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Cognitive rehabilitation using immersive virtual reality in stroke patients

Submission date
22/12/2023

Recruitment status
Recruiting

Registration date
03/01/2024

Overall study status
Ongoing

Last Edited
21/07/2025

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Stroke is one of the most common causes of death and long-term disability in the entire world. Post-stroke patients suffer not only motor impairments but also cognitive function deterioration. It is important to look into ways that could improve the rehabilitation of stroke patients. The aims of this study are:
1. To test the feasibility and effectiveness of short-term visual memory training tasks in immersive virtual reality in stroke patients;
2. To test the effect of these tasks on emotional state and motor functions in stroke patients.

Who can participate?
Stroke patients aged 18 to 85 years

What does the study involve?
The participants are randomly allocated to three groups: the experimental group (who, during the conventional rehabilitation program, participate in short-term visual memory training in immersive virtual reality); the active control group (who, during the conventional rehabilitation program, participate in short-term visual memory training in non-immersive virtual reality) and the passive control group (who participate in a conventional rehabilitation program).

What are the possible benefits and risks of participating?
Participants can benefit from participation in this study expecting to improve their cognitive functions and have the opportunity to try innovative methods. Participating in the study also is associated with possible risks such as dizziness, and cybersickness which are related to immersive virtual reality, even the tasks were created in order to avoid these symptoms.

Where is the study run from?
Vytautas Magnus University (Lithuania)

When is the study starting and how long is it expected to run for?
February 2022 to October 2025

Who is funding the study?
Lietuvos Mokslo Taryba (Research Council of Lithuania)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
S-MIP-23-137

Study information

Scientific Title
The potential of cognitive rehabilitation in immersive virtual reality on near and far transfer effects in stroke patients

Study objectives
1. Stroke patients who enroll in conventional rehabilitation and short-term visual memory training in immersive virtual reality improve cognitive functions and emotional state more than stroke patients who enroll just in conventional rehabilitation;
2. Stroke patients who enroll in conventional rehabilitation and short-term visual memory

training in immersive virtual reality improve cognitive functions and emotional state more than stroke patients who enroll in conventional rehabilitation and short-term visual memory training in non-immersive virtual reality;
3. Stroke patients who enroll in conventional rehabilitation and short-term visual memory training in non-immersive virtual reality improve cognitive functions and emotional state more than stroke patients who enroll in conventional rehabilitation;

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/02/2022, Vilnius Regional Biomedical Research Ethics Committee (M. K. Čiurlionio g. 21, Vilnius, LT-03101, Lithuania; +370 614 26126; rbtek@mf.vu.lt), ref: 2022/2-1408-880

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Cognitive function improvement in post-stroke patients

Interventions
All stroke patients who agree to participate complete pre-assessment and post-assessment. After the consent, they will be randomly allocated into one of the three groups. The randomization will be made each time rolling the dice (1-2 numbers mean participants randomly allocated to the passive control group; 3-4 numbers - active control group; and 5-6 numbers - experimental group).

The pre-assessment includes the collection of demographic and clinical information. Demographic information includes sex, education, residence and the dominant hand. Clinical information included the type of stroke, its localization, the stroke stage, the use of medications, and leading diseases. Furthermore, questions about adverse symptoms (e.g. dizziness, cybersickness, air tightness, visual or coordination impairments, etc.) were included during the intervention. All participants completed pre-assessment and post-assessment.

Patients in the experimental group participate in short-term visual memory training in immersive virtual reality and conventional rehabilitation.
Patients in the active control group participate in short-term visual memory training in non-immersive virtual reality and conventional rehabilitation.
Patients in the passive control group participate in conventional rehabilitation.

The system of immersive virtual reality tasks in this study consists of two components:
1. An app installed on the Oculus Quest 2 head-mounted display (HMD) and
2. A tablet where a researcher can see the broadcasted view of the tasks.

The two tasks were created based on four stages which are proposed by (Cordoso et al., 2017)
1. The initial development stage
2. The program construction
3. The program testing
4. The final development stage

Sixteen experts (one neurologist, 3 physical medicine and rehabilitation physicians, 3 health psychologists, 4 occupational therapists, 3 physiotherapists, and 2 Doctors of Psychology) were asked to perform tasks in immersive VR and fill in the evaluation form. During the evaluation of validity, three aspects were assessed:
1. Suitability of the procedure
2. Suitability of the first task
3. Suitability of the second task. The content validity index showed that the procedure, the first task, and the second task were suitable for stroke patients.

The first task is about recalling the cooking ingredients that are shown for the exact amount of time. The second task is about recalling the sequence of the cooking ingredients. Patients in the experimental group complete the tasks in immersive virtual reality using head-mounted display and the active control group complete these tasks using a tablet. The tasks in both settings are identical. Additionally, participants in the experimental or active control group attend ten 30-minute sessions (five times per week for two weeks) of short-term visual memory training.

Intervention Type
Behavioural

Primary outcome measure
1. Short-term visual memory is assessed using The Medical College of Georgia Complex Figures (MCGCF), forms A and B, during pre-assessment and post-assessment.
2. General cognitive functions and five domains (attention, memory, verbal fluency, language and visuospatial abilities) Addenbrooke's Cognitive Examination III forms A and B during pre-assessment and post-assessment.
3. Visual search, working memory, and executive functions are measured using the Trail Making tests Part A and Part B during pre-assessment and post-assessment.
4. Memory and learning are assessed using The Mnemonic Similarity Task C and D parts during pre-assessment and post-assessment.

Secondary outcome measures
1. Depression symptoms are measured using The Patient Health Questionnaire – 9 at pre-assessment and post-assessment.
2. Anxiety symptoms are measured using The Generalized Anxiety Disorder scale - 7 at pre-assessment and post-assessment.

3. Psychomotor functions are measured using The Finger Tapping Test at pre-assessment and post-assessment.

The several questionnaires additionally include during the post-assessment of experimental and active control groups:
4. The sense of presence in a virtual environment is measured using The Igroup Presence Questionnaire (IPQ) at post-assessment.
5. The system's usability is measured using The System Usability Scale (SUS) at post-assessment.

Overall study start date
15/02/2022

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of stroke
2. No severe cognitive impairment (fully understand the purpose and terms of the study)
3. The native language is Lithuanian
4. At least 3 days after the arrival at the rehabilitation center
5. Being able to sit

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
156

Total final enrolment
132

Key exclusion criteria
1. To be over the age of 85 years
2. To have epilepsy
3. To have such a degree of aphasia that a patient cannot understand spoken instructions and cannot answer meaningfully

4. To have the psychiatric diagnoses established
5. To experience unilateral neglect
6. To be characterized by severe motor disorders that restrict movements of both hands
7. To have other communication impairments that may prevent the patient from understanding task instructions or the purpose of the study

Date of first enrolment
01/03/2022

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Lithuania

Study participating centre
Abromiškės Rehabilitation Hospital
Sanatorijos g. 72
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/04y7eh037

Funder(s)

Funder type
Government

Funder Name
Lietuvos Mokslo Taryba

Alternative Name(s)
Research Council of Lithuania, LIETUVOS MOKSLO TARYBA - Lithuania, Lietuvos mokslo taryba., LMT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Lithuania

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal on pilot study and general findings.

Intention to publish date
01/03/2024

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available on request. Also, the datasets generated during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			02/01/2024	No	No
Statistical Analysis Plan			02/01/2024	No	No
Results article		18/07/2025	21/07/2025	Yes	No