Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effects of adding virtual reality to dual-task gait training on balance, gait quality and quality of life in stroke survivors: a randomized clinical trial

Protocol summary

Study aim

This clinical trial aims to assess the effects of immersive virtual reality treadmill exercises, using a head-mounted display (HMD), on balance, gait quality, and quality of life in chronic stroke patients under dual-task conditions.

Design

Randomized clinical trial with a control group, parallel groups, double-blind. Randomization was done using the website www.sealedenvelope.com

Settings and conduct

Study location: Parsa Private Physiotherapy Clinic (Shahid Kalantari Street 4 Mashhad); Study population: Stroke patients; Blinding: group allocation, outcome assessors, and statistical analysts; Blinding method: Sealed envelope

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients must have hemiplegia resulting from a single stroke (subacute or chronic phase); be able to walk 10 meters independently or with a single-point stick; and score greater than 24 on the Mini-Mental State Examination. Exclusion criteria: speech disorders following stroke; hemianopia or visual eye field disorders; vestibular disorders; auditory defect; major cardiac problems or uncontrolled hypertension; any other neurological disorder; orthopedic problems and other factors that impact walking.

Intervention groups

Control group: Receiving 15 sessions of conventional physical therapy (Functional electrical stimulation and resistance exercise), followed by 20 minutes dual-task treadmill walking. Intervention group: Receiving 15 sessions of conventional physical therapy (Functional electrical stimulation and resistance exercise) followed by 20 minutes dual-task treadmill walking while using a Virtual Reality tool (Head mounted display)

Main outcome variables

Berg Balance Scale; Modified Four Square Step Test; Activity-Specific Balance Confidence; Timed Up and Go; 6 Minute Walk Test; 10 Meter Walk Test; Stroke Specific Quality of Life Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241027063509N1**
Registration date: **2025-03-29, 1404/01/09**
Registration timing: **prospective**

Last update: **2025-03-29, 1404/01/09**
Update count: **0**

Registration date

2025-03-29, 1404/01/09

Registrant information

Name

Mohammad Javad Dolatabadian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-19, 1404/01/30

Expected recruitment end date

2026-04-19, 1405/01/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effects of adding virtual reality to dual-task gait training on balance, gait quality and quality of life in stroke survivors: a randomized clinical trial

Public title
Investigating the Effects of Dual-Tasking with Virtual Reality on Stroke Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hemiplegia resulting from a single stroke Sub-acute and chronic phase Being able to walk 10m without or with single point stick Score greater than 24 in the mini-mental state examination
Exclusion criteria:
patients with speech disorders following stroke patients with hemianopia or visual eye field disorders patients with vestibular disorders patients with auditory defect patients with major cardiac problems or uncontrolled hypertension patients with any other neurological disorder patients with orthopedic issues and other factors that impact walking, like osteoarthritis or undergoing a complete hip joint replacement
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomly assign patients to study groups, a random block design will be employed. Five blocks of six will be generated randomly using the website [Sealed Envelope](https://www.sealedenvelope.com/). For example, the generated sequences may look as follows: [AAABSB], [ABABAB], [GBAAAB], [ABBAAI], [BBAA], [BABABA].
Blinding (investigator's opinion)
Triple blinded
Blinding description
The physiotherapist responsible for outcome assessment is blinded to group assignments. Patients are randomly assigned to control or intervention groups; therefore, the group allocator is also blinded to the treatment groups. Similarly, the statistician analyzing the data is also blinded to group assignments, with the data provided to him in a coded format.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
School of Paramedical Sciences and Rehabilitation, University Campus, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
917794864
Approval date
2024-06-29, 1403/04/09
Ethics committee reference number
IR.MUMS.FHMPM.REC.1403.095

Health conditions studied

1

Description of health condition studied
Cerebrovascular accident
ICD-10 code
I63.9
ICD-10 code description
Cerebral infarction, unspecified

Primary outcomes

1

Description
Balance score in Berg Balance Scale
Timepoint
Before intervention and immediately after 15 sessions of intervention
Method of measurement
To measure effect of the intervention on balance, the Berg Balance Scale is used: The Functional Balance Assessment, developed by Katherine Berg, is a performance-based test designed to evaluate balance. The assessment takes approximately 10 to 20 minutes to complete and consists of 14 tasks. Each task is scored on a scale from 0 to 4, with 0 indicating the lowest level of performance and 4 the highest. A total score of 20 or less suggests that the patient will require a wheelchair.

Scores between 21 and 40 indicate that the patient will need assistance with walking. Patients scoring above 40 are considered capable of walking independently.

Secondary outcomes

1

Description

Dynamic balance score in Modified Four Square Step Test.

Timepoint

Before intervention and immediately after 15 sessions of intervention

Method of measurement

The Modified Four Square Step Test is a performance-based assessment designed to evaluate dynamic balance. To conduct this test, a one-square-meter area is marked on the ground and divided into four equal squares using tape, numbered 1 to 4 in a clockwise direction. The test subject stands in square 1 facing square 2 and first completes a full clockwise rotation around square 1, returning to square 1. This is followed by a full counterclockwise rotation, again returning to square 1. The therapist records the time from the first foot contact in the initial step to the last foot contact in the final step.

2

Description

Balance score in Activity-Specific Balance Confidence questionnaire

Timepoint

Before intervention and immediately after 15 sessions of intervention

Method of measurement

The Activity-Based Balance Confidence Questionnaire is a patient-centered instrument designed to measure an individual's confidence in their balance during daily activities, without experiencing unsteadiness or fear of falling. This questionnaire consists of 16 items. The participant is required to express their level of confidence in their balance for each of these 16 activities as a percentage, where 0% indicates no confidence and 100% indicates complete confidence.

3

Description

Mobility score in Timed up and go test.

Timepoint

Before intervention and immediately after 15 sessions of intervention

Method of measurement

The test aims to evaluate fall risk and monitor balance progression during various activities, including sitting, standing, and walking. The procedure requires the patient to wear their regular shoes and, if needed, use a walking aid. The patient starts in a seated position and, upon the therapist’s instruction, stands up. The patient then walks a distance of 3 meters, turns around, walks back to the chair, and sits down. The test duration is recorded from the moment the patient begins to rise until they are fully seated.

4

Description

Walking speed in 10 Meters walk test

Timepoint

Before intervention and immediately after 15 sessions of intervention

Method of measurement

This test is designed to measure walking speed over a short distance and can be conducted in two forms: at maximum speed or at the patient's normal speed. To perform the test, a stopwatch and a clear, flat, unobstructed 10-meter pathway are required, with markers placed at 2 meters and 8 meters. The patient stands at the starting point and begins walking upon the therapist's command, continuing to the endpoint at either maximum or normal speed, depending on the test type. The therapist records the time taken to traverse the distance between the 2-meter and 8-meter markers, which is then used to calculate walking speed.

5

Description

Distance traveled in "six-Minutes walk test"

Timepoint

Before intervention and immediately after 15 sessions of intervention

Method of measurement

This test assesses aerobic capacity and endurance by measuring the distance covered in 6 minutes. The distance serves as an outcome measure to compare changes in functional capacity over time.

6

Description

Quality of life score in Stroke Specific Quality of Life Scale questionnaire

Timepoint

Before intervention and immediately after 15 sessions of intervention

Method of measurement

The Stroke-Specific Quality of Life Scale (SS-QOL) is a patient-centered assessment tool specifically designed to evaluate the quality of life of individuals who have experienced a stroke. Patients are instructed to respond to each question based on their experiences over the past week. This self-report scale includes 49 items across 12 domains: participation (6 items), energy (3 items), upper extremity function (5 items), self-care (5 items), social roles (5 items), family roles (3 items), goals (3 items), language (5 items), thinking (3 items), and personality (3 items). The items are rated on a 5-point scale, resulting in a minimum score of 49 and a maximum score of 245

Intervention groups

1

Description

Intervention group: The intervention for both groups consists of 15 sessions conducted over 5 consecutive weeks, with a frequency of three sessions per week.The intervention group receives electrotherapy and standard exercises for 40 minutes per session, similar to the control group. The control group performs strengthening exercises for the shoulder and elbow extensors, hip extensors and abductors, and knee extensors and flexors on a treatment table. The primary difference between the groups lies in the rehabilitation activities focused on walking. In both groups, each session includes:- 20 minutes of electrotherapy using Functional Electrical Stimulation (FES)- 20 minutes of standard therapeutic exercises for stroke patients- 20 minutes of walking exercises on a treadmill. During treadmill walking, a harness is used to protect patients from the risk of falling, although it does not provide any weight suspension. The treadmill speed starts at 0.8 kilometers per hour and is increased by 0.1 to 0.2 kilometers per hour in each session, depending on the patient's condition, until the maximum tolerable speed is reached. Additionally, during treadmill walking, patients in both groups are assigned cognitive tasks by the therapist, focusing on attention spans and executive functions. In the intervention group, patients begin walking in a simulated environment resembling a street, shopping center, etc., using virtual reality head mounted display that provide a fully immersive experience.

Category

Treatment - Devices

2

Description

Control group: The intervention for both groups consists of 15 sessions conducted over 5 consecutive weeks, with a frequency of three sessions per week. Each session lasts 60 minutes. The intervention group receives electrotherapy and standard exercises for 40 minutes per session, similar to the control group. The control group performs strengthening exercises for the shoulder and elbow extensors, hip extensors and abductors, and knee extensors and flexors on a treatment table. The primary difference between the groups lies in the rehabilitation activities focused on walking. In both groups, each session includes:- 20 minutes of electrotherapy using Functional Electrical Stimulation (FES)- 20 minutes of standard therapeutic exercises for stroke patients- 20 minutes of walking exercises on a treadmill. During treadmill walking, a harness is used to protect patients from the risk of falling, although it does not provide any weight suspension. The treadmill speed starts at 0.8 kilometers per hour and is increased by 0.1 to 0.2 kilometers per hour in each session, depending on the patient's condition, until the maximum tolerable speed is reached. Additionally, during treadmill walking, patients in both groups are assigned cognitive tasks by the therapist, focusing on attention spans and executive functions.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Parsa Physiotherapy Clinic

Full name of responsible person
Mohammad Parsa

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No. 318, Basement level one, Shahid Kalantari 4, Shahid Kalantari Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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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
Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hossein Negahban

Position

professor, Department of Physiotherapy, Mashhad University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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