Cognitive Rehabilitation Using Immersive Virtual Reality in Stroke Patients

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Study Protocol

Hypothesis

1. Stroke patients who enroll in conventional rehabilitation and short-term visual memory training in immersive virtual reality improve cognitive functions more than patients who enroll in conventional rehabilitation and short-term visual memory training in non-immersive virtual reality; or who enroll only in conventional rehabilitation.
2. The effectiveness of short-term visual memory training in immersive virtual reality will be better for those who tend to have lower depression and anxiety rates and those who have higher presence sense scores.
3. Cognitive function improvement in stroke patients who enroll in conventional rehabilitation and short-term visual memory training in immersive virtual reality will cause improvement in other non-targeted cognitive functions, emotional state and physical health.

Participants

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

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

Study Design.

Single-centre interventional randomized controlled trial. All participants will be the patients of Abromiškės Rehabilitation Hospital, where they have ongoing rehabilitation. All stroke patients who meet the criteria of the inclusion criteria will be invited to participate in the study. The researcher presents the study objective, the procedure and all the information which is in the written informed consent. Each patient, who will be invited to the study will be given written informed consent. Participants will be randomly assigned to 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. 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 pre-assessment and post-assessment will be conducted for all participants. To control the cofounding variables number and variety of conventional rehabilitation procedures were recorded.

Sample Size. The sample size was calculated within each group in order to detect small effect size pre/post differences, at beta power of 0.8 and alpha level of 0.05. Preliminary sample size was calculated using the G*Power software. In order to detect a small effect size of repeated measures within or between factors calculated total sample size is 30 - 36 participants per group.

Intervention. Participants, who underwent short-term memory training in immersive or non-immersive virtual reality (experimental and active control group), participated in ten 30-minute sessions (five times per week for two weeks). Both tasks in immersive and non-immersive virtual reality were created using the Unreal Engine 5 game engine. The development process was based on four stages which were proposed by Cordoso et al. (2017). The validity of the tasks was evaluated by the sixteen experts (for more see Janavičiūtė et al., 2022).

The first task is *Object recall task* (Figure 1), where the participant is asked to memorize products that are shown for a limited time. After that, they appear among other products and the participant is asked to identify products that were shown in the first place.

The second task is *The sequence recall task*, where the participant is asked to memorize the sequence of the highlighted products (the participant sees many products but only a particular number of products highlighted in a particular order). The participant is asked to recall the sequence and put the products in the bowl in the same order they highlighted.

The amount of the products increases after two successful attempts.

Fig. 1. The object recall task illustration.

Fig. 2. The sequence recall task illustration.

Measures

All participants underwent pre-assessment and post-assessment. Furthermore, demographic information (sex, education, residence, marital status and the dominant hand) and clinical records (stroke type, localization, stroke stage, the use of medications, leading diseases) were collected.

Short-term visual memory is assessed using The Medical College of Georgia Complex Figures (MCGCF), forms A and B (Ingram et al., 1997).

General cognitive functions and five domains (attention, memory, verbal fluency, language and visuospatial abilities) Addenbrooke's Cognitive Examination III, forms A and B (Hsieh et al., 2013).

Visual search, working memory, and executive functions are measured using the Trail Making tests Part A and Part B (Reitan, 1955) during pre-assessment and post-assessment.

Memory and learning are assessed using The Mnemonic Similarity Task C and D parts (Stark, Kirwan, & Stark, 2019) during pre-assessment and post-assessment.

Depression symptoms are measured using The Patient Health Questionnaire – 9 (Kroenke et al., 2001) at pre-assessment and post-assessment.

Anxiety symptoms are measured using The Generalized Anxiety Disorder scale - 7 (Spitzer et al., 2006) at pre-assessment and post-assessment.

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

The sense of presence in a virtual environment is measured using The Igroup Presence Questionnaire (IPQ, Schubert et al., 2001) at post-assessment.

The system's usability is measured using The System Usability Scale (SUS) at post-assessment.

Pilot study and changes during and after the pilot study

The pilot study was conducted. Participants who gave informed consent were randomly allocated to one of the two groups (experimental and control group). Participants who enrolled in the experimental group underwent conventional rehabilitation and short-term visual memory training in immersive virtual reality (iVR). Meanwhile, the control group underwent only conventional rehabilitation. The pilot study included two instead of three groups because the objective was to determine the procedure, feasibility, and preliminary results. A few measures were changed during the pilot study because of the floor or ceiling effect.

Short Term Memory Test (STMT), Vasserman, Dorofeeva, & Meyerson, 1997) was used to measure short-term visual memory but we decided to change it because of the lack of sensitivity and specificity. Furthermore, this measure is not popular among researchers worldwide and we did not find enough studies which describe the results of this measure and the comparison of the results would be impossible. We decided to use the Medical College of Georgia Complex Figures (Ingram et al., 1997) which is suitable for older people and there is no significant difference between this method and The Rey–Osterrieth Complex Figure in the copy and recall scores (Yasugi & Yamashita, 2010).

Also, after the pilot study, we added one additional measure – the Mnemonic Similarity Task (MST, Stark, Kirwan, & Stark, 2019). It is a computerized task for the detection of learning and memory change. The authors indicate that this task is very sensitive for minimal memory changes in a short period of time. This measure is often used in publications to assess memory and this means the comparison of the results will be easy which will benefit for scientific community. This measure is reliable, furthermore, it contains alternative forms to avoid the learning effect.

Finally, an additional group was added – the active control group, which contains short-term memory training in non-immersive virtual reality. Participants in this group get the identical tasks as the participants in the experimental group but in the non-immersive virtual reality. Immersive virtual reality is experienced through a head-mounted display, while non-immersive virtual reality is experienced through a tablet.

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