

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Designing and evaluating a serious game based on virtual reality in order to promote cognitive motor rehabilitation of stroke patients in daily life activities

Protocol summary

Study aim

1. Extraction of clinical, physical content, exercises or skills related to cognitive motor rehabilitation of stroke patients in daily life activities. 2. Development of serious game software based on virtual reality according to the life cycle method of game development. 3. Evaluating the sense of presence in a serious virtual reality game and evaluating its effectiveness.

Design

- Eligible participants were randomly assigned to the control group (i.e., standard medical care) or the experimental group (i.e., standard medical care plus playing a serious game) using a random number generator.

Settings and conduct

- Patients with stroke tested from a serious game based on virtual reality consisting of a virtual world with items related to motor activities of daily life (eating, cutting fruit, combing, opening a door, talking on a mobile phone, taking a bath) - cognitive (recall, sequence and awareness) installed on the VIVE Cosmos model virtual reality system along with two hand controllers that act as the patient's hands.

Participants/Inclusion and exclusion criteria

Six months have passed (according to the effectiveness of the intervention) after the stroke and I have a stable and cooperative clinical condition.

Intervention groups

- Basic tests are done one week before the first session and post-intervention tests are done one week after the last session for all subjects. - Three half-hour training sessions to learn how to use virtual reality equipment and serious gaming environment and how to deal with rehabilitation items of daily life activities before starting the study. - The evaluator will only participate in pre- and post-intervention evaluations and will be blind to the assignment of the participating group.

Main outcome variables

Cognitive motor rehabilitation of stroke patients

General information

Reason for update

Blinding of individuals was added due to forgetfulness in registration.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240517061821N1**

Registration date: **2024-07-25, 1403/05/04**

Registration timing: **prospective**

Last update: **2025-02-13, 1403/11/25**

Update count: **1**

Registration date

2024-07-25, 1403/05/04

Registrant information

Name

Vahid Fatehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3361 4240

Email address

vahidfatehi97@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty	Blinding description
Actual recruitment end date	Assessors and patients are blinded to the scenarios and assignments.
empty	Placebo
Trial completion date	Not used
empty	Assignment
Scientific title	Other
Designing and evaluating a serious game based on virtual reality in order to promote cognitive motor rehabilitation of stroke patients in daily life activities	Other design features
	Two groups were randomly selected: the experimental group and the control group
Public title	
Designing and evaluating a serious game based on virtual reality in order to promote cognitive motor rehabilitation of stroke patients in daily life activities	Secondary Ids
Purpose	empty
Supportive	Ethics committees
Inclusion/Exclusion criteria	
Inclusion criteria:	<u>1</u>
It has been sprayed for six months (according to the effectiveness of the intervention) after a stroke Have a stable and cooperative clinical condition Participants had to score above 22 on the Minimal or Summary Mental Status Examination (MMSE) for cognitive characteristics Scored higher than 18 in Vogel-Meier assessment (upper limb) (Persian version) to evaluate sensorimotor function. It is possible to work with the Purdue pegboard tool to check finger function.	Ethics committee
Exclusion criteria:	Name of ethics committee
Physical inability to independently use the virtual reality system (that is, both limbs do not have the necessary movement function or have less movement, which is determined by the Fogel-Meier and Purdue pegboard tests. Vision issues (eg, visual impairment, also report any metal implants due to orthopedic conditions or other neurological disorders such as Parkinson's disease, vestibular defects, peripheral neuropathy, or unstable epilepsy). Such as lack of awareness of the environment, forgetfulness, loss or cases that did not receive the required score in the Mental Status Test (MMSE).	Tabriz University of Medical Sciences (Research Ethics Committee)
	Street address
	university street
	City
	Tabriz
	Province
	East Azarbaijan
	Postal code
	5159115705
	Approval date
	2024-04-22, 1403/02/03
	Ethics committee reference number
	IR.TBZMED.REC.1403.077
Age	Health conditions studied
From 18 years old	<u>1</u>
Gender	Description of health condition studied
Both	Cognitive motor rehabilitation of stroke patients
Phase	ICD-10 code
N/A	ICD-10 code description
Groups that have been masked	
- Participant - Care provider - Investigator - Outcome assessor - Data analyser	Primary outcomes
Sample size	<u>1</u>
Target sample size: 20	Description
Randomization (investigator's opinion)	Level of cognitive rehabilitation and motor rehabilitation
Randomized	Timepoint
Randomization description	One week before the start of the study and one week after the study
The randomization method is simple, it is an individual randomization unit using statistical software.	Method of measurement
Blinding (investigator's opinion)	Persian version of the Vogel-Meier Scale (PFMA) for upper limb assessment - total score Persian version of the Independent Function Measure (PFIM) for assessing personal performance and mental state examination (MMSE) for assessing the patient's cognitive status
Double blinded	

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 people in the experimental group (i.e. standard medical care plus playing a serious game), eight weeks of intervention including 16 sessions, each session lasting 30 minutes.

Category

Rehabilitation

2

Description

Control group: 10 people in the control group who only receive standard medical care in eight weeks of intervention including 16 sessions, each session lasting 30 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Razi Hospital

Full name of responsible person

Zahra Salahzadeh

Street address

Daneshgah St

City

Tabriz

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East Azarbaijan

Postal code

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Phone

+98 41 3177 6002

Email

vahidfatehi97@gmail.com

2

Recruitment center

Name of recruitment center

Neuroscience Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Farhoudi

Street address

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+98 41 3177 6002

Email

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Web page address

3

Recruitment center

Name of recruitment center

Alavi Hospital - Neurology Department - Ardabil City

Full name of responsible person

Vahid Abbasi

Street address

Ardabil Province, Ardabil, Sahali Street, Maadi Street

City

Ardabil

Province

Ardabil

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56139 74156

Phone

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Email

vahidfatehi97@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology

Street address

university street

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Tabriz

Province

East Azarbaijan

Postal code

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Phone

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Email

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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

Tabriz University of Medical Sciences

Proportion provided by this source

50

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**

Tabriz University of Medical Sciences

Full name of responsible person

Vahid Fatehi

Position

PhD student in health information management

Latest degree

Master

Other areas of specialty/work

Health Information Management

Street address

The main street of Tabriz University, next to Madani Hospital, Faculty of Medical Information and Management, first floor, Department of Health Information Technology

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Fax**Email**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Fax**Email**

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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

Not applicable