

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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

City

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

City

Tehran

Province

Tehran

Postal code

۱۳۴۸۷ - ۱۵۴۵۹

Phone

+98 21 2222 7124

Email

salehi200@yahoo.com

Person responsible for scientific 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

City

Tehran

Province

Tehran

Postal code

1348715459

Phone

+98 21 2222 7124

Email

salehi200@yahoo.com

Person responsible for updating data

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

City

Tehran

Province

Tehran

Postal code

1348715459

Phone

+98 21 2222 7124

Email

salehi200@yahoo.com

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