Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of three Conventional, Virtual Reality and Artificial intelligence balance training programs on balance and gait of elderly people

Protocol summary

Study aim

This study will be conducted with the aim of Comparison of three Conventional, Virtual Reality and Artificial intelligence balance training programs on balance and gait of elderly people.

Design

The present study is a stratified trial (male and female), with equal randomization (one-to-one ratio), in parallel, and includes a pretest/posttest design with a two-month follow-up that will be conducted on 48 elderly residents of a nursing home. Participants will be randomly divided into three groups: artificial intelligence exercises (n=16), virtual reality (n=16), and Conventional balance exercises (n=16).

Settings and conduct

The exercises in the intervention groups are performed for 8 weeks, 3 sessions per week for one hour, every other day. To assess the balance and gait of the subjects, balance indices (standing balance test, single-leg standing, rise and go time, functional reach, activity-specific balance confidence scale) and gait indices (gait speed, gait cadence, and gait stability ratio) are used.

Participants/Inclusion and exclusion criteria

Inclusion criteria included: 1- Obtaining informed consent from the elderly to participate in the study 2- Age range between 60-75 years 3- Mini-Mental State Examination (MMSE) score of 24 or higher 4- Ability to walk independently for at least 6 meters without using an assistive device and exclusion criteria included: 1- Having a serious visual or hearing impairment 2- Participants with significant cognitive impairment 3- Participants with unstable medical conditions (such as recent myocardial infarction, uncontrolled diabetes, fractures in the lower extremities) in the past 6 months.

Intervention groups

Intervention groups: artificial intelligence, virtual reality, and Conventional balance exercises

Main outcome variables

Balance situation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041645N2**
Registration date: **2025-04-18, 1404/01/29**
Registration timing: **prospective**

Last update: **2025-04-18, 1404/01/29**
Update count: **0**

Registration date

2025-04-18, 1404/01/29

Registrant information

Name
Saaed Yousefi Babadi
Name of organization / entity
The University of Guilan
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-20, 1404/01/31

Expected recruitment end date

2025-06-24, 1404/04/03

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of three Conventional, Virtual Reality and Artificial intelligence balance training programs on balance and gait of elderly people

Public title
The effect of artificial intelligence exercises on the balance of the elderly
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Receiving the consent of the elderly to participate in the study The age range between 60-75 years Mini-Mental State Examination (MMSE) score of 24 or higher Ability to walk independently for at least 6 meters without using an assistive device
Exclusion criteria:
Serious visual or hearing impairment Participants with significant cognitive impairment Participants with unstable medical conditions (such as recent myocardial infarction, uncontrolled diabetes, fractures in the lower extremities) in the past 6 months
Age
From **60 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
University of Guilan (Research Ethics Committee)
Street address
5th Kilometer of Persian Gulf Highway, Rasht, Guilan Province, Iran
City
Rasht
Province
Guilan
Postal code
۴۱۹۹۶۱۳۷۷۶
Approval date
2024-12-29, 1403/10/09
Ethics committee reference number
IR.GUILAN.REC.1403.182

Health conditions studied

1

Description of health condition studied
balance
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Balance is the ability to maintain the body’s center of mass over its base of support.
Timepoint
One week before and after carrying out training interventions
Method of measurement
Balance indices (standing balance test, single-leg standing test, stand-to-walk test, functional reach test, and activity-specific balance confidence scale) are used to assess the subjects' balance.

2

Description
Gait indices refer to a set of parameters used to evaluate an individual's gait pattern and performance.
Timepoint
One week before and after carrying out training interventions
Method of measurement
Gait tests (gait speed, gait cadence, and gait stability ratio) are used to evaluate gait indices.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Balance training with virtual reality (VR) has been proposed as an alternative to traditional balance training, where the technology simulates activity

to promote motor learning and transfer to real-world tasks. (The VR training group) conducted training sessions using an Xbox Kinect, which includes a Kinect sensor and console. The sensor was an infrared camera that detected the player's position and movements without the need for a special controller, and with it the subject controlled various games.

Category
Rehabilitation

2

Description
Intervention group: The AI training program used an AI conversational platform to deliver balance and gait exercises. The program consisted of a series of interactive conversations between subjects and an AI trainer, with exercises tailored to the needs and goals of the participants. The conversations instructed the AI platform to design an 8-week exercise program for healthy individuals aged 60 to 75 to improve their physical performance based on the principles of exercise prescription for the elderly.

Category
Rehabilitation

3

Description
Intervention group: Conventional balance exercises include exercises with reduced support, closing the eyes, increasing movement speed, and adding appropriate movements.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Golden years

Full name of responsible person
Mohammad Ali Alian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Guilan

Full name of responsible person
Mansoureh Jahantab

Street address
Persian Gulf Highway (5 km on Qazvin Road) Rasht, Gilan

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Grant name

Grant code / Reference number

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

Title of funding source
University of Guilan

Proportion provided by this source
5

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
University of Guilan

Full name of responsible person
Saaed Yousefi Babadi

Position
PhD student in Sport Injuries & Corrective Exercises, Faculty of Physical Education and Sport Scienc

Latest degree
Master

Other areas of specialty/work
Geriatrics

Street address
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University

Full name of responsible person

Saeed Yousefi Babadi

Position

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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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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

The only part of the information, such as information on the main outcomes or the like, can be shared.

When the data will become available and for how long

Start the access period 6 month after the publication of the research results in a scientific journal

To whom data/document is available

Data will be available to all scientific researchers

Under which criteria data/document could be used

Only to help scientific research and with the written permission of the researcher can be used

From where data/document is obtainable

To receive data/document via email and phone, contact the researcher

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

Data/document is provided by email to other investigators

Comments