

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of single and dual-task balance and gait training on gait harmonic ratio and functional balance in older adults

#### Protocol summary

##### Study aim

Study and compare the effects of single and dual-task balance and gait training on gait harmonic ratio and functional balance in older adults and taking advantage of the outcomes to improve gait and balance and decrease the risk of falling

##### Design

A randomized, single-blind clinical trial with a parallel group design. The subjects are randomized with Permuted Block into three groups (two interventional and one control groups).

##### Settings and conduct

Subjects are recruited from the older adults who refer to Jahandidegan Center in Shiraz city. the study is single-blinded and the assessor of balance and gait outcome is unaware of subjects allocation to the groups.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: age of 65 years old or more, obtain score 24 or more out of 30 in MMSE and score lower than 7 in GDS, the ability to walk without assistive devices for at least 20 meters exclusion criteria: neurologic, orthopedic and musculoskeletal disorders that can affect gait, history of head injury, cardiovascular and respiratory disorders, chest pain with activity, cancer, history of surgery in lower limbs, spinal column or head during the past 6 months and the need to use Oxygen capsule

##### Intervention groups

group 1: single-task training (6 weeks of single-task balance and gait training) group 2: dual-task training (6 weeks of dual-task balance and gait training) group 3: control group (without intervention)

##### Main outcome variables

Fullerton Advanced Balance scale (FAB); Timed Up & Go test; Activities-specific Balance Confidence. gait performance under single- and dual-task conditions

#### General information

##### Reason for update

The actual recruitment dates were added.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180429039470N1**

Registration date: **2018-06-17, 1397/03/27**

Registration timing: **prospective**

Last update: **2020-12-13, 1399/09/23**

Update count: **2**

##### Registration date

2018-06-17, 1397/03/27

##### Registrant information

##### Name

Reza Salehi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 8051

##### Email address

salehi.re@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-12, 1397/03/22

##### Expected recruitment end date

2018-08-21, 1397/05/30

##### Actual recruitment start date

2018-06-30, 1397/04/09

##### Actual recruitment end date

2018-07-16, 1397/04/25

##### Trial completion date

2018-09-23, 1397/07/01

## Scientific title

Effects of single and dual-task balance and gait training on gait harmonic ratio and functional balance in older adults

## Public title

Effects of gait and balance training on gait and balance in older adults

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

age 65 years old or more obtain score 24 or more out of 30 in MMSE obtain score lower than 7 in GDS the ability to walk without assistive devices for at least 20 meters

### Exclusion criteria:

neurologic disorders including Parkinson's, MS, stroke, peripheral neuropathy that can affect gait performance specific orthopedic and musculoskeletal disorders including knee replacement or fracture history of head injury cardiovascular and respiratory disorders severe chronic pain and chest pain with activity cancer history of surgery in lower limbs, spinal column or head during the past 6 months the need to use Oxygen capsule

## Age

From **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Investigator
- Outcome assessor

## Sample size

Target sample size: **69**

Actual sample size reached: **69**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Permuted Block Randomization Randomization was achieved with an online randomization application to provide random permuted blocks with a block size of 6.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The assessor of balance and gait outcome was unaware of subjects allocation to the groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

#### Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan St., Ahvaz

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

15794 - 61357

#### Approval date

2018-06-09, 1397/03/19

#### Ethics committee reference number

IR.AJUMS.REC.1397.212

## Health conditions studied

## 1

### Description of health condition studied

gait and balance in older adults

### ICD-10 code

R26.89

### ICD-10 code description

Other abnormalities of gait and mobility

## Primary outcomes

## 1

### Description

Gait performance

### Timepoint

Baseline, at the end of the sixth week and 3 months after the trial

### Method of measurement

Gait harmonic ratio

## Secondary outcomes

## 1

### Description

balance performance

### Timepoint

Baseline, at the end of the sixth week and 3 months after the trial

### Method of measurement

Fullerton advanced balance scale (FAB)

## 2

### Description

Functional activity

### Timepoint

baseline, at the end of the sixth week and 3 months after the trial

**Method of measurement**

Timed Up & Go test

**3****Description**

Balance confidence

**Timepoint**

Baseline, at the end of the sixth week and 3 months after the trial

**Method of measurement**

Activities-specific Balance Confidence scale

**Intervention groups****1****Description**

Intervention group 1: single-task gait and balance training This group will receive 6 weeks of balance training, 3 sessions per week. Each session will take 40-60 minutes and each exercise will repeat 5-8 times. Each exercise takes 30 seconds, with a 15-second rest between exercises.

**Category**

Rehabilitation

**2****Description**

Intervention group 2: dual-task gait and balance training This group will receive 6 weeks of balance training concomitant with a cognitive task (including naming, remembering and backward counting) , 3 sessions per week. Each session will take 40-60 minutes and each exercise will repeat 5-8 times. Each exercise takes 30 seconds, with a 15-second rest between exercises.

**Category**

Rehabilitation

**3****Description**

Control group: without intervention This group will receive no intervention during the 6-week period of the trial.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shiraz Jahandidegan Center

**Full name of responsible person**

Roya Razavi

**Street address**

Kholdebarin Park, Beesat St., Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code****Phone**

+98 71 3647 5010

**Email**

razaviroya41@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan St., Ahvaz

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Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Phone**

+98 61 3336 2414

**Email**

Badavi-m@ajums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz University of Medical Sciences

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Reza Salehi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

School of Rehabilitation Sciences; Madadkaran Aly;  
Shahnazari Av.; Madar Sq.; Tehran

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Tehran

**Province**

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**Postal code**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Reza Salehi

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Ph.D.

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

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**Full name of responsible person**

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**Email**

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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**

The data of the participant alone is useless.

**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**

The results of primary outcomes will be shared.

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

two months after the publication of the results.

**To whom data/document is available**

academic researchers

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

Once accessed, individuals have the right to use the study protocol for rehabilitation purposes.

**From where data/document is obtainable**

Samira Javadpour will be responsive through email.  
samira.javadpour@yahoo.com

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

After receiving the request and mentioning the reasons for the request, the data will be answered within a maximum of one month.

**Comments**