

IR.UI.REC.1396.065

**Health conditions studied****1****Description of health condition studied**

elderly (fall)

**ICD-10 code**

W01

**ICD-10 code description**

Fall on same level from slipping, tripping and stumbling

**Primary outcomes****1****Description**

Quality of life

**Timepoint**

First and after 12 weeks of practice

**Method of measurement**

SF36 survey

**2****Description**

balance confidence

**Timepoint**

First and after 12 weeks of practice

**Method of measurement**

Activities-Specific Balance Confidence scale

**3****Description**

center of pressure displacement

**Timepoint**

First and after 12 weeks of practice

**Method of measurement**

foot scan system was used

**4****Description**

Electromyography

**Timepoint**

First and after 12 weeks of practice

**Method of measurement**

ME 6000 Electromyography

**5****Description**

dynamic balance

**Timepoint**

First and after 12 weeks of practice

**Method of measurement**

Dynamic balance of subjects was measured by time up and go test.

## 6

### **Description**

static balance

### **Timepoint**

First and after 12 weeks of practice

### **Method of measurement**

with functional reach test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Control group: No practice and doing everyday activities

#### **Category**

N/A

### 2

#### **Description**

First intervention group: anticipatory postural adjustment training group. they performed 8 weeks of APA-focused training (catching and throwing a ball) three sessions per week and each session one hour. The exercise protocol included 10 minutes of warm-up, 40 minutes of the main training and 10 minutes to cool-down. Variables such as the number (low/high), distance (near/far), the direction (inside the chest/overhead), the type of catching (ground/air), the weight and type of ball (light/heavy, volleyball, basketball, medicine ball), how to sit (fixed chair, movable chair and Swiss Ball), how to stand (large base of support/small base of support), and walking (slow/fast) during the program were manipulated to increase exercise pressure and exercise variation.

#### **Category**

Rehabilitation

### 3

#### **Description**

Second intervention group: current balance training group. they performed 8 weeks of training, three sessions per week and each session one hour. The exercise protocol included 10 minutes of warm-up, 40 minutes of the main training and 10 minutes to cool-down. Variables such as Joints flexibility exercises, muscle strength exercises, balance exercises and walking were modified during the program to increase exercise pressure and exercise variation.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

university of isfahan

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

Hamed Arghavani

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Hezarjerib street, university of Isfahan

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

The University of Isfahan

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

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##### **Street address**

, Deputy of Research and Technology of Isfahan

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##### **Email**

rokni@sci.ui.ac.ir

#### **Grant name**

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

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

Yes

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

The University of Isfahan

#### **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**

The University of Isfahan

**Full name of responsible person**

Hamed Arghavani

**Position**

PhD Candidate of Corrective Exercise and Sport Injury

**Latest degree**

Master

**Other areas of specialty/work**

Sport Medicine

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**Full name of responsible person**

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

University of isfahan

**Full name of responsible person**

Hamed Arghavani

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

All data can be shared after unrecognizable people.

**When the data will become available and for how long**

Start the access period from 1 month after printing results up to 1 year.

**To whom data/document is available**

Only researchers working in academic and scientific institutions can access the data.

**Under which criteria data/document could be used**

Any use for scientific use and observance of ethics is permissible.

**From where data/document is obtainable**

Faculty of physical education, University of Isfahan, Hamed Arghavani hamed\_arghavani1365@yahoo.com +98 9359799744

**What processes are involved for a request to access data/document**

After filing an application by email or contact, data will be sent within a week.

**Comments**