Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Actual recruitment end date

empty

Trial completion date

empty

Scientific 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

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

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

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.

Exclusion criteria:

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).

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple, it is an individual randomization unit using statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Assessors and patients are blinded to the scenarios and assignments.

Placebo

Not used

Assignment

Other

Other design features

Two groups were randomly selected: the experimental group and the control group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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

Health conditions studied

1

Description of health condition studied

Cognitive motor rehabilitation of stroke patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Level of cognitive rehabilitation and motor rehabilitation

Timepoint

One week before the start of the study and one week after the study

Method of measurement

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

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
Province
East Azarbaijan
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Phone
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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
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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
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56139 74156
Phone
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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
City
Tabriz
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Postal code
5166614711
Phone
+98 41 3177 6002
Email
vahidfatehi97@gmail.com
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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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

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Position

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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