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Suitability, usability and safety of fully immersive Virtual Reality applications for motor and cognitive rehabilitation in stroke patients preliminary data.

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RESEARCH ARTICLE

SUITABILITY, USABILITY AND SAFETY OF FULLY IMMERSIVE VIRTUAL REALITY APPLICATIONS FOR MOTOR AND COGNITIVE REHABILITATION IN STROKE PATIENTS: PRELIMINARY DATA

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Abstract

Background: The use of immersive Virtual Reality (VR) in stroke rehabilitation appears to be promising for the improvement of motor and cognitive functions.

Methods: The purpose of this pilot study was to investigate the suitability, usability and safety of VR applications that combine motor and cognitive training. Patients suffering from stroke in a subacute phase, and with Mini Mental State Examination (MMSE) ≥18/30, participated in the study. In the context of the REACT project, two IVR applications were designed and created, combining the use of motor and cognitive skills. Full immersion was achieved using the Head Mounted Display (HMD) Oculus Rift S. The intervention lasted for 4 weeks. The Suitability Evaluation Questionnaire (SEQ) was used for measurements. Values are expressed in the median (25th-75th percentile).

Results: Four patients [age: 64.5(61.0-69.5) years, gender:1 female / 3 male] in the 3rd-14th week of rehabilitation were finally included. Overall, the patient's SEQ score was 61(55-63). No adverse effects were reported, only one patient reported mild confusion 5.0(4.8-5.0) in one assessment. No differences were found in the comparison between first and second evaluation [61(58-62) vs 61(48-64), p>0.05].

Conclusions: The primary results of this study show that the equipment is usable, safe, and suitable for use in the rehabilitation of patients with stroke in the early stages of rehabilitation. However, more large-scale studies are needed to investigate the validity and effects of VR applications in the neurorehabilitation of various disorders.

Keywords: Immersive virtual reality, stroke, neurorehabilitation, cognitive rehabilitation, motor rehabilitation.

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INTRODUCTION

Thousands of people are affected each year by hemorrhagic or ischemic stroke. As a result, patients experience multiple physical, cognitive, and psychological difficulties which have a significant effect on their activities and quality of everyday life. The clinical characteristics of people with stroke vary depending on the site and the extent of brain damage. The most common implications include hemiparesis or hemiplegia on the opposite side from brain damage, gait, and balance disorders, cognitive, communication deficits and emotional and behavioral difficulties.[1,2]

Traditional methods such as traditional physiotherapeutic approaches, neuromuscular electrical stimulation, activity specific and functional task practice, constraint induced movement therapy, neuropsychological strategies, have been used in neurorehabilitation.[3] Virtual Reality (VR) is a new promising technology increasingly used as a tool in neurorehabilitation, due to several potential advantages. Rehabilitation principles can be easily integrated into VR to promote cognitive and motor learning, as well as motor control. Furthermore, VR activities are goal oriented; difficulty and intensity can be adapted and personalized to the patient's needs. Also, the patients can interact safely in a 3D environment simulating everyday life which provides greater ecological validity. In addition, learning can be encouraged since multi-sensory stimuli are provided, as well as feedback and internal motivation to participate in environments where problem-solving skills are practiced.[4,5]

Systematic reviews have shown that IVR can be effective as a rehabilitation tool in the physical recovery of stroke patients, improving the balance, gait, and mobility of the upper extremity (UE).[6] Previous studies have suggested that these applications can be safe and effective to improve UE skills.[7-10] Some of them, based on commercial games and activities simulated to daily living, have enhanced UE dexterity after stroke.[11,12]

Moreover, IVR could also be effective in the rehabilitation of cognitive functions such as attention and concentration, memory and visuospatial abilities and navigation.[12-16] To date, there has been only a small number of IVR studies that combine motor and cognitive rehabilitation, mostly in elderly people with Mild Cognitive Impairment.[15,17,18]

On the other hand, the IVR applications could evoke nausea, dizziness, disorientation, eye strain and headache, symptoms that are known as "Stimulation Sickness".[19] These could be caused by several factors, such as immersive content, complex graphical environment or even exposure time.[20] These symptoms have been reportedly noticed only in a minor number of studies, with blurred vision and nausea being the most persistent side-effects.[8,15,21] Most studies have reported great acceptance of VR equipment.[22,23]

The purpose of this study was to assess the usability, suitability, and safety of a fully IVR environment, that combines motor and cognitive exercises, in stroke patients in the early stages of rehabilitation. It was hypothesized that this IVR environment would be easy to use, appropriate and safe in patients suffering from stroke.

METHODOLOGY

Study design

The current pilot study conducted at a Rehabilitation Center inAttica, Greece. The intervention consisted of 8 sessions (2/week, that lasted for 30' for 4 weeks). The sessions were conducted in the presence of a physiotherapist, an occupational therapist, and a neuropsychologist. All participants provided signed informed consent. The study was approved by the ethics committee of the rehabilitation center.

Sample

All participants met the following criteria: a) aged 18 years old and above, b) have been diagnosed with stroke and were in the subacute phase, c) were able to maintain the sitting position in the wheelchair, d) had an MMSE (Mini-Mental State Examination) score greater than or equal to 18. The exclusion criteria were: a) a medical history of seizures, b) a psychiatric diagnosis, c) people with major hearing impairments and d) major vision problems.

A total of 4 in-patient adults, which had been diagnosed with a stroke and were in the 3rd-14th week of rehabilitation, participated in the study. Furthermore, all patients followed an additional rehabilitation program, which included sessions of

physiotherapy, occupational therapy, speech therapy, hydrotherapy, cognitive training and psychological support.

Intervention

This study was part of the project: ''Virtual Reality and Medical Rehabilitation, REACT '' (Project Code: T1ΕΔΚ-03859). For the purposes of this project, the research team designed and developed two IVR applications that combine motor and cognitive training; these were ''Animals in the Farm'' and ''Shapes and Colors''.

Animals in the Farm

In the application "Animals in the Farm" patients were in a rural vehicle, and they were transferred to a farm. During this ride, they listen to a type of preferred music, which they can change by selecting a picture using their hand. At the farm, being in a sitting position, they were asked to direct the animals according to their species (goat -sheep), as indicated by the signs, on the right or the left sheepfold. To do this, each patient had to move upper limb in a horizontal abduction/adduction and shoulder flexion through three levels of difficulty. The first level was when the upper limb was at 0-40^{o} shoulder flexion, the second one was at 40-80^{o} and the third one at 80-120^{o}. Throughout the activity the score was visible in the middle of the screen (Figures 1, 2). In the farm there was a virtual assistant, the NPC (Non-Player Character) that was giving instructions, as well as feedback to the participants on whether the exercise was done appropriately.

The main purpose of this activity is to increase the strength and range of motion of the UE, coordination, and at the same time to improve cognitive abilities such as attention, concentration and visuospatial orientation. At the end of each session, patients can select a non-interactive rewarding scene (boat ride or balloon ride).

Shapes and Colors

The application "Shapes and Colors" aimed to train patients with cognitive deficits in the identification, categorization, and naming of basic colors. Patients were seated in front of a physical and virtual table and could use their left or right hand to perform the exercise. In the VR environment, NPC verbally and visually demonstrated the instructions of the exercises.

During the task of identification, patients were asked to identify a ball by color, comparing it to others on the table. During categorization, they were asked to place in the box, which was in front of them, the objects that have the same color as the box (red). Finally, at the naming task, the virtual assistant asked the patients to indicate and point a ball with a certain color, between a pair of balls (red-blue, blue-yellow, yellow-green), (Figures 3-5).

During both games patients were in a sitting position in their wheelchair. At the same time patients also trained the cognitive functions of attention and concentration as well as visuospatial abilities. These activities could also be performed with the hemiplegic upper limb, if there was a sufficient range of motion and muscle strength.

Technological equipment

At the application "Shapes and Colors" the Oculus Rift S HMD (Head Mounted Display) was used with 2 controllers. At "Animals in the Farm" the same HMD was used in combination with the Kinect V2 sensor.

During the first trial, a therapist informed each patient about the procedure and helped them adapt the HMD on their heads and hold the controllers. Throughout the games, the therapist could watch the games from the computer display.

Evaluation

To assess the suitability, usability, and safety of the IVR system, the Suitability Evaluation Questionnaire (SEQ) was used. Our team translated this questionnaire from English into Greek. This questionnaire is designed specifically for virtual environments. It consists of 14 questions in total, of which 13 are closed questions with answers based on the 5-point Likert scale, and the 14th question is an open one. SEQ's score ranges from 13 to 65, with 13 indicating poor suitability and 65 excellent suitability (24). Each patient completed the SEQ for each application after the first and the last session.

Questions assess enjoyment, success, presence, the feeling of being part of the virtual environment, how real the virtual environment looks and if there is any difficulty understanding the instructions. Also, other questions measure the difficulty of using the equipment, whether this system will help users in their rehabilitation, and four questions are related to the adverse effects that might be caused by IVR. Questions that are related to side effects are question 7 which assesses the general feeling of discomfort, question 8 is about dizziness and nausea, question 9 is about discomfort in the eyes. Finally, question 10 is about disorientation and confusion.[24]

In addition, the research team added some questions to the therapist who were asked to answer three questions, two closed questions (1. how easy it was for patients to use the system, 2. how easy it was for therapists to use the system) using the 5-point Likert scale and a third open question if there were any suggestions for improving applications. The minimum total score of the therapist's questions is 2 (poor usability) and the maximum is 10 (excellent usability).

Statistical Analysis

All statistical tests were conducted with the IBM SPSS Statistics v25. Values reported are median (25^{th}-75^{th} percentile). Wilcoxon signed-rank test was employed to compare SEQ scores at different time points and between applications.

RESULTS

The total number of participants in the study were 4, (1 woman and 3 men) aged 64.5 (61.0-69.5) years. The MMSE and the Functional Independence Measure (FIM) scores were 22.5 (19.5-26.25) and 40 (33.5-53.25), respectively. Demographic and other characteristics of patients are presented in Tables 1 and 2.

In Figure 6, data from SEQ are shown in detail for each assessment/ patient. The results show that the scores out of all the questionnaires were 61 (55-63). Specifically, in "Animals in the Farm" the score was 62 (55.5-65) and in "Shapes and Colors", it was 60.5 (49.5-62.0). Moreover, at the first evaluation of the applications it was 61(58-62) and in the second evaluation 61(48-64) (Figure 7). There was not any difference between the SEQ scores at the first and the second evaluation [61(58-62) vs 61(48-64), p=0.892] and between applications, "Animals in the Farm" and "Shapes and Colors" [62.0(55.5-65.0) vs 60.5(49.5-61.8), p=0.276]. The questions that examine the presence of side effects, as mentioned above, are 7-10. Median, 25^{th}-75^{th} percentile, mean and SD are mentioned in Table 3.

The therapist's questionnaire was answered by the one who guided and assisted the patient during the intervention. A total of 11 out of the 14 questionnaires were completed due to organizational difficulties. As far as the overall ease of use of the system by the patient and the therapist, the score was 10 (9-10). During the first evaluation it was 9.5 (6.8-10) and in the second one 10 (9-10) (Figure 8). Also, in this case, not any difference was found between therapists' responses to the first and second evaluations [9.5(6.8-10.0) vs 10.0(9.0-10).0, p=0.18].

Moreover, the therapists recommended at the exercise of Categorization (from the application "Shapes and Colors"), that appearance of fewer objects, or otherwise, they suggested a change in the arrangement of the objects since they were too many and in very close proximity to each other which resulted to incorrect grasp. Additionally, therapists reported some technical difficulties of the system that occurred during the use. These were some difficulties to use the controllers and NPC's time response to user actions, which was either fast or slow. Overall, the therapists gave positive feedback on the use of this system for the purposes of stroke neurorehabilitation.

DISCUSSION

Virtual Reality is a new technology increasingly used in clinical trials, as a promising tool for the neurorehabilitation of patients with stroke. However, there is still a lack of data regarding effectiveness as well as the safety of this technology.

The purpose of this pilot study was to assess the suitability, usability, and safety of IVR applications that combine motor and cognitive training, for the early stroke rehabilitation. Two applications developed and used, "Animals in the Farm" and "Shapes and Colors", ought to improve UE mobility, gross motor skills, attention, and concentration, visuospatial abilities, identification, categorization, and naming of basic colors.

The four participants were adults who had suffered a stroke 3-14 weeks before the beginning of this intervention and were hospitalized in a rehabilitation center. To assess the suitability, usability, and safety of the VR as well as the presence of side-effects, SEQ questionnaire was used. Furthermore, there were three more extra questions for the therapists related to the ease of use of the equipment.

Based on the results, it seems that this system is quite suitable, easy to use and safe for patients suffering from stroke and being in the early stages of rehabilitation. Also, there were not documented any differences in the comparison of SEQ results between the applications and between the first and second evaluations; however, further studies are required to reach definite conclusions.

Comparing the results of SEQ per patient, it was observed that in three out of four patients, the score increased or remained unchanged from the first to the second evaluation. One patient decreased the score at the second evaluation. The questions with decreased score were related to the overall experience from the program, control of the system, how real the virtual environment feels, difficulty of handling the equipment, and system's usefulness in the rehabilitation process.

However, it is important to mention that one patient, who used only "Shapes and Colors", showed a significant increase in the score from the first to the second evaluation (in questions related to experience, presence in the virtual environment, feeling of success and control, the content of instructions, the difficulty of activities and confusion). This patient, during the first session, had significant difficulty in understanding the instructions and managing the equipment. In the next session, however, these difficulties no longer existed, and this is reflected by the increased score of the followed assessment.

According to these, results of this study agree with recent studies indicating the acceptance, usability, and safety of the IVR system by patients with stroke.[15,22] Most studies used the Simulator Sickness Questionnaire (SSQ), which measures symptoms associated with nausea, disorientation, and eye discomfort due to presence in a virtual environment.[25] In some studies, there was positive and high acceptance of the IVR system from the patients.[15,22]

REACT applications have been designed from scratch for people with neurological diseases that are in the early stages of rehabilitation in contrast to some studies where they used commercially available applications.[11,14] Specifically, the applications have been based on the principles of neurorehabilitation and the activities are simple, goal-oriented, can be adapted to the needs of each patient and personalized, as well as there is a visual and acoustic feedback.[4,5] Furthermore, graphics are simple and not complicated to avoid the "Simulation Sickness'' side effects.[20] Also, the games include "reward" activities, such as a ride on a boat or air-balloon, after the end of every session.

Another one advantage of this study is the combination of motor and cognitive training in one application. The applications have been designed by a multidisciplinary team consisting of physiotherapist, occupational therapists, and neuropsychologist. In most of the IVR studies, the motor and cognitive training have been implemented separately. The combination of cognitive and motor training has been performed in patients with mild cognitive impairment[17,18] or in non-IVR stroke rehabilitation.[26,27]

Another important point to note is that patients did not experience any side effects. Only one patient reported a small confusion at the first session, maybe because of the general difficulty using the equipment. In the next evaluation, however, he improved the understanding and using of the equipment, and he was not confused or disoriented anymore. In addition, one more patient reported a slight dizziness during the intervention, which did not affect the completion of the task.

It is also important that in this study questions to therapists were additionally included to provide feedback on the difficulties the patient may have experienced, as well as their experience as therapists when using the equipment. The high scores in these questions indicate that there were not any significant difficulties, either from the patients or the therapists. Therefore, therapists scores appear to confirm the SEQ results on equipment usability. Furthermore, the therapists' comments on the design and technical problems will be helpful for further improvements.

Limitations

Although the applications were designed to improve hemiplegic UE, this was not eventually examined since the participants had

low muscle tone and muscle strength to grasp and move the controllers. Also, the application "Animals in the Farm" was designed to be used only with the right UE; as a result, one of the participants, with right hemiplegia, did not participate in this activity. Finally, due to the small sample size, the generalization of the results cannot be conducted. Even so, there have been collected enough data to help in future improvements and adaptations.

Future work

This system should be tested to a larger sample of patients with various neurological disorders to reach results with adequate power. A randomized control trial is recommended to compare IVR with traditional methods of rehabilitation, which would assess the motor and cognitive functions before and after the intervention. Follow-ups would be beneficial to indicate the long-term benefits.[28] Also, an initial session of familiarization is proposed to assist patients on handling with the equipment; this issue, in turn, potentially affects SEQ scores. Other studies have included adaptation and familiarization sessions with the equipment prior to the interventions.[10]

In this study, patients due to the absence of voluntary movement in the hemiplegic UE, could not use this hand in the VR. In future studies, patients with little or no muscle power could derive maximum benefits from "mirror therapy" in IVR. As observed in a study, participants with moderate to severe mobility deficits in the UE, improved significantly after training with "mirror therapy" in the IVR environment.[9]

Almost all patients expressed their wish to involve their hemiplegic UE within the virtual environment. Due to the absence of active movement this was not possible. However, it would be quite interesting if this system could be combined with a robotic UE system, as in the study of Norouzi-Gheidari et al.,[29] where they supported the upper limb with a UE exoskeleton. Furthermore, IVR might also be combined with a Brain Computer Interface to give a chance to patients with no voluntary movements to benefit from participating in the IVR environment.[30]

CONCLUSIONS

These preliminary data indicate that the IVR applications, designed in the REACT project, and combine motor and cognitive training, are suitable, usable, and safe for the early rehabilitation of stroke patients. However, more large-scale studies, and studies that combine IVR with other technologies are needed to investigate the effects of VR in neurorehabilitation .

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ANNEX

FIGURE 1. Scene from "animals on the farm".

FIGURE 1. Snapshot while a patient is using "animals on the farm".

FIGURE 3. Identification of red balls at "shapes and colors".

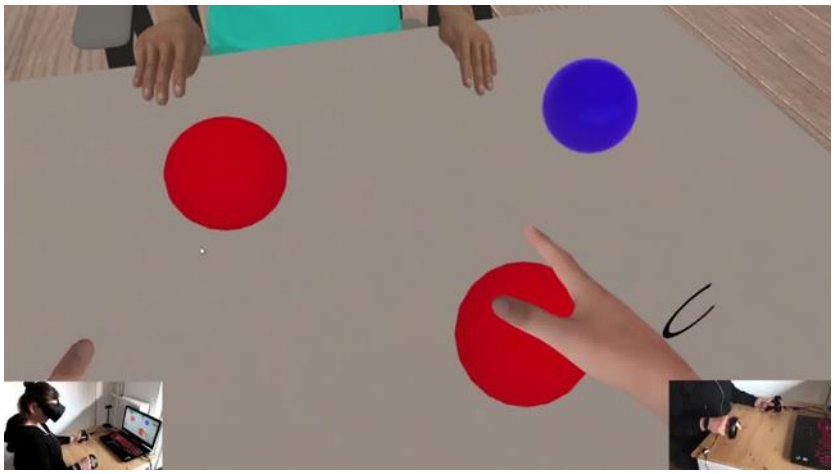

FIGURE 4. NPC demonstrates how to categorize red objects with red box from "shapes and colors".

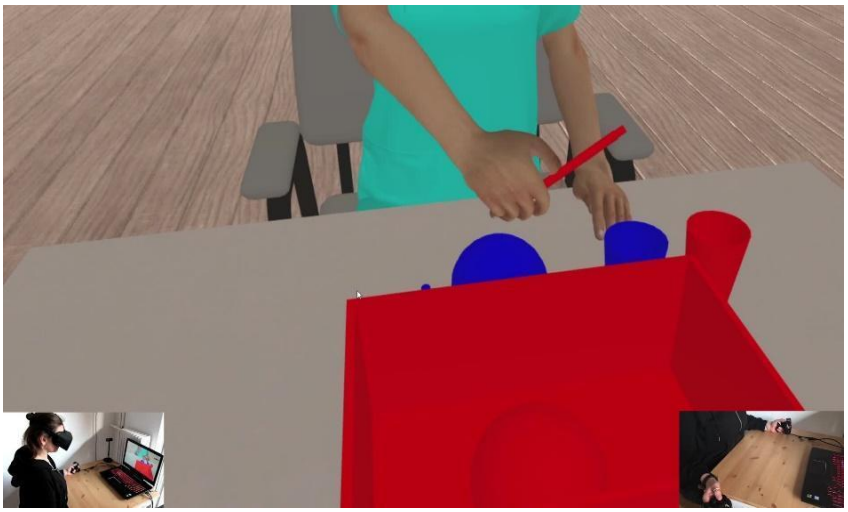

FIGURE 5. A patient indicates a blue ball from yellow one at "shapes and colors".

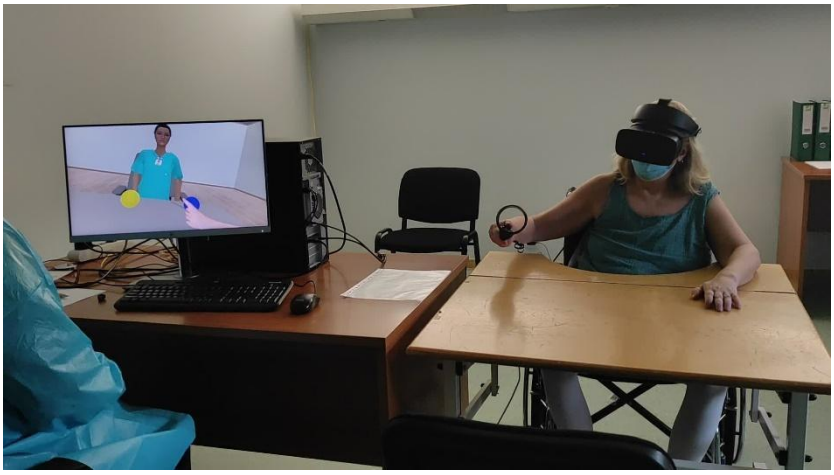

FIGURE 5. SEQ scores for each application per patient.

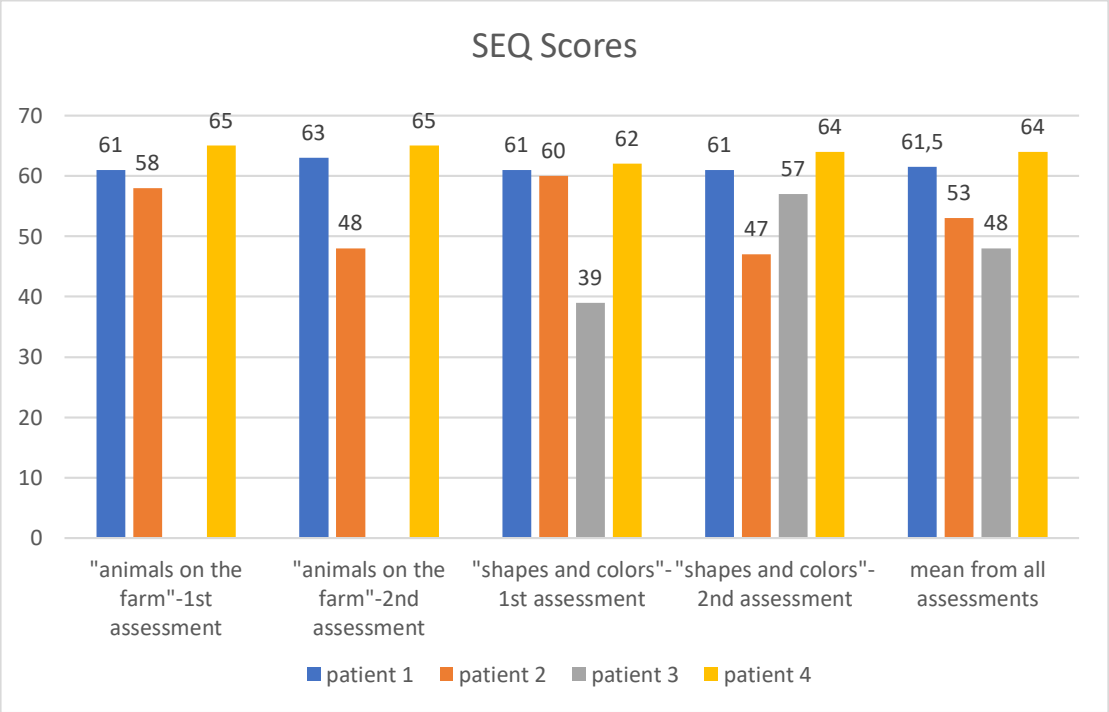

FIGURE 7. Boxplots for SEQ results.

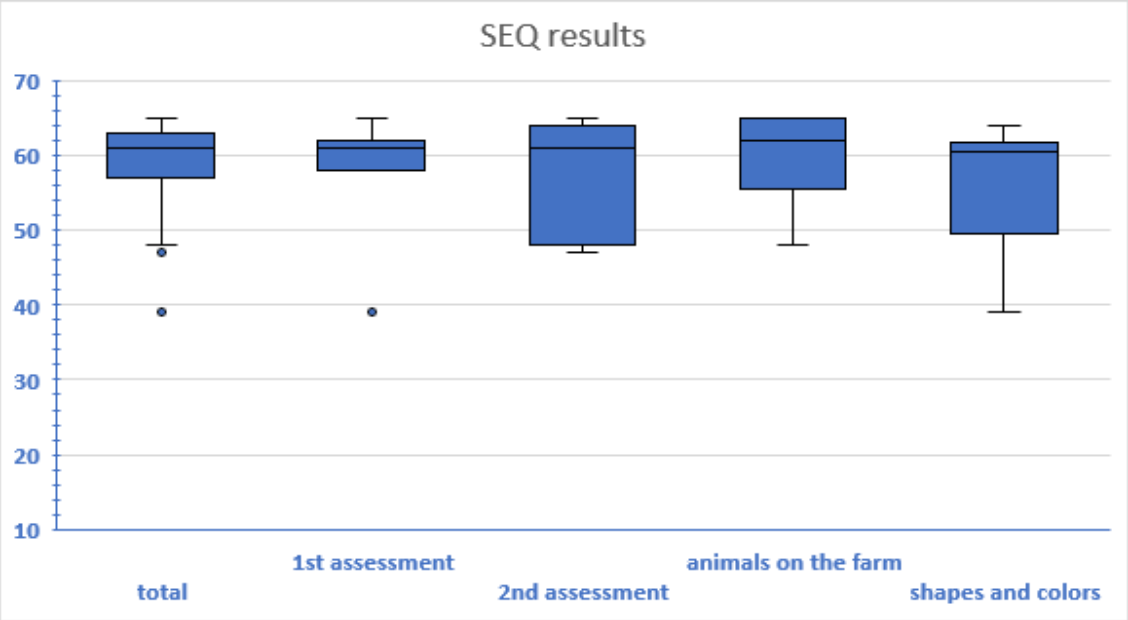

FIGURE 8. Total scores from questionnaire given to therapist

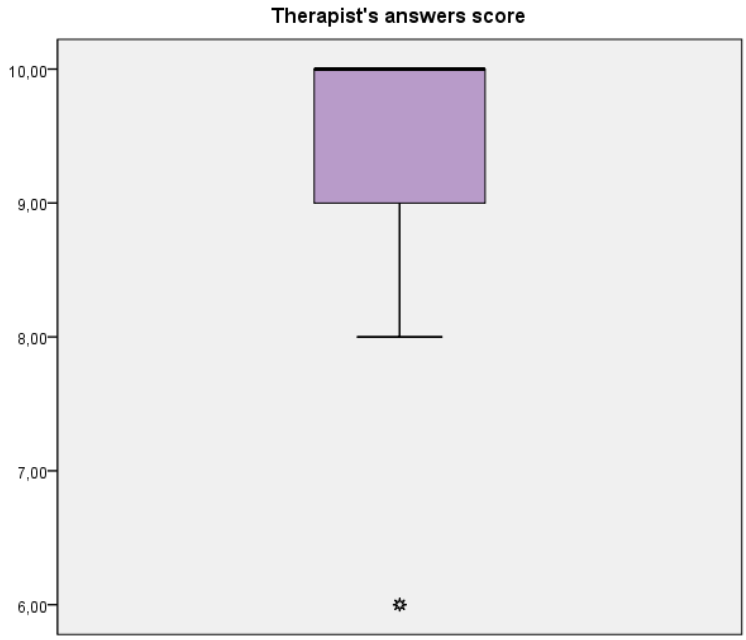

TABLE 1. Demographic characteristics of participants

Participant	Gender	Age (years)	Diagnosis	Weeks after diagnosis	FIM	MMSE
1	Female	60	ischemic stroke, left hemiplegia	3	56/126	27/30
2	Male	61	intracerebral bleeding, left hemiplegia	13	45/126	19/30
3	Male	68	cerebral infarction, right hemiplegia	3	35/126	24/30
4	Male	70	cerebral infarction, left hemiplegia	14	33/126	21/30

TABLE 2. Information about participants' games

TABLE 2

Participant	UE used	Games played		Sessions attended
		Animals	Shapes	
1	right	√	√	8
2	right	√	√	8
3	left		√	6
4	right	√	√	5

TABLE 3. Questions 7-10, results.

Results from questions 7-10				
Question	*Median*	*25th-75th Percentile*	*Mean*	*SD*
Q7. Did you feel discomfort during your experience with the system?	*5*	*5-5*	*4.9*	*0.4*
Q8. Did you experience dizziness or nausea during your practice with the system?	*5*	*5-5*	*5*	*0.0*
Q9. Did you experience eye discomfort during your practice with the system?	*5*	*5-5*	*4.9*	*0.3*
Q10. Did you feel confused or disoriented during your experience with the system?	*5*	*4.75-5*	*4.6*	*0.8*