Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative Effects of the Otago Exercise Program and Virtual Reality Therapy on Static and Dynamic Balance, Gait Speed, and Fall Efficacy in Older Adults: A Randomized Controlled Trial**

Protocol summary

Study aim
compare the effects of the Otago Exercise Program and Virtual Reality Therapy on static and dynamic balance, gait speed, and fall efficacy in older adults

Design
Randomized parallel-group, single-blind (outcome assessor) trial with three groups (Otago, VR, Control) in 66 older adults. Randomization: variable block sizes via Random Allocation Software. Non-pharmacological; measurements at pre-test, post-test, and follow-up.

Settings and conduct
This study will be conducted at a nursing home in Yasuj. After screening and informed consent, eligible participants are randomly allocated to three groups. Interventions are performed at the center under researcher and physiotherapist supervision. A blinded outcome assessor evaluates all participants at pre-test, post-test, and follow-up.

Participants/Inclusion and exclusion criteria
Participants include older adults aged 65 to 80 years with at least one fall in the past 12 months, ability to walk independently, and a Timed Up-and-Go test score of less than 15 seconds. Exclusion criteria include neurodegenerative diseases, recent stroke, severe visual or hearing impairments, contraindications to physical activity, severe heart disease, uncontrolled diabetes, and use of beta-blockers or antidepressant medications.

Intervention groups
Three groups: Otago (12 weeks, three 45-minute sessions per week including strengthening and balance exercises), Virtual Reality (12 weeks, three 40-minute sessions per week using Kinect and balance games), and Control (no intervention, assessed only at designated time points).

Main outcome variables
Static and dynamic balance (Berg Balance Scale and Timed Up-and-Go test), gait speed (10-meter walk test), and fall efficacy (Falls Efficacy Scale-International) are measured at three time points: pre-test, post-test, and follow-up.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240718062460N2**
Registration date: **2026-07-16, 1405/04/25**
Registration timing: **prospective**

Last update: **2026-07-16, 1405/04/25**
Update count: **0**

Registration date
2026-07-16, 1405/04/25

Registrant information

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ayoub hashemi

Name of organization / entity
University of yasouj

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-07-20, 1405/04/29

Expected recruitment end date
2026-11-06, 1405/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effects of the Otago Exercise Program and Virtual Reality Therapy on Static and Dynamic Balance, Gait Speed, and Fall Efficacy in Older Adults: A Randomized Controlled Trial**

Public title

Comparison of the Effectiveness of Otago Exercise Program and Virtual Reality on Balance and Fall Prevention in Older Adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 65 and 80 years Community-dwelling (not residing in a nursing home) History of at least one fall in the past 12 months Able to walk independently Ability to perform the Timed Up-and-Go (TUG) test with a score of less than 15 seconds Signed informed consent form to participate in the study

Exclusion criteria:

Diagnosis of neurodegenerative diseases such as Parkinson's disease Stroke within the past 12 months Visual or hearing impairment that prevents following the interventions Absolute contraindications to physical activity Concurrent participation in other studies or exercise programs similar to the Otago program Severe pathology in the musculoskeletal, neurological, or vestibular systems Severe heart disease Uncontrolled or severe diabetes Use of beta-blockers or antidepressant medications

Age

From **65 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

After completion of the screening process and obtaining informed consent, eligible participants will be randomly assigned to three groups (Otago, Virtual Reality, and Control) with a 1:1:1 allocation ratio. The randomization method will be random block design with variable block sizes (4 and 6) to maintain balance in sample size across groups and prevent allocation bias. The unit of randomization is at the individual level. The allocation sequence within blocks will be generated using Random Allocation Software. No stratified randomization will be performed in this study.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blinding is applied at the level of the outcome assessor. All tests and measurements related to outcome variables (including static and dynamic balance, gait speed, and fall efficacy) will be performed by a trained assessor who is completely blinded to the allocation of study groups (Otago, Virtual Reality, and Control). This assessor has no role in the randomization process, intervention implementation, or participant care, and is solely responsible for collecting pre-test, post-test, and follow-up data. Other groups in this study are not blinded: Participants: are aware of the type of intervention they receive (since Otago exercises and virtual reality are distinguishable). Principal investigator: is aware of group allocation and supervises the proper implementation of interventions. Physiotherapist and clinical caregivers: are aware of the type of intervention each participant receives. Data analyst: is the principal investigator who is aware of group allocation. Data Safety and Monitoring Committee: has not been established for this study (low-risk study with non-pharmacological interventions). Therefore, the only individual who remains blinded in this study is the outcome assessor, who, through allocation concealment and lack of access to the randomization list, prevents bias in data collection.

Placebo

Not used

Assignment

Parallel

Other design features

1. Three-group design with two active interventions and one non-intervention control group: This study includes two active interventions (Otago Exercise Program and Virtual Reality Therapy) and one control group (receiving no intervention), allowing direct comparison of the effectiveness of traditional and novel approaches alongside a control group.2. Repeated measurements at three time points: Outcome variables will be assessed at three time points: pre-test (before starting interventions), post-test (immediately after the 12-week intervention period), and follow-up (to evaluate the sustainability of intervention effects).3. Non-pharmacological interventions applicable in rehabilitation centers: Both interventions are designed to be implementable in elderly care homes and rehabilitation centers, requiring no complex equipment (except for the Kinect device for the virtual reality group).4. Progression of exercises tailored to individual ability: In the Otago program, exercise progression is based on a four-level difficulty system to match each participant's functional capacity and prevent injury.5. Continuous safety monitoring throughout the study: All training sessions are conducted under the direct supervision of the researcher and a physiotherapist, and exercise intensity in the virtual reality group is monitored using the Borg Rating of Perceived Exertion (RPE) scale.6. Low-risk clinical trial: Given the non-invasive and non-pharmacological nature of the interventions and prior evidence supporting the safety of both methods, this

study is classified as a low-risk trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Shahrood University of Technology

Street address
Faculty of Physical Education and Sport Sciences, Shahrood University of Technology, University Blvd., Haft Tir Sq.

City
Shahrood

Province
Semnan

Postal code
3619995161

Approval date
2026-01-28, 1404/11/08

Ethics committee reference number
IR. SHAHROODUT.REC. 1404.030

Health conditions studied

1

Description of health condition studied
Falls in older adults and age-related balance disorders

ICD-10 code

ICD-10 code description
سالمندی

Primary outcomes

1

Description
Description of Primary Outcome Measure 1 :Static and dynamic balance: Measured using the Berg Balance Scale, which consists of 14 functional items, each scored from 0 to 4. The total score ranges from 0 to 56, with scores below 45 indicating an increased risk of falls. This test is administered at three time points: pre-test, post-test, and follow-up. Description of Primary Outcome Measure 2 :Gait speed: Measured using the 10-Meter Walk Test, in which participants are asked to walk a distance of 10 meters at their usual pace, and the time is recorded. The average of two trials is calculated as gait speed (meters per second). Measurements are taken at three time points: pre-test, post-test, and follow-up. Description of Primary Outcome Measure 3 :Fall efficacy (fear of falling): Measured using the Falls Efficacy Scale-International, a 16-item questionnaire with a 4-point Likert scale (1 = not at all confident to 4 = not confident at all). The total score ranges from 16 to 64, with higher scores indicating greater fear of falling. This questionnaire is completed at three time points: pre-test, post-test, and follow-up.

Timepoint
Outcome variables are measured at three time points: Pre-test: one week before the start of interventions. Post-test: immediately after the completion of the 12-week intervention period/ Follow-up: 4 weeks after the end of interventions (to assess the sustainability of effects)

Method of measurement
Measurement Method for Outcome Variable 1 (Static and Dynamic Balance) :Berg Balance Scale .Measurement Method for Outcome Variable 2 (Gait Speed) :10-Meter Walk Test . Measurement Method for Outcome Variable 3 (Fall Efficacy) :Falls Efficacy Scale-International

Secondary outcomes

1

Description
Fear of falling: Measured using the Falls Efficacy Scale-International, a 16-item questionnaire with a 4-point Likert scale (1 = not at all confident to 4 = not confident at all). The total score ranges from 16 to 64, with higher scores indicating greater fear of falling. This questionnaire is completed at three time points: pre-test, post-test, and follow-up.

Timepoint
Measurement of fear of falling is performed at three time points: Pre-test: one week before the start of interventions. Post-test: immediately after the completion of the 12-week intervention period. Follow-up: 4 weeks after the end of interventions

Method of measurement
Falls Efficacy Scale-International

Intervention groups

1

Description
Intervention Group 1 (Otago Exercise Program):Participants in this group perform the Otago Exercise Program for 12 weeks, three sessions per week, with each session lasting 45 minutes. The program consists of five main parts: General Warm-Up Exercises (5 minutes), Lower Limb Strengthening including Heel Raises, Knee Bends, and Half-Squats (15 minutes), Static Balance Exercises including Single-Leg Stance and Tandem Stance (10 minutes), Dynamic Balance Exercises including Forward and Backward Walking, Side Stepping, and Turning (10 minutes), and Cool-Down and Range of Motion Exercises (5 minutes). The progression of exercises is based on the four-level difficulty system of the original Otago Program to adapt to each participant's functional ability. All sessions are conducted under the supervision of a physiotherapist and are carried out at the nursing home.

Category
Rehabilitation

2

Description
Intervention Group 2 (Virtual Reality Therapy):Participants in this group receive Virtual Reality Therapy for 12 weeks, three sessions per week, with each session lasting 40 minutes, using the Kinect device (manufactured by Microsoft Corporation) and a display screen. Each session includes 10 minutes of warm-up and stretching, and 30 minutes of main exercises in the form of balance-based games, including Hula Hooping, Soccer, Tightrope Walking, Skiing, and Yoga Movements. Participants control the movements of the virtual character in the game by shifting their body weight and use visual feedback to improve postural control. The intensity of exercises is controlled using the Borg Rating of Perceived Exertion Scale. All sessions are conducted under the supervision of the researcher and a physiotherapist and are carried out at the nursing home.

Category
Rehabilitation

3

Description
Control Group: Participants in this group do not receive any intervention and are only assessed at the measurement time points (pre-test, post-test, and follow-up) for evaluation of outcome variables.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ferdows Nursing Home

Full name of responsible person
Ayoub hashemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University

Full name of responsible person
Seyed Mohammad Zamani Nejad

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Web page address
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
yasouj 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
Yasouj University

Full name of responsible person
Ayoub Hashemi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physical Education & Sport Science

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Person responsible for updating data

Contact
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Ayoub Hashemi
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Latest degree
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Other areas of specialty/work
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Street address
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Individual participant data including demographic information, static and dynamic balance scores (Berg Balance Scale), gait speed (10-Meter Walk Test), and falls efficacy questionnaire scores (FES-I) at three time points (pre-test, post-test, and follow-up). All data will be shared as de-identified Excel files (without personal identifiers such as names, surnames, and national ID codes).
When the data will become available and for how long
Access to de-identified data will begin 6 months after publication of the main study results and will remain available for up to 5 years thereafter. Upon request by qualified researchers, data will be shared after approval by the ethics committee and in compliance with confidentiality requirements.
To whom data/document is available
Access to data and study documents will be granted exclusively to researchers affiliated with academic institutions and reputable research centers who have an approved research proposal and ethics clearance. Requests from industry or private sector researchers will be reviewed on a case-by-case basis upon submission of a valid research plan and ethics committee approval. All requests must include the purpose of data use, analysis methods, and publication plans. Upon approval by the research team, de-identified data will be shared with the applicant.
Under which criteria data/document could be used
Data and study documents may be used exclusively for academic and scientific research purposes, subject to the following conditions: Submission of a valid research proposal with clear objectives and transparent methodology Commitment to use data solely for the stated purposes in the request Commitment to maintain confidentiality and refrain from attempting re-identification of participants Proper citation of the data source in all publications and reports Submission of analysis reports to the primary research team Prohibition of commercial use or financial gain
From where data/document is obtainable

Applicants wishing to access study data and documents should submit a written request to the Principal Investigator. Contact details are as follows: Principal Investigator: Dr. Ayoub Hashemi (Assistant Professor, Department of Motor Behavior, Yasuj University) Email Address: a.hashemi@yu.ac.ir Phone Number: +98 917 683 5715 Postal Address: Faculty of Literature and Humanities, Department of Sports Sciences, Yasuj University, Postal Code: 7591874934 Application Procedure: Requests must be submitted via email, including a research proposal, purpose of data use, and a confidentiality commitment form. After review by the research team and approval by the ethics committee, de-identified data will be shared with the applicant.

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

The process for reviewing and responding to requests for study data and documents is as follows: Step 1: Submission of Request The applicant submits a written request along with a research proposal, data use objectives, proposed analysis methods, and a confidentiality commitment form via email to the Principal Investigator. Step 2: Initial Review by Research Team (1 to 2 weeks) The Principal Investigator and research team review the request for scientific merit, ethical compliance, and alignment with study objectives. Additional information may be requested from the applicant during this stage. Step 3: Referral to Ethics Committee (2 to 4 weeks) After initial approval, the request is forwarded to the Ethics Committee for Biomedical Research at the university for final review. The committee verifies the confidentiality commitment and adherence to ethical standards. Step 4: Data Preparation and Provision (1 to 2 weeks) Upon receiving final approval, the research team prepares de-identified data in Excel format or other agreed formats and provides it to the applicant via a secure link or email. Total Estimated Time: Approximately 4 to 8 weeks from the date of submission of a complete and valid request. Note: Incomplete documentation or required revisions may extend this timeframe.

Comments

This study is a low-risk, non-pharmacological clinical trial that will be prospectively registered in the Iranian Registry of Clinical Trials (IRCT) before participant enrollment. All procedures will be conducted in accordance with the Declaration of Helsinki and the ethics guidelines of the Ministry of Health. Participant safety is a top priority; all exercise sessions will be supervised by a physiotherapist, and necessary safety equipment will be available. In the event of any adverse event, the intervention will be stopped and appropriate care provided. Participants may withdraw from the study at any time without incurring any costs or limitations, and this will not affect their routine care services. All personal information of participants will remain confidential and will be presented in final reports as aggregated, non-identifiable data.