Safety, Feasibility, and Acceptability of a New Virtual Rehabilitation Platform: A Supervised Pilot Study

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ABSTRACT

PURPOSE: Stroke is the leading cause of disability in adults worldwide, with hemiparesis being the most prevalent consequence. The use of video games and movement sensors could contribute to improving patients' chances of recovery. We performed a supervised pilot study to validate the safety, feasibility, and acceptability of a new virtual rehabilitation platform in patients with chronic post-stroke upper limb hemiparesis.

METHODS: The participants (n = 9) participated in 40 rehabilitation sessions, twice a week, for a period of 20 weeks. Their experiences with the platform were documented using a Likert-scale survey. Changes in motor function were evaluated using the Chedoke Arm and Hand Activity Inventory (CAHAI) and the Wolf Motor Function Test (WMFT).

RESULTS AND CONCLUSIONS: All participants expressed that they enjoyed the experience and felt comfortable using the platform. Preliminary results showed significant motor recovery (P = .0039) according to the WMFT scores. Patients with significant impairment showed no improvement in upper limb task-oriented motor function after therapy.

The new platform is safe and well-accepted by patients. The improvement in motor function observed in some of the participants should be attributed to the therapy since spontaneous functional recovery is not expected in chronic stroke patients.

KEYWORDS: Neurorehabilitation, video games, stroke, upper extremity, motor function

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Introduction

With the increasing life expectancy across many developing countries, chronic and vascular diseases have risen as the leading causes of death and acquired disability. Among such diseases, stroke is the second most common cause of death and the leading cause of acquired disability in adults worldwide.[1-4]

According to the World Stroke Organization, there are 13.7 million new strokes every year, showing a high prevalence of disease with more than 80 million stroke survivors in 2019.[5] Even though the stroke mortality rate has decreased in the last 10 years, its incidence has considerably increased,[6] resulting in more stroke survivors with some degree of physical or cognitive disabilities.

Motor impairment of one side of the body (hemiparesis) is the most common long-term consequence of stroke, affecting approximately 80% of stroke survivors and resulting in some degree of long-term disability with a great impact on the patient's quality of life.[7-9] Physical rehabilitation has shown positive effects on motor recovery after stroke,[10] but outcomes are variable, depending on factors such as time since stroke, frequency of sessions, and the type of rehabilitation intervention.[11,12]

The frequency of therapy is particularly relevant, as evidence shows that the best results are obtained with high-intensity therapy, as part of a training session program, for 7 days a week, or even with schemes having 2 training sessions per day.[3,4]

Recovery is best achieved when therapy is initiated within the first 3 months of the stroke, and is intensive and regular.[13,14] It is well established that neurochemical and neuroanatomical changes in the vicinity of the affected brain area occur within the first few days/weeks after the stroke, corresponding to the state of increased neuroplasticity.[15-17] These changes respond to a process known as spontaneous biological recovery, and animal studies have shown that early training can increase the gains associated with spontaneous recovery.[18]

This and other studies support the existence of a "time window of opportunity," with a maximum duration of 3 to 6 months, when the best rehabilitation results are obtained.[19-21] Significant spontaneous functional recovery is not expected in chronic stroke patients,[17] therefore, motor recovery is associated with some type of intervention than with no treatment.[12,22] Moderate improvement in motor skills have been reported in chronic stroke patients who were administered high-intensity therapy.[23-27]

In countries with weak health systems, stroke survivors rarely receive therapy with the opportunity and frequency necessary to obtain the best possible recovery. This is due to the saturation of rehabilitation centers, a shortage of specialized therapists, and the socioeconomic situation of patients which makes it difficult for them to attend their appointments. Therefore, the need to find rehabilitation alternatives that are available to a greater number of patients at an early stage of their recovery is of particular importance.

The use of interactive technologies as an auxiliary rehabilitation therapy has been explored for more than a decade, and in recent years, a considerable amount of evidence has been accumulated in relation to the possible benefits of the use of serious games and virtual reality in the motor recovery of patients with stroke-related hemiparesis.[28,29] The use of video games and movement sensors to perform specific exercises is a versatile tool of virtual therapy, and is likely to be useful for improving altered motor function in neurological patients, such as those who have suffered a stroke.[9,30,31] The therapy consists of performing a series of simulation exercises using virtual environments that allow patients to engage in the repetitive practice of specific tasks. This type of rehabilitation has been tested using devices such as the Microsoft Kinect,[24,32-34] Leap Motion sensor,[35,36] and Nintendo Wii gaming system,[30] among others. Although favorable results have been reported with the use of commercial video games associated with these motion sensors in patients with hemiparesis,[30,37] the best results seem to be achieved with those applications developed expressly for rehabilitation and focused on task-specific training.[38]

Many studies have corroborated the effectiveness and impact of virtual rehabilitation compared to conventional therapy.[25,29,33,34,36,39] Evidence showing favorable effects of virtual therapies on motivation and adherence,[40,41] as well as demonstrating a significant improvement in patient mood and commitment to their rehabilitation process now exists.[9,42] However, in our opinion, the greatest impact of virtual rehabilitation lies in the possibility that many of these platforms can be used by patients from home,[23,26,43-45] allowing therapy to begin early and exercises to be performed as often as indicated, without depending on the availability of appointments or transportation to rehabilitation units.

The Laboratory of Research and Development of Interactive Applications for NeuroRehabilitation (LANR, https://lanr.ifc.unam.mx) has developed an original video game platform associated with position and movement sensors to complement rehabilitation therapies for patients with upper limb hemiparesis. The applications developed by LANR are serious games, designed with the advice of neuro-rehabilitation professionals, focusing on training certain movements that help regain lost functions. We hope that the playful component of our games, along with the constant visual and auditory feedback they provide to the user, will be stimulating and attractive to patients. However, the ultimate objective of our platform is tele-rehabilitation, so that once we have been able to test its safety and feasibility, we might offer the patients the option of using the platform from home.

This supervised pilot study aimed to demonstrate the usability, safety, and possible benefits provided by the LANR virtual rehabilitation platform in patients with chronic post-stroke upper limb hemiparesis who were referred to the rehabilitation service of the National Institute of Neurology and Neurosurgery of Mexico. Some improvements in upper-limb mobility in participants were anticipated.

Methods

Participants

We recruited patients who were referred to the Occupational Therapy Area of the Rehabilitation Service of the National Institute of Neurology and Neurosurgery (INNN) in Mexico City between January and December 2019. The protocol was authorized by the ethics committee of the hospital.

The inclusion criteria included patients with upper limb hemiparesis, secondary to an ischemic or hemorrhagic stroke, with more than 6 months and less than 20 years of evolution, who were within an age range of 18 to 90 years.

The Fugl-Meyer et al.[46] upper extremity (FMA-UE) motor function test was applied to all candidates, and only those with a score $\geqslant$10 (0-66) were accepted to the next stage. This test was applied to confirm that the recruited patients were physically able to perform virtual therapy.

The Token test[47] was applied to determine the patient's ability to understand verbal instructions, and only patients with a score $\geqslant$17 (0-36) were accepted for participation in the protocol.

The exclusion criteria were as follows: joint instability (shoulder, elbow, or wrist), severe concurrent medical problems such as congestive heart failure or seizures, severe aphasia, apraxia, hemi spatial neglect, visual handicaps not corrected with glasses, non-compensated hearing disorders, or receiving other treatments such as botulinum toxin or electrical transcranial stimulation (reported by the treating physician).

Once the details of the proposed intervention were explained to the patients and their families, they signed an informed consent form to participate in the protocol.

All information collected from the participants, as well as their medical history, was treated confidentially. Access to this information was restricted exclusively to members of the laboratory and for the purposes of this research.

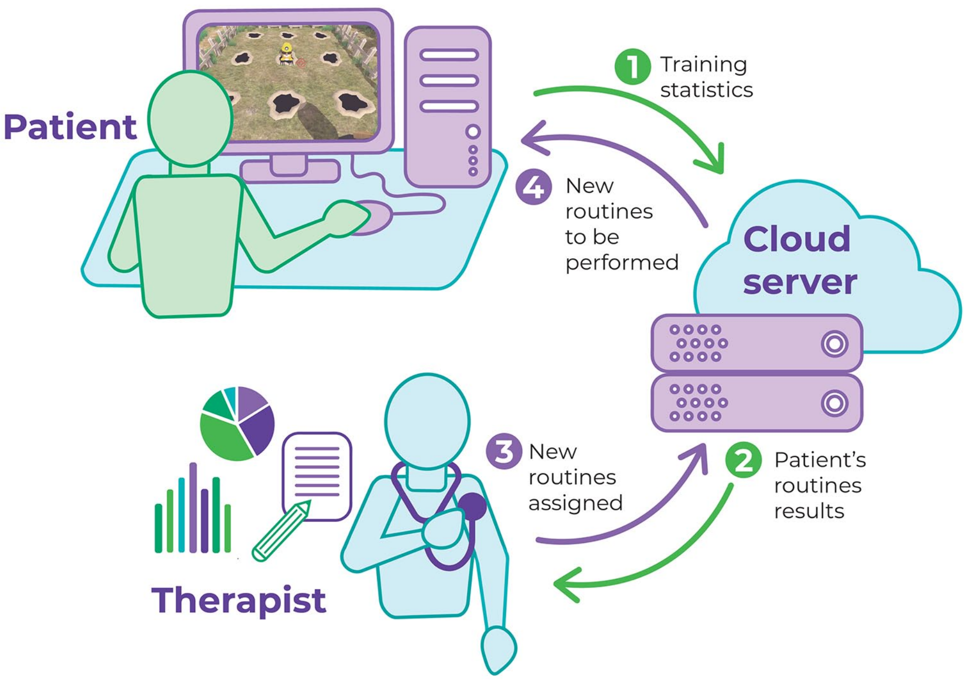

Figure 1. LANR's platform information flow. From the patient's game execution results to the server (1), the information is then reviewed by the therapist (2), new routines are assigned (3), and back to the patient's interface (4).

LANR virtual rehabilitation platform

The platform was developed for use in tele-rehabilitation. It consists of a series of video games and a central server in which both patients and therapists are registered. The server stores the results of all routines performed by patients, allowing the therapists to monitor each patient's progress and assign new routines depending on the data collected during the routine execution (Figure 1).

All games were developed from scratch (copyright protected) using the Unity game engine. Each one is associated with a specific sensor to optimize the data collection for the movements of different arm and hand joints. In addition to using commercial sensors in LANR, we developed our own original devices to fulfill patient needs.

All the games handle different levels of difficulty, including parameters such as speed, number of repetitions, and predictability of the movements to be executed. They also include tools for designing personalized routines, thus making the challenges always appropriate for the patient's abilities and demanding effort only up to the extent of their capabilities.

The 4 video games on the platform used during this intervention were developed to cover the rehabilitation process from the most proximal joints (shoulder) to the most distal ones (fingers):

- Penal Madness©: This game works with the Kinect sensor and aims to increase muscle strength and joint range of the shoulder in the frontal and sagittal planes. The user plays the role of a soccer goalkeeper, extending the arm, trying not to flex the elbow, and reaching the targets shown on either side of the body. The target settings, including the side of the body, distance, and number of shots, can be customized by the therapist (Figure 2a).
- Topocrisis©: This game is played with an ergonomic mouse and its function is to increase the muscle strength and joint range of the shoulder, elbow, forearm, and wrist, with arm movements in the horizontal plane on a table. The dynamics of the game resemble the classic "Whack-a-mole," showing a field with holes, and the patient must place the pointer on each mole that appears in one of the holes. The level of mouse sensitivity can be adjusted in each game to promote wide movements (involving the shoulder), shorter displacements (mainly using the elbow and forearm), or linear horizontal movements alone, with the highest mouse sensitivity (to exercise lateral movements of the wrist). The orientation of the movements in horizontal, vertical, diagonal, or combined lines can also be defined for each game. The speed at which moles appear and the number of moles in each game can also be adjusted (Figure 2b).
- Charlie's Escape©: In this game, the user controls an avatar by hand movements, detected using the Leap Motion controller. The goal is to help the patient regain grasp function as well as the hand's fine motricity. The avatar advances at a constant speed when the user's hand is closed. If an obstacle appears, the user must either open the hand or separate the thumb from the rest of the fingers to make the avatar jump to avoid the obstacle. Opening the hand before an obstacle is presented will

Figure 2. Screenshots of the LANR video rehabilitation platform's video games used in this intervention. (a) Penal Madness, (b) Topocrisis, (c) Charlie's Escape, and (d) Sandwichmania.

stop the avatar's movement. It is possible to configure the speed, the number of obstacles, and the distance between them (Figure 2c).

- Sandwichmania©: In this game, the user wears a laboratory-developed glove (patent pending) which detects contact between the thumb and the other fingers, thus improving the hand's fine motricity. With each finger representing a different ingredient, the user is guided on preparing a sandwich by making contact between the tip of each finger and the thumb, following the exact order and number of ingredients that are indicated. The number of sandwiches and ingredients of each sandwich can be configured (Figure 2d).

Outcome assessments

To assess the participants' experience with the LANR videogame platform, a 4-point-based 20-question Likert-scale survey and 6 open questions were provided to all participants. The scale's maximum score of 4 indicated that the patient strongly agreed with the statement, and the minimum of 1 indicated strong disagreement. To cover topics such as the enjoyment, usability, safety, immersion, and esthetics of the platform, the survey was constructed based on the System Usability Scale (SUS),[48] the Flow Short Scale[49] and Pallesen's et al.[42] guided interview. For this survey, we chose a 4-point scale in order to find specific answers and avoid neutral opinions.

The surveys were administered at the end of the intervention by team members who had not interacted with patients during therapy.

Evaluating the effectiveness of interventional therapy in improving upper extremity motor function requires sensitive and reliable assessments of functional activity. Changes in motor function were evaluated using 2 assessments:

The Wolf Motor Function Test WMFT[50] is a quantitative measure of upper limb motor ability through timed and functional tasks. It quantitatively evaluates a broad range of upper-extremity functions. It consists of 17 items, including 15 functional and 2 strength tasks. The score for each task is obtained by evaluating the quality of movement in terms of motor coordination and fluidity, using a 6-point scale (0 [task was not even tried with the paretic arm or took more than 120 seconds to complete]-5 [performance is equal to that of the non-paretic limb]). In this study, we used the sum of the functional ability scale (WMFT-FAS) of the 15 functional tasks (maximum score, 75). WMFT has been found to be a valid and reliable measure of upper extremity function.[51]

The Chedoke Arm and Hand Activity Inventory CAHAI[52] measures upper limb ability on bilateral functional tasks. CAHAI ver. 7 was used in this study. This test evaluates upper limb strength, dexterity, coordination, and grasp, and has been

Table 1. Statistics of the sample composition.

PATIENTS INFORMATION	N = 9
Gender (male/female)	6/3
Age (years ± SD)	52.67 ± 14.76
Schooling (years ± SD)	10.55 ± 3.74
Stroke type (ischemic/hemorrhagic)	6/3
Stroke location (MCA/other)	5/4
Affected body side (left/right)	3/6
Dominant side (left/right)	0/9
Evolution (years ± SD)	4.33 ± 7.02
Previous strokes (yes/no)	2/7
Token (scores ± SD)	28.05 ± 6.35
Fugl Meyer (scores ± SD)	30.3 ± 15.47
Cardiovascular diseases (yes/no)	3/6
Aphasia (yes/no)	4/5

associated with activities of daily living.[53] Each task is graded 1 to 7 according to the quality of the movements and the involvement of both hands during each task execution, with a total maximum score of 49.

Both tests were applied before starting the video game therapy and at the end of the 40 sessions. All the tests were video-recorded. Each test score was the average of the score granted by the applicator and those assigned by the other 3 members of the team, who were blinded to whether it was a pre- or post-intervention test, and who had not interacted with the patients, neither during their therapy, nor during the evaluations.

Intervention

Two upper limb motricity assessments were applied to all participants at the beginning and end of the intervention, in order to evaluate the effectiveness of the therapy.

The therapy consisted of 40 rehabilitation sessions, including 15 to 20 minutes of warm-up exercises consisting of passive and active stretches, followed by 45 minutes of therapy with video games from the LANR platform, while visiting the hospital twice a week, over a period of 20 weeks. Participants did not receive any other rehabilitation therapy during the duration of the intervention.

Games were assigned by the LANR team members in a personalized manner to each patient, depending on their individual abilities and limitations. Most games were performed using the paretic arm. One of the games (Penal Madness) involved movement of both arms, and in some cases, patients were instructed to perform the exercises with their non-paretic arm to get used to the game before trying with the paretic arm.

Results

Of the 18 patients recruited for the protocol, only 9 completed the 40 sessions of the rehabilitation program. In all cases, dropping out was associated with mobility problems, either because the patients were unable to pay for transportation to go to the clinic or because their relatives were no longer able to accompany them. Table 1 presents the demographic data of the participants.

Of the 9 participants who completed the protocol, 6 were male and 3 were female, with an average age of 53 years. Furthermore, the stroke was of ischemic origin in 6 of them, and 5 had the lesion at the medial cerebral artery (MCA). The average evolution time from the stroke was 7 years, and 2 patients had suffered from previous strokes.

Platform usability and safety

Table 2 shows the results of the satisfaction survey administered to all participants after the intervention. For all questions that were posed in a negative way, participants tended to give lower scores, and higher scores were given to affirmatively-posed questions. The participants strongly agreed to having had an enjoyable experience, according to the statements "I liked playing the games" and "I had fun playing the games," which had average ratings of 4 and 3.67, respectively. This was in concordance with the average rating of 1.33 for the statement "Playing LANR games was uncomfortable for me." The esthetics of the games were also highly accepted by the participants, as indicated by the average ratings of 3.67 for question 13 (referring to the games' colors) and 3.78 for question 14 (referring to the games' music). The participants perceived that the games were very accessible to them as the statements "The games are easy to use," "The games' instructions were always clear for me," and "Learning to play the games was easy," each had an average rating of >3. Furthermore, the participants didn't perceive significant errors in the games, according to the average rating of 1.67 for question 16.

The statement, "The games were a useful tool for my rehabilitation," with an average rating of 3.55, indicated that the participants felt that the games were helpful. Based on the answers to questions 2, 4, 5, and 6, all with an average rating of >3, the participants perceived that the difficulty level of each game was neither too easy nor too hard for them, favoring a flow state (as described by Park et al.[54]), in which they were highly focused on their tasks. Some participants expressed frustration due to some technical problems with the computer equipment during the intervention, as reflected in the average score of 2.55 for the statement, "I often needed technical support."

From the survey, questions 18, 19, and 20 directly addressed topics related to pain, fatigue, and stress during the use of the

Table 2. Feedback values of the participants on the Likert survey after virtual therapy with the LANR video games.

QUESTIONS FOR PARTICIPANTS ON THE 4-POINT LIKERT SCALE (MAXIMUM, 4)*	PARTICIPANT ID									MEAN (SD)
	1	2	3	4	5	6	7	8	9	
1. I liked playing the games.	4	4	4	4	4	4	4	4	4	4 (0)
2. I had fun playing the games.	4	4	3	4	4	4	3	3	4	3.67 (0.47)
3. The games were a useful tool for my rehabilitation.	4	4	3	4	4	2	4	3	4	3.55 (0.68)
4. I could easily concentrate while playing.	4	4	4	4	3	4	4	4	4	3.89 (0.31)
5. I lost track of time while playing.	3	3	3	4	4	3	4	3	4	3.44 (0.49)
6. The games were within my abilities.	4	3	4	3	2	4	4	3	4	3.44 (0.68)
7. I was worried of making mistakes while playing.	2	2	3	2	3	1	2	3	1	2.11 (0.74)
8. Learning to play the games was easy.	3	3	4	4	3	4	3	3	2	3.22 (0.63)
9. I often needed technical support.	3	3	3	1	4	2	2	3	2	2.55 (0.83)
10. I always knew when I was doing an incorrect movement	3	3	3	4	3	3	3	3	3	3.11 (0.31)
11. The games were easy to use.	3	3	4	4	3	4	3	3	4	3.44 (0.49)
12. The games' instructions were always clear for me.	4	3	3	4	4	4	4	4	4	3.78 (0.41)
13. The games' music was pleasant.	3	3	4	4	4	4	4	4	4	3.78 (0.41)
14. The games' colors were pleasant.	3	3	3	4	4	4	4	4	4	3.67 (0.47)
15. The games had distracting elements.	2	3	3	1	2	1	1	1	2	1.78 (0.78)
16. The games presented errors that made them difficult to use.	2	3	2	1	2	1	1	2	1	1.67 (0.67)
17. Playing LANR games was uncomfortable for me.	2	2	1	1	2	1	1	1	1	1.33 (0.47)
18. I felt pain while playing.	2	2	1	1	2	1	1	1	1	1.33 (0.47)
19. I felt tired after playing.	2	2	1	1	2	1	2	2	1	1.55 (0.49)
20. I felt stressed while playing.	2	2	1	1	3	1	1	1	1	1.44 (0.68)

*4-point Likert scale, with "strongly disagree" = 1; "disagree" = 2; "agree" = 3; and "strongly agree" = 4; SD, standard deviation.
All the statements used in this study were deliberately rephrased in terms that the patients could easily understand.

Table 3. Feedback from patients that used the LANR virtual rehabilitation platform. Some of the answers to our open questions.

Question: How did you feel when you played the LANR games?
"Good, I felt I would move my hand again very soon."
"I felt good, motivated. I felt an improvement. I acquired more movement and displacement."
"They have been very useful for the movement of my arm and also for my posture."
"I felt good. They (the games) were relaxing."
Question: What did you like most about the video games?
"They were very entertaining."
"Charlie's Escape has helped me coordinate my right hand, and with Topocrisis, I have seen I can move my arm more than before."
"It was functional for me. I acquired more movement."
"They helped me perform movements that I could not do before. They are useful tools."
Question: Were you willing to take the LANR platform home?
"Yes, because I think I would do more therapy at home."
"If I could, I would take them home, so that I could play for another 40 minutes twice a day."
Question: Would you recommend the platform to other patients?
"I would recommend the system; I have seen a lot of improvement to do so."
"I would recommend the games, because they helped me gain confidence with my movements."
"Yes, because the games would help them recover in a cheerful way, without pressure."
Question: What would you improve about the video games?
"I would increase their difficulty, because at certain point the games become too easy"
"Sometimes I felt that the game of the goalkeeper failed to indicate mistakes, I was standing correctly, but the game indicated that my posture was wrong."

platform, and patients strongly agreed that they did not experience any of these adverse conditions, with average scores of 1.33, 1.55, and 1.44, respectively. One patient reported feeling stressed only at the beginning, due to his lack of experience using this kind of technology. During the study, none of the patients reported any adverse effects such as pain, sickness, or dizziness.

No incidents that required suspension of the exercises occurred. These findings suggest that the platform is safe for use.

Some of the answers given by the patients to open questions are presented in Table 3 (all answers are reported in Appendix 1). In summary, the overall perception of the participants toward the games was that they were comfortable, entertaining, and motivating, and that they could be even more useful if they had been able to take them home.

Training dose and intensity

The dose of exercise for each game was assigned according to the participants' capabilities, as shown in Table 4. Activities in the games were divided into sets consisting of 10 exercises each, with a 20-seconds resting time between them. When patients showed signs of fatigue, the therapy was suspended for 3 minutes and resumed with another game. The movements made with each game are as follows:

- Penal Madness: Shoulder abduction in the paretic arm (SA-P) and shoulder flexion in both arms (SF-B).
- Charlie's scape: Closed hand, with opening and closing movements to evade every obstacle (H-OC).
- Topocrisis: Elbow extension and flexion to reach each mole that appeared (E-FE).
- Sandwich mania: Fine finger clamping between the thumb and other fingers of the hand (F-FC).

As can be seen from the table, participants 1, 2, and 3 were not able to perform the movements required to play Penal Madness due to low functional motricity of the shoulder; however, they had enough hand motricity to play Charlie's

Table 4. Doses of each game for the participants that used the LANR virtual rehabilitation platform.

ID	PENAL MADNESS		CHARLIE'S ESCAPE		TOPOCRISIS		SANDWICHMANIA	
	SETS	DURATION (MIN)*	SETS	DURATION (MIN)*	SETS	DURATION (MIN)*	SETS	DURATION (MIN)*
1	Unable	0	2 H-OC	10	5 E-FE	35	Unable	0
2	Unable	0	2 H-OC	10	5 E-FE	35	Unable	0
3	Unable	0	2 H-OC	10	5 E-FE	35	Unable	0
4	4 SA-P 3 SF-B	25	2 H-OC	10	3 E-FE	10	Unable	0
5	3 SA-P 2 SF-B	15	3 H-OC	15	4 E-FE	15	Unable	0
6	2 SA-P 2 SF-B	10	2 H-OC	10	3 E-FE	10	3 F-FC	15
7	2 SA-P 2 SF-B	10	5 H-OC	25	3 E-FE	10	Unable	0
8	2 SA-P 2 SF-B	10	3 H-OC	10	3 E-FE	10	4 F-FC	15
9	2 SA-P 2 SF-B	10	3 H-OC	10	3 E-FE	10	4 F-FC	15

Abbreviations: E-FE, elbow flexion and extension; F-FC, fingers-fine clamp; H-OC, hand opening and closing; SF-B, shoulder flexion-both; SA-P, shoulder abduction-paretic.
*Set duration varied depending on the difficulty level.

Table 5. Participant's Fugl-Meyer, CAHAI and WMFT scores.

PATIENT	FMA-UE	CAHAI			WMFT		
		PRE	POST	DIFFERENCE	PRE	POST	DIFFERENCE
1	12	7	7	0	16	17	1
2	14	7	7	0	16	18	2
3	14	7	7	0	16	18	2
4	21	12	10	−2	24	26	2
5	38	24	28	4	46	51	5
6	53	25	33	8	45	59	14
7	32	34	40	6	57	61	4
8	34	34	41	7	61	67	6
9	55	45	46	1	60	73	13
Mean (Total)		21.67	24.33	2.67*	37.89	43.33	5.44**
SD (Total)		14.16	16.54	3.64	19.8	23.28	4.85

Abbreviations: CAHAI, the Chedoke Arm and Hand Activity Inventory; FMA-UE, the Fugl-Meyer assessment for the upper-extremity; WMFT, the Wolf Motor Function Test.
*Wilcoxon matched-pairs signed-rank test P-value = 0.0938 (CAHAI Pre- and Post- means were not significantly different, $P > 0.05$).
**Wilcoxon matched-pairs signed-rank test P-value = 0.0039 (WMFT Pre- and Post- means were significantly different, $P < 0.05$).

Escape. On the other hand, Sandwichmania required at least a mild fine finger clamp function; consequently, only participants 6, 8, and 9 could play the game. During the intervention, more playing time was given for those games that the participant was able to play but were also more demanding, thus prioritizing rehabilitation of the most proximally affected joints.

As all the devices were connected to the computer from the beginning of the session, the time invested in switching activities was minimal.

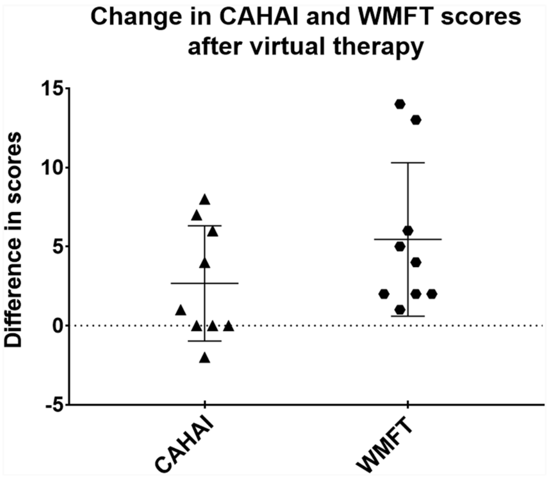

Figure 3. Changes in CAHAI and WMFT scores in each patient after virtual therapy.

Outcome preliminary results

The scores obtained from applying the standardized upper limb mobility tests to each participant are shown in Table 5. The Fugl-Meyer upper limb motor function test (FMA-UE) was used as a measure of the degree of impairment at baseline, and the range obtained was 12 to 55 points, out of a total of 66. WMFT-PRE shows the scores of this test at the beginning of the intervention, while WMFT-POST shows the scores at the end of the intervention (maximum score, 75). The CAHAI scores before and after virtual therapy are reported as CAHAI-PRE and CAHAI-POST, respectively (maximum score, 49).

To test if the observed changes in both tests were significantly different, a 2-tailed Wilcoxon matched-pairs signed rank test was applied, which is a non-parametric version of the *t*-test for paired samples (*t*-test could not be applied due to the small sample size). As can be seen from the table, only the changes in the WMFT showed significant changes before and after the intervention ($P = .0039$).

The high standard deviation of the average gain indicates a variable response to therapy among participants. To explore this variation, the individual data of the observed change for each patient in both tests were plotted (Figure 3). On the CAHAI test, there was a group of 5 patients that showed no gain, or even a slight loss in motor function, while 4 patients showed consistent gain. On the WMFT test, there were also a group of 4 patients that showed very little gain, 3 patients with some gain, and 2 patients with significantly higher scores after the intervention.

Considering only those patients who showed some gain in either test (responders), we estimated the Reliable Index Change (RIC) and the Minimum Clinically Important Difference (MCID), using the distribution-based approach suggested by Copay et al.[55] As can be seen from Table 6, a significant change was observed in all participants in the WMFT, and in 4 participants in the CAHAI.

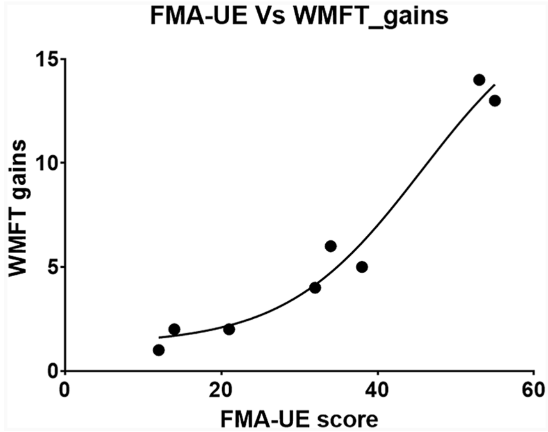

Figure 4. Relation between FMA-UE initial score versus WMFT individual gain after virtual therapy.

To try and find a cut-off point that would allow us to determine the limit between the participants who responded to the treatment and those who did not, the degree of impairment of each patient at the beginning of the intervention, measured by the FMA-UE, was plotted against WMFT gains, which indicated that the task-oriented function recovered after virtual therapy (Figure 4). As can be seen from the graph, the data show a pattern that resembles a sigmoidal curve ($R^2 = 0.9724$), indicating that, for very small values of FMA-UE scores, there is no noticeable gain, but at a certain point, the behavior of the curve changes, showing a noticeable increase in motor function gain.

Discussion

The results showed that the virtual rehabilitation platform developed at the LANR was safe and very well-received by participants, who reported that it was an enjoyable and comfortable experience, and that they felt in control of the situation while using the games for rehabilitation.

Preliminary results also showed a certain degree of motor recovery in the upper limb in patients with chronic upper limb hemiparesis after 40 sessions of rehabilitation therapy with the LANR video game platform, according to the measurements obtained with the WMFT.

This protocol does not allow for a comparison between the results of virtual rehabilitation and conventional occupational therapy, since the control groups were not managed, and this was not the objective of this pilot intervention. The motivation of this protocol was to validate the safety, feasibility, and acceptability of the LANR rehabilitation platform. The impact of the LANR platform is expected to be observed when tele-rehabilitation is applied, which is the ultimate objective of this platform.

Although the sample size was very small, it allowed us to make some preliminary statements:

(1) There were no safety issues with using the platform. Participants expressed a high level of satisfaction using

Table 6. Reliable Index Change (RCI[a]) and Minimum Clinically Important Difference (MCID[b]) of patients who responded to the treatment.

PATIENT	CAHAI-PRE	CAHAI-CHANGE	RCI-CAHAI	MCID-CAHAI	WMFT-PRE	WMFT-CHANGE	RCI-WMFT	MCID-WMFT
5	24	4	2.05*	<0.5 SD	46	5	2.69*	>0.5 SD*
6	25	8	4.10*	>0.5 SD*	45	14	7.53*	>0.5 SD*
7	34	6	3.08*	>0.5 SD*	57	4	2.15*	>0.5 SD*
8	34	7	3.59*	>0.5 SD*	60	6	3.23*	>0.5 SD*
9	45	1	0.51	<0.5 SD	61	13	6.99*	>0.5 SD*
Mean	32.4	5.2			53.8	8.4		
SD	8.5	2.77			7.73	4.71		
SEM	3.8	1.24			3.45	2.10		

Abbreviations: SD, standard deviation; SEM, standard error of the mean.
[a]RCI = Patient change/√*SEM* (RCI > 1.96, true change in 95% confidence).[55]
[b]MCID corresponds to 0.5 SD in various studies.[55]

the virtual LANR rehabilitation platform, indicating that they found it comfortable, felt motivated to perform their exercises, and were able to concentrate during the therapy. As has been previously mentioned, motivation and enjoyment when undergoing therapy are essential for better results and greater adherence to treatment by patients, which will result in better outcomes.[9,40-42] For this sample, the platform was safe and comfortable to use.

(2) Preliminary data show that the LANR videogame platform provides moderate upper limb mobility recovery in patients with chronic hemiparesis due to stroke, and is comparable to other reported results from similar protocols.[9,56-58]

(3) The beneficial effects of therapy with the LANR virtual rehabilitation platform seem to be reflected in patients with a certain degree of mobility, determined by a Fugl-Meyer score of >21 points. This finding might be related to previously reported studies on differential recovery after stroke, which have demonstrated that the ability to recover is dependent on the degree of damage to the corticospinal tract.[2] This should be considered in future interventions for chronic patients, as the LANR platform does not seem to provide any noticeable functional gain in highly impaired patients.

Considering that the ultimate objective of the LANR platform is that of tele-rehabilitation, it would be expected that during later stages of its validation, in which continuous therapist supervision is no longer required and patients can perform the exercises from home with a higher frequency and intensity, even better results could be observed. In this regard, it is worth mentioning the importance of training family members in the use of these technologies, both to support patients in carrying out their therapies and to be part of the process. This would have an additional beneficial effect, as it has been reported that the involvement of family members in carrying out therapy is an important factor for patient progress.[59]

Considering that the window of increased plasticity in patients who have suffered a stroke lasts from 3 to 6 months,[13,21] it would be expected that the best results from any type of rehabilitation therapy would be observed when therapy is initiated at a subacute stage, and with high frequency.[3,4] To explore this scenario, we intend to carry out a new protocol with subacute patients, offering them the possibility of performing virtual rehabilitation therapy from home.

The following elements should be considered for future interventions based on the results of this pilot study:

(1) In the inclusion criteria, a Fugl-Meyer score of >21 points should be considered for chronic patients, since this intervention cannot offer improvement in patients with greater impairment.

(2) During the intervention, there were some problems with the use of technology; therefore, a trained support team must be available to deal with possible problems that participants may have when using the platform from their homes.

(3) Participants stated that they required support from LANR staff to start using the games, so initial training sessions should be provided for patients and family members before patients take the games home.

(4) The high dropout rate observed (50%) was associated with transportation problems, and so, we hope that in the future intervention, in which we intend to implement tele-rehabilitation, the dropout rate will be much lower.

Conclusion

The present pilot study describes the LANR virtual rehabilitation platform, which uses a series of task-oriented video games alongside movement sensors, and presents results related to the participants' experience and upper extremity motor evolution. The results show that the LANR platform seems to be safe and confident, as participants strongly agreed that they had an enjoyable experience and felt comfortable using the platform. Preliminary results also showed some recovery in motor function of the upper extremities. The observed improvement in motor function should be attributed to the therapy, since no spontaneous functional recovery is expected in chronic patients.

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Author Contributions

AMEG and YSRG designed the intervention, coordinated the activities, and wrote the manuscript. JJAC, GISC, XAEM, TMBS, PFC, ALER, SEVA and DAM, contributed to the refinement of the protocol, applied the standardized tests, and worked with the participants. GISC and ALER organized the results. YSRG, JJAC and DAM designed the videogames. HP supervised the intervention and helped to obtain financial support. JHF provided expert advice on the intervention, submitted the protocol to the hospital's ethics committee, and helped to recruit participants. LP helped to recruit participants and applied the FM-UE test to all candidates.

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Appendix 1. Feedback from participants that used the LANR virtual rehabilitation platform.

Question: How did you feel when you played LANR games?
Participant 1.—"Good, I felt good playing." *Participant 2.—"Good, I felt I will move my hand again very soon."* *Participant 3.—"They have been very useful for the movement of my arm and also for my posture."* *Participant 4.—"I felt good, motivated. I felt an improvement. I acquired more movement and displacement."* *Participant 5.—"I felt good. They (the games) were relaxing."* *Participant 6.—"At the beginning I was nervous and had a bit of anxiety, but after some time I really enjoyed playing the games."* *Participant 7.—"Motivated. I knew the games were good for me"* *Participant 8.—"Good."* *Participant 9.—"It was a new experience; I had fun playing the games."*
Question: What did you like the most about the video games?
Participant 1.—"They were very entertaining." *Participant 2.—"I liked playing them."* *Participant 3.—"Charlie's Escape has helped me coordinate my right hand, and with Topocrisis, I have seen I can move my arm more than before."* *Participant 4.—"It was functional for me. I acquired more movement."* *Participant 5.—"They helped me perform movements that I could not do before. They are useful tools."* *Participant 6.—"They helped me recover some of my finger movements."* *Participant 7.—"I liked I could unblock several new scenarios in Charlie's Escape and all of them were very pretty."* *Participant 8.—"I knew I needed to exercise my body in order to recover, I liked that the games helped me do that."* *Participant 9.—"I liked the goalkeeper's game because it was very dynamic."*
Question: What did you like the least about the video games?
Participant 1.—"I felt I was spending a lot of time playing, when in reality it was quickly." *Participant 2.—"Just some errors I noticed while playing"* *Participant 3.—"Nothing, I liked all the games."* *Participant 4.—"All seems good to me, nothing was unpleasant."* *Participant 5.—"Nothing."* *Participant 6.—"The games are fine; I just wasn't used to play videogames."* *Participant 7.—"At the beginning it was hard to spot the object that indicates when Charlie must jump, it is very small."* *Participant 8.—"Maybe the score texts that in some games were very tiny for me to read."* *Participant 9.—"The game with the goalkeeper sometimes didn't recognize correctly when I moved my arms to the front."*
Question: Were you willing to take the LANR platform home?
Participant 1.—"Yes, definitely." *Participant 2.—"Yes, because I think I would do more therapy at home."* *Participant 3.—"If I could, I would take them home, so I could play another 40 minutes twice a day."* *Participant 4.—"Yes."* *Participant 5.—"Yes, so I can continue with my exercises."* *Participant 6.—"Yes, because they would help me to recover even more."* *Participant 7.—"Yes."* *Participant 8.—"Yes."* *Participant 9.—"Yes, I'm just not sure if they would work on my computer."*
Question: Would you recommend the platform to other patients?
Participant 1.—"Yes." *Participant 2.—"Yes, because they teach well how to do the exercises."* *Participant 3.—"I would recommend the system; I have seen a lot of improvement."* *Participant 4.—"I would recommend the games, because they helped me gain confidence with my movements."* *Participant 5.—"Yes, because the games would help them to recover in a cheerful way, without pressure."* *Participant 6.—"Yes, I think this kind of technology could help a lot of people."* *Participant 7.—"Yes."* *Participant 8.—"Yes."* *Participant 9.—"Yes, especially to people with arm and hand movement problems."*
Question: What would you improve about the video games?
Participant 1.—"I would make them even more entertaining." *Participant 2.—"Nothing."* *Participant 3.—"I would just correct the little errors I sometimes experienced while playing."* *Participant 4.—"I would increase their difficulty, because at certain point the games become too easy"* *Participant 5.—"Sometimes I felt the game of the goalkeeper failed to indicate mistakes, I was standing correctly, but the game indicated my posture was wrong."* *Participant 6.—"Sometimes the game suddenly stopped, but maybe it was a problem with the computer."* *Participant 7.—"The size of the objects in Charlie's Escape."* *Participant 8.—"I would like similar games, but focused on leg movements."* *Participant 9.—"Nothing."*