

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating Immersive Virtual Reality Training on Dynamic Stability, Gait Parameters, and User Experience of Patients with Cerebrovascular Accidents: A Study Protocol for a Randomized Controlled Trial

#### Protocol summary

##### Study aim

Evaluation of the effect of pervasive virtual reality on dynamic stability and walking in stroke patients and their user experience over time.

##### Design

Clinical trial with a control group, with parallel groups, without blinding, randomized, on 32 patients. The table of random numbers generated by the computer was used for randomization.

##### Settings and conduct

All exercise sessions will take place within the physiotherapy department of the Sports Medicine Research Center, Tehran University of Medical Sciences, under the strict supervision of a physiotherapist a sports medicine physician, and a neurologist. All participants in the study will be measured before the start of the study, after the intervention (3 weeks later), and 2 months after the treatment.

##### Participants/Inclusion and exclusion criteria

People who benefit the most from the intervention will be included in the study, and people who may be harmed by the intervention will not be included in the study. Only people who voluntarily signed the consent to enter the study will be included in the study.

##### Intervention groups

The VR training group will receive 30 min per day for 3 weeks (5 days/week) of VR-assisted gait rehabilitation. Participants will receive 30 min per day for 3 weeks (5 days/week) of functional gait rehabilitation training.

##### Main outcome variables

Non-linear measures of walking including the Lyapunov exponent and Floquet multipliers, User experience (UX) evaluated by applying the AttarkDiff questionnaire, Timed Up and Go test (TUG), The 6-Minute Walk Test/ The Simulator Sickness Questionnaire, The Falls Efficacy Scale-International (FES-I), The Berg Balance scale (BBS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231031059916N1**

Registration date: **2023-11-12, 1402/08/21**

Registration timing: **prospective**

Last update: **2023-11-12, 1402/08/21**

Update count: **0**

##### Registration date

2023-11-12, 1402/08/21

##### Registrant information

##### Name

Amirhossein Memari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8863 0227

##### Email address

memari\_ah@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-21, 1402/11/01

##### Expected recruitment end date

2024-05-21, 1403/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluating Immersive Virtual Reality Training on Dynamic Stability, Gait Parameters, and User Experience of Patients with Cerebrovascular Accidents: A Study Protocol for a Randomized Controlled Trial

## Public title

Evaluating Immersive Virtual Reality Training on Dynamic Stability, Gait Parameters, and User Experience of Patients with Cerebrovascular Accidents: A Study Protocol for a Randomized Controlled Trial

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with ischemic stroke were diagnosed according to WHO criteria Between 30 and 80 years old Within 6-12 months after stroke onset before enrollment Ability to walk without support or assistive device for at least 10 meters Adequate communication skills to understand and follow orders

### Exclusion criteria:

Patients with Pregnancy Patients with an injury or cognitive disorder who cannot follow instructions and training Patients with Cardiac arrhythmias or a pacemaker Patients with Major vascular disease Patients with Impaired consciousness and mental disorders requiring drug therapy Patients with Severe visual impairments

## Age

From **30 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **32**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The randomization process is done by the study coordinator, after determining the exact number of participants, he gives a code to each of them using a table of random numbers generated by the computer. The researcher puts his hand on one of the numbers and moves in a predetermined direction and records the numbers and assigns them to two groups, which leads to the equal allocation of participants to two groups.

## 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

Ethics committee of Tehran University of Medical Sciences

##### Street address

No. 23, 16 Azar Ave., Keshavarz Blvd, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1417863181

#### Approval date

2023-02-18, 1401/11/29

#### Ethics committee reference number

IR.TUMS.NI.REC.1401.091

## Health conditions studied

### 1

#### Description of health condition studied

Cerebrovascular accidents/ ischemic stroke

#### ICD-10 code

Y80.1

#### ICD-10 code description

Therapeutic (nonsurgical) and rehabilitative physical medicine devices associated with adverse incidents

## Primary outcomes

### 1

#### Description

Non-linear measures of walking including the Lyapunov exponent and Floquet multipliers calculating local and orbital stability

#### Timepoint

All participants in the study will be measured before the start of the study, after the intervention (3 weeks later), and 2 months after the treatment.

#### Method of measurement

Lyapunov exponent formula:  $y(i) = 1/\Delta t \langle \ln |d_j(i)| \rangle$   
Floquet multipliers formula:  $S_{(k+1)} = F(S_k)$

### 2

#### Description

User experience (UX) evaluated by applying the AttarkDiff questionnaire

#### Timepoint

All participants in the study will be measured before the start of the study, after the intervention (3 weeks later), and 2 months after the treatment.

#### Method of measurement

User experience (UX) evaluated by applying the AttarkDiff questionnaire

## Secondary outcomes

### 1

#### Description

The timed Up and Go test (TUG) to assess mobility in adults or predict their risk of falls

#### Timepoint

All participants in the study will be measured before the start of the study, after the intervention (3 weeks later), and 2 months after the treatment.

#### Method of measurement

The timed Up and Go test (TUG), subjects are asked to rise from a standard armchair, walk to a marker 3 m away, turn, walk back, and sit down again.

### 2

#### Description

The 6-Minute Walk Test

#### Timepoint

All participants in the study will be measured before the start of the study, after the intervention (3 weeks later), and 2 months after the treatment.

#### Method of measurement

The 6-Minute Walk Test is a sub-maximal exercise test used to assess aerobic capacity and endurance. The distance covered over a time of 6 minutes is used as the outcome by which to compare changes in performance capacity.

### 3

#### Description

Assessing the virtual environment's effects on an individual's health

#### Timepoint

All participants in the study will be measured before the start of the study, after the intervention (3 weeks later), and 2 months after the treatment.

#### Method of measurement

The Simulator Sickness Questionnaire

### 4

#### Description

Fear of falling

#### Timepoint

All participants in the study will be measured before the start of the study, after the intervention (3 weeks later), and 2 months after the treatment.

#### Method of measurement

The Falls Efficacy Scale-International (FES-I)

### 5

#### Description

Evaluating balance

#### Timepoint

All participants in the study will be measured before the start of the study, after the intervention (3 weeks later), and 2 months after the treatment.

#### Method of measurement

The Berg Balance scale (BBS)

## Intervention groups

### 1

#### Description

Intervention group: The VR training group will receive 30 min per day for 3 weeks (5 days/week) of VR-assisted gait rehabilitation. Participants will be instructed on the option selection process by focusing on the desired options for a brief duration. Once the participants put on the VR glasses and headset, they can freely move their heads and explore the virtual environment, allowing them to observe their surroundings, including the ground and their feet. Each participant will engage in a 30-minute session of VR utilization. Participants will be assigned training scores based on their successful fulfillment of the specific requirements for each stage within the different training scenarios. The virtual training scenes within the study can be flexibly customized based on the individual needs and preferences of the participants. Additionally, the difficulty level of the VR scenes can be adaptively modified according to each participant's lower extremity motor ability, enabling a personalized and tailored VR experience.

#### Category

Rehabilitation

### 2

#### Description

Control group: Participants will receive 30 min per day for 3 weeks (5 days/week) of functional gait rehabilitation training. The functional gait rehabilitation training may include (1) walking and picking up various objects from the ground, (2) walking on a nonlevel surface, (3) walking a slalom, (4) stepping in hoops, and (5) stepping over a stick that is fixed between pylons. They also will receive 30 min per week for 3 weeks of regular active exercise training. The physiotherapist in charge will make necessary adjustments to the exercise intensity and type based on the individual patient's abilities. They will also assess and monitor the progress, safety, and quality of movement exhibited by the patient during the exercise sessions.

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rehabilitation Clinic of the Sports Medicine Research Center, Tehran

##### Full name of responsible person

Amirhossein Memari

##### Street address

No. 7, in front of Shariati Hospital clinic, after Geisha

Bridge exit, Jalal Al Ahmad Street, Tehran

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammadali Sahraeian

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sportpsych@tums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Amirhossein Memari

**Position**

Director of Social Neuroscience Group Tehran

University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran-helal institute of applied science and technology

**Full name of responsible person**

Vahideh Moradi

**Position**

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**Other areas of specialty/work**

Orthopedics

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Tara Mahmoodi

**Position**

Resaercher at Sport Medicine Research Center

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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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**

If a judge or an expert wants data and information, the data will be provided without the names of the participants by referring to the corresponding author or

project manager.

**When the data will become available and for how long**

If a judge or an expert wants data and information, the data will be provided without the names of the participants by referring to the corresponding author or project manager.

**To whom data/document is available**

If a judge or an expert wants data and information, the data will be provided without the names of the participants by referring to the corresponding author or project manager.

**Under which criteria data/document could be used**

If a judge or an expert wants data and information, the data will be provided without the names of the participants by referring to the corresponding author or project manager.

**From where data/document is obtainable**

If a judge or an expert wants data and information, the data will be provided without the names of the participants by referring to the corresponding author or project manager (Amirhossein Memari, Email: mehranamir@yahoo.com).

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

If a judge or an expert wants data and information, the data will be provided without the names of the participants by referring to the corresponding author or project manager via Email (Amirhossein Memari, Email: mehranamir@yahoo.com).

**Comments**