

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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](http://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)

##### Phone

+98 51 3731 8172

##### Email address

dolatabadianmj4012@mums.ac.ir

##### 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

##### Street address

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

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##### Province

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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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TafaghodiM@mums.ac.ir

#### 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  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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