Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Effects of Vestibular Training on Balance Performance and Sensory Reweighting in Older Women

Protocol summary

Study aim

This study aimed to evaluate the effects of vestibular rehabilitation training on balance performance and sensory reweighting in older women.

Design

Randomized, parallel-group, single-blind controlled clinical trial with pretest-posttest assessment.

Settings and conduct

The study was conducted at the biomechanics laboratory of Yazd University, Iran. Participants attended baseline and post-intervention assessment sessions. Balance performance was assessed using a force plate under different sensory conditions before and after the 8-week intervention period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: female participants aged 55 years and older; no history of falls or musculoskeletal injury within the previous six months; no history of lower-limb surgery; absence of neurological, musculoskeletal, or systemic disorders affecting gait or balance; ability to participate independently in exercise sessions. Exclusion criteria: regular participation in structured physical activity programs; uncontrolled hypertension; history of severe chest pain, myocardial infarction, or type 1 diabetes; cognitive or psychological disorders affecting functional performance.

Intervention groups

Intervention group: Participants performed supervised vestibular rehabilitation exercises three sessions per week for eight weeks, including eye, head, shoulder, and balance exercises under different sensory conditions. Control group: Participants continued their usual daily activities and did not receive any structured intervention during the study period.

Main outcome variables

Balance index; sensory system contributions to postural control including visual, vestibular, and proprioceptive dependence

General information

Reason for update

Acronym

VRT-Balance

IRCT registration information

IRCT registration number: **IRCT20251115068000N1**
Registration date: **2026-05-19, 1405/02/29**
Registration timing: **retrospective**

Last update: **2026-05-19, 1405/02/29**
Update count: **0**

Registration date

2026-05-19, 1405/02/29

Registrant information

Name

Mostafa Haj Lotfalian

Name of organization / entity

Yazd University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-30, 1403/09/10

Expected recruitment end date

2025-02-28, 1403/12/10

Actual recruitment start date

2024-11-30, 1403/09/10

Actual recruitment end date

2025-02-28, 1403/12/10

Trial completion date

2025-02-28, 1403/12/10

Scientific title
Effects of Vestibular Training on Balance Performance and Sensory Reweighting in Older Women

Public title
Vestibular Training for Balance Improvement in Older Women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Female participants aged 55 years and older No history of falls or musculoskeletal injury within the previous six months No history of lower-limb surgery No neurological, musculoskeletal, or systemic disorders affecting gait or balance Ability to participate independently in exercise sessions Written informed consent provided

Exclusion criteria:
Regular participation in structured physical activity programs (two or more sessions per week) Uncontrolled hypertension (blood pressure >160/100 mmHg) History of severe chest pain, myocardial infarction, or type 1 diabetes Cognitive or psychological disorders affecting functional performance Inability to complete the intervention or assessment sessions

Age
From **55 years** old to **72 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly assigned in a 1:1 ratio to either the vestibular rehabilitation training (VRT) group or the control group using a computer-generated randomization sequence created by Random Allocation Software. The sequence was prepared by an independent researcher who was not involved in participant assessment or intervention administration. Allocation concealment was ensured using sealed opaque sequentially numbered envelopes (SNOSE). Each envelope was opened sequentially only after baseline assessment and participant enrollment. The unit of randomization was the individual participant.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study was designed as a single-blind trial in which the outcome assessor was blinded to group allocation. Data analysis was also performed using coded group labels so that the data analyst was unaware of group assignments. Due to the nature of the exercise intervention, blinding of participants and researchers was not feasible.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of yazd university

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Safaeia, Daneshgah Blvd

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یزد

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Yazd

Postal code
۸۹۱۵۸۱۸۴۱۱

Approval date
2024-11-27, 1403/09/07

Ethics committee reference number
IR.YAZD.REC.1403.079

Health conditions studied

1

Description of health condition studied
Imbalance

ICD-10 code
R42

ICD-10 code description
Dizziness and giddiness

2

Description of health condition studied
Imbalance

ICD-10 code
R26.89

ICD-10 code description
Other abnormalities of gait and mobility

Primary outcomes

1

Description
Body sway based on center of pressure displacement during different balance conditions in older women.

Timepoint
Measurements were performed at two time points: at baseline (pre-intervention) and after completion of the 8-week vestibular rehabilitation training program (post-

intervention).

Method of measurement

Balance index was measured using a force plate system by recording center of pressure (COP) displacement in anterior–posterior and mediolateral directions at a sampling frequency of 400 Hz. The standard deviation of COP displacement was calculated as the balance index.

2

Description

Sensory reweighting index based on changes in body sway during different balance conditions in older women.

Timepoint

Measurements were performed at two time points: before the intervention (pre-test) and after completion of the 8-week vestibular rehabilitation training program (post-test).

Method of measurement

The sensory reweighting index was calculated using force plate data by analyzing changes in center of pressure fluctuations across different balance conditions. The least squares method implemented in MATLAB software was used to estimate the contribution of sensory systems to balance control.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vestibular rehabilitation training was performed for 8 weeks, three sessions per week, under the supervision of a physiotherapist. Each session included eye, head, and shoulder movement exercises performed in supine, sitting, and standing positions, along with balance-related activities including sit-to-stand transitions, ball throwing and catching, and walking with eyes closed on flat surfaces and stairs. Each exercise was performed in two 30-second sets with 30 seconds of rest between sets. Exercise intensity was progressively increased throughout the intervention period.

Category

Rehabilitation

2

Description

Control group: Participants in the control group did not receive vestibular rehabilitation training or any structured exercise program during the 8-week study period and continued their usual daily activities. Balance and sensory reweighting assessments were performed at the same time points as in the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Biomechanics Laboratory, Yazd University

Full name of responsible person

Mostafa Haj Lotfalian

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Daneshgah Blvd, Biomechanics Laboratory, Faculty of Psychology and Educational Sciences, Yazd University, Yazd, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University

Full name of responsible person

Mohammad Taghi Sadeghi

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https://yazd.ac.ir/offices/research/people/head

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University

Full name of responsible person

Mostafa Haj Lotfalian

Position

Assistant porfessor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Biomechanics

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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

Data related to the study protocol and statistical analysis plan may be available from the corresponding author upon reasonable request after publication of the study results. Individual participant data, informed consent forms, and identifiable information will not be publicly shared to protect participant confidentiality.

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

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

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

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study protocol and statistical analysis plan related to the randomized controlled trial investigating the effects of vestibular rehabilitation training on balance performance and sensory reweighting in older women.

When the data will become available and for how long

The study protocol and statistical analysis plan will be available upon reasonable request after publication of the study results for up to five years.

To whom data/document is available

Researchers and academic investigators with scientific interest in the study topic.

Under which criteria data/document could be used

The documents may be used for academic and scientific purposes only. Requests should include a clear scientific rationale and must comply with ethical and confidentiality regulations.

From where data/document is obtainable

Requests should be directed to the corresponding author via email.

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

Submitted requests will be reviewed by the research team. If approved, the requested documents will be shared electronically within a reasonable period of time.

Comments