Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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)

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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

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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/Δt<Ln□ d_j (i)□>
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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

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Iran-helal isntitute of applied science and technology

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Assistant Professor

Latest degree
Ph.D.

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Person responsible for updating data

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Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Tara Mahmoodi

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Resaercher at Sport Medicine Research Center

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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