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A Usability Study in Patients With Stroke Using MERLIN, a Robotic System Based on Serious Games for Upper Limb Rehabilitation in Home Setting

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Abstract

Background: Neuroscience and neurotechnology are changing stroke rehabilitation. Robotic devices as well as telerehabilitation have become of great interest and are increasingly being used to train the upper extremities after stroke. Its use in home settings allows to extend institutional rehabilitation by increasing and prolonging therapy. The aim of this study is to assess the usability of MERLIN robotic system based on serious games for the upper limb rehabilitation in stroke patients in a home environment.

Methods: 12 participants with a stroke in three different stages of evolution (subacute, chronic of short evolution and long-term chronic) with impaired arm/hand function were recruited to use the MERLIN system for 3 weeks: one week of training at the Maimonides Biomedical Research Institute of Cordoba (IMIBIC), and 2 weeks at patients' home. Evaluation of usability involved System Usability Scale (SUS), Adapted Intrinsic Motivation Inventory (IMI), Quebec User Evaluation of Satisfaction with assistive Technology (QUEST), and ArmAssist Usability Assessment Questionnaire which were evaluated post-intervention. Clinical outcomes on upper extremity motor function were assessed pre- and post-intervention.

Results: Finally, 9 patients participated in the study, 3 drop-off due to the COVID-19. The usability assessment reported a high level of satisfaction: mean SUS score was 71.94 % (SD=16.38), mean QUEST scale was 3.81 (SD=0.38), and mean IMI score was 6.12 (SD=1.36). The results of the ArmAssist Questionnaire was an average of 6 out of 7, which indicates that MERLIN is easy to learn, easy to use and intuitive. Regarding clinical assessment, Fugl-Meyer scores showed moderated improvements from pre- to post-intervention in the total score of motor function ($p = 0.002$). There were no significative changes in Modified Ashworth scale outcomes ($p = 0.169$)

Conclusions: This usability study indicates that home-based rehabilitation for upper limb with MERLIN system is safe, useful, feasible and motivating. The telerehabilitation suppose an important step towards an intensive rehabilitation to be bring to home.

Trial registration: ClinicalTrials.gov, NCT04405609. Registered 06 January 2020 - Retrospectively registered, https://clinicaltrials.gov/ct2/show/NCT04405609

Background

Stroke is one of the leading causes of death, physical disability, and economic burden worldwide. There are over 13.7 million new strokes each year. 5.5M people die annually and most stroke survivors have chronic disabilities, with limitations and restrictions in their daily life activities (1, 2).

The prevalence of people living with the effects of stroke that creates a greater demand of rehabilitation services has increased in last years (3). The paralysis on upper limb is predominant impairment after stroke and only the 10–20% of the patients recover completely from it partially due to the complexity of the movement required for upper limb function (4, 5). The main aim of the rehabilitation for the patients is the promotion on the recovery of lost functions, which directly affects in the independence and the reintegration of patients in their daily and social life activities (6). Nowadays, intensity, repetition and significative activities functional oriented and challenging are considered key aspects to make stroke patients' rehabilitation effective (7, 8). There is evidence that those aspects lead for a better recovery and higher levels of independence (9). However, the increase in the

affected population and the limited health resources make very difficult the supply of services using a traditional approach.

Currently, neuroscience and neurotechnology are changing stroke rehabilitation (10). In a moment when the rehabilitation services resources are lower than the demands, robotic assisted rehabilitation and home-based telerehabilitation have become of interest (11). In the last years, robot-based neurorehabilitation systems have been considered a solution to increase the number of movement repetitions which is considered really beneficial for the patients' recovery (12, 13). These technologies have the advantage of measuring objectively the movements doing safe and intensive rehabilitation exercises thanks to the precision of movements that the robots could provide (14, 15). In addition, home-based telerehabilitation allows to extend institutional rehabilitation increasing and prolonging the therapy (16). On the other hand, game-based telerehabilitation combined with robotic systems have created a motivating and engagement environment for patients (17). Serious games designed specifically for the tasks to be performed can increase the quality and quantity of the therapy due to an enjoyable environment (18). The purpose of this manuscript is to present the usability validation of MERLIN robotic system based on serious games for the upper limb rehabilitation in patients with a stroke brought to homes. In this study the ease-to-use, consistency and acceptance of the system have been evaluated. The research done also pretends to demonstrate the feasibility of including the robotic therapy as complement of regular daily rehabilitation program.

Methods

Participants

Jakob Nielsen's theory (19) is widely accepted regarding the number of users enough to evaluate a system with the aim of detecting most of the usability problems that can affect a product. According to Nielsen between three and five users could identify the 85% of the most relevant usability problems. In this case, it was decided to recruit 12 patients in different stages of post-stroke upper limb recovery evolution due to the heterogeneity of the study population, in order to test as many system features as possible.

Patients with a stroke were recruited at the University Hospital Reina Sofía of Cordoba, Spain. Participants were divided in three different groups depending on their stage: subacute between 2–6 months of evolution, chronic of short evolution between 6–12 months and long-term chronic (more than 12 months). Four patients were recruited from each stage. The inclusion criteria to participate in the study were: subjects over 18 with upper limb hemiparesis after stroke, unilateral paresis and cognitive ability to understand, accept and actively participate in the usability study. The patients who presented bilateral motor deficit, severe spasticity, psychiatric illness, and/or cognitive impairment were excluded.

Having Wi-Fi at home, as well as a table of 110 × 68 cm to have enough space for MERLIN system installation was also considered a requirement to participate in the study. All the subjects were duly informed about the study and all of them gave written consent before the first session.

Study design

This interventional study is an open label trial with a single group and a longitudinal design. Each patient used the MERLIN system for 3 weeks: one week of training at the IMIBIC (Maimonides Biomedical Research Institute

in Cordoba, Instituto Maimónides de Investigación Biomédica de Córdoba, in Spanish) facilities with a physiotherapist supervision, and 1 week at patient's home with the physiotherapist supervision and 1 week at patient's home by their own with physiotherapist remote support and supervision to organize the rehabilitation sessions.

Arm and hand functions were evaluated the first day before starting the training as baseline, and the last day of participation. System usability and participants' motivation was evaluated the last day of their participation using different validated scales as it will be explained later in this manuscript.

The MERLIN robotic-assisted telerehabilitation system

The MERLIN robotic telerehabilitation system has been developed to bring the neurorehabilitation to the post-stroke patients homes with the aim of providing daily, intensive, motivating and patient tailored rehabilitation, with therapists' indirect supervision (20). The system is composed by the ArmAssist (AA) cost-effective robotic system based on serious games developed by TECNALIA, and the Antari Home Care platform (21) to supervise, organize and customize the patients' daily training remotely, which has been developed by GMV (22). The AA system is a modular solution which includes an affordable and portable robotic device for an upper limb complete rehabilitation, and a software platform based on serious games for the patients engagement and training assessment (18). The AA robotic device can measure the patient's self-directed active movements which are performed on a mat put on a regular table thanks that the robotic system includes different sensors (see Fig. 1) The key movements that can be measured are shoulder horizontal abduction-adduction, flexion-extension in the elbow (vertical force), prono-supination movements of the wrist and hand opening and closing (grasping) (23). This version of the system is addressed to patients that can actively do the movements and thus is more appropriate for the patients that are in mildly or moderate motor impairment according to Fugl-Meyer scale.

The AA system facilitates recovery of upper limb motor control and function through, interactive gaming goal-oriented, and functional tasks assisted, that require variable cognitive engagement designed to motivate the user to train longer and more effectively. It includes games for both training and assessment (24). 7 training games are available, which were co-designed with patients and physiotherapists (25). The games can be configured to train shoulder abduction/adduction, wrist prono-supination, hand open/close, or elbow flexion-extension and combinations of those movements. The game demands to the user doing the exercise beyond the threshold of the patient's range motion. This threshold is previously set using the assessment games, and can be modified when needed, i.e. when motor improvement is detected by the physiotherapist. Different levels can be also configured for each patient depending on the motor and cognitive capabilities. The games have been designed suitable for the target group taking into account the possible cognitive or vision problems, for example (26). Additionally to those designed games, the system offers the option to play online games available in Internet using the robot device as a regular mouse. This option is recommended for patients with good movement control and cognitive capabilities.

In the MERLIN system, the patients could access to the daily therapy previously organized by the physiotherapist, as well as to a summary of the results obtained during the therapy (see Fig. 3 Right). A communication tool with the therapist, similar to mailing, was also added.

The AA system has been previously tested in clinical setting by therapists and patients with positive results on acceptance (11) and effectiveness with the improvements in the motor function of the patients after the use of it

(24). Previous studies also demonstrated that the therapy using AA system is enjoyable and motivating because engages patients (27). In this study, the system has been adapted for a home use. With this aim, the software was prepared to work on a tablet, a package was designed to transport the system, and the mat was adapted (see Fig. 2).

As it was previously explained, the Antari HomeCare platform has been also integrated in the MERLIN system. This telecare platform which is prepared for managing patients' treatments and doing an online follow-up, was adapted for customizing the rehabilitation therapies remotely. Using this online platform, the therapist customized each patient therapy selecting the games to be used and the movement to train, the number of days to be repeated, the time to play each game. Also, the evolution of the patient and the score obtained in the different games or tasks proposed for each day, as well as duration and frequency of training could be checked by the therapist using this online system (see Fig. 3 Left). The communication tool similar to mail is also accessible via Antari HomeCare system.

Intervention sessions

Rehabilitation therapy included 11 sessions using MERLIN system to be done in 3 weeks. The first week was used as training to teach users and caregivers how to use the system correctly as well as getting used to the rehabilitation system, robot movements and protocol times. Training sessions were organized every day with a duration of one hour per day at IMIBIC facilities (see Fig. 4 Left). Special emphasis was addressed in the correct positioning of the arm and shoulder for a proper rehabilitation. In addition, each participant received a user manual copy which also included a telephone number to contact in case of any technical or clinical issue. The physiotherapist installed the system at the participant's home in the beginning of the second week, the chair height was adjusted and explained to the patient the correct position for the back and shoulder for doing the training and having the arm in a comfortable position during the rehabilitation when supervision was not available (see Fig. 4 Right). 3 sessions of 30 minutes were held on alternative days. During this week the patient did the assigned therapy for each day with the physiotherapist supervision. Third week have same structure but participants trained using the system completely autonomously at home. The physiotherapist used the tele-care platform daily, to follow up remotely the participants' progress and system use as well as organizing next session.

The training movements and games used for that purpose were selected by the physiotherapist, who decided the therapy intensity level and movements to train according to the patient's evolution or cognitive conditions. The therapist organized the rehabilitation sessions beforehand using the tele-care platform prepared with that aim. Prior starting the therapy, patients were requested to do a calibration process to set up the threshold according to their range of motion. This allows that participants were challenged to exercise at their maximum capacity. Then, during the system use, the range of motion for each game and patient was controlled by the system itself.

Assessment

Study data were collected and managed using REDCap (28) electronic tool hosted at FIBICO (Foundation for Biomedical Research in Cordoba; Fundación para la Investigación Biomédica de Cordoba in Spanish) (29). REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data

downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources (30, 31). REDCap is HIPAA (Health Insurance Portability and Accountability Act) (32) and 21 CFR Part 11 (33) compliant, which means that it complies a minimum security for data in clinical investigations. However, no personal data were recorded on REDCap to comply with the European General Data Protection Regulation (GDPR) (34) as participants were European citizens.

Primary outcomes measurements. Usability and acceptance data.

Feasibility of use of the system and motivation were evaluated by patients using semi-structured interviews and different usability questionnaires with Likert scales during the clinical trials which had a duration of 3 weeks of intervention. Used validated scales were: System Usability Scale (SUS) (35), Adapted Intrinsic Motivation Inventory (IMI adapted) (36), Quebec User Evaluation of Satisfaction with assistive Technology (QUEST) (37), and AA Usability Assessment Questionnaire (18).

SUS scale is used to evaluate the usability of the system. Scores are ranging to 0–100%, where a high score means better usability with a threshold of 68%. The IMI is a multidimensional questionnaire which measures interest/enjoyment, perceived competence, pressure/tension, value/usefulness, felt pressure and tension, and perceived choice that patients experience during the performance of an intervention with the device. This scale consists of 20 item questionnaire with options from 1 ‘strongly agree’ to 7 ‘strongly disagree’. The purpose of QUEST is to evaluate the patient’s satisfaction with the device and with the services they experienced. It consists of 12 questions: 8 related to the device and 4 related to services, which must be rated in a Likert from 1 ‘Not satisfied at all’ to 5 ‘Very satisfied’, AA Usability Assessment Questionnaire consists of 17 items survey. It was specifically designed for the AA device which is used in MERLIN system. The questions are rated by patients and therapists from 1 ‘strongly agree’ to 7 ‘strongly disagree’ to evaluate the satisfaction with the system and the therapy. It also includes 3 open-ended questions about the participant’s subjective opinion such as the aspects that she like most, the identified negative aspects, and any proposals for improve the system.

In addition two short questions were added to ask to participants about their willingness-to-pay for the MERLIN system as therapy.

Secondary outcome measurements. Clinical information.

With the aim of quantifying general arm function and any effect of the system on it, clinical standardized scales were used, before patients start with the therapy using MERLIN and after finishing the clinical trial. Upper Limb Fugl Meyer Scale (Fugl-Meyer) (38) and Modified Ashworth Scale (MAS) (39) were used to evaluate the clinical condition of the patients before their enrolment in the study to confirm their participation according to the inclusion criteria. Same scales were repeated at the end of the therapy using MERLIN to confirm the system safety and did not cause negative effects on the patient such as arm function reduction. Fugl-Meyer and MAS could be used also to measure the effectiveness of the system although small improvements were expected due to the short duration of the intervention achieve clinical evidence.

The Fugl-Meyer is an index to assess the sensorimotor impairment in individuals. MAS measures muscle tone during passive soft tissue stretching by rotating a joint and estimating the resistance, and it is used as a simple measure of spasticity.

Statistical analysis

Statistical outcomes were analysed using IBM SPSS Statistics© (40) software for Windows© Operating System. Descriptive summary statistics (mean with standard deviation, SD) was used to process the quantitative data provided by the Likert scales items in SUS, QUEST and IMI Adapted. The qualitative data obtained in the open-ended questions were analysed using thematic analysis.

To the Clinical assessment, a one-tailed, paired t-test, with a significance level of $p < .05$, was used to compare pre- and post-intervention Fugl Meyer and MAS outcome measures.

Results

Participants

This clinical study was planned to start in September 2019 and finishing in June 2020. During the clinical study the COVID-19 global pandemic blew-up, which had a significant impact in the study. It was foreseen that 12 patients with a post-stroke hemiparesis participated in the research, but 9 of them completed the intervention study. 3 patients dropped-out the study after the recruitment period due to the COVID-19. Special effort was done in recruiting additional participants to complete the study, but patients were not willing to participate in the study during the research period. Patients with a post-stroke upper limb impairment included in this research, usually have comorbidity such as hypertension, mellitus diabetes, atherosclerosis, heart disease, etc. that include this population in the risk group of COVID-19. Aware of this situation, the mobility limitation restriction in the country by the Government for some time, and because the fear of the infection, it was not possible to include additional participants at the end of the study. However, it was considered that the results are also reliable with 9 patients as it was previously explained.

66.7% of the participants were men and 33.3% women. The age range of them was between 41 and 89 with an average of 63.89. 66.7% have left hemiparesis and 33.3% right.

In addition to the therapy received with MERLIN system during the usability study, the 88.9% of the patients also received other sessions of Occupational Therapy or Physiotherapy (public or private). The characteristics of the nine participants are showed in Table 1.

Table 1
Patients demographic information.

	Age	Gender	Hemiparesis	Dominant Hand	Stroke date	Employment situation	Other therapies
P1	59	M	L	R	31-08-2019	Medical leave	Y
P2	60	M	R	R	22-05-2019	Medical leave	Y
P3	70	F	L	R	12-04-2019	Retired	Y
P4	74	M	R	R	05-04-2019	Retired	Y
P5	41	M	L	R	16-09-2016	Medical leave	Y
P6	42	F	L	R	01-05-2018	Unemployed	Y
P7	89	M	L	R	20-08-2019	Retired	N
P8	69	F	L	R	02-05-2019	Retired	Y
P9	71	M	R	R	18-11-2019	Retired	Y

Gender: M = Male, F = Female; Hemiparesis/Dominant Hand: L = Left, R = Right; Other therapies: Y = Yes, N = No

The participants were also asked about any adverse event that could happen during the clinical trial at the end of each session. No relevant adverse events were reported. Participants reported only two inconveniences that have been previously foreseen in the user manual: 1) some chafing on the skin due to contact with the robot protruding elements; and 2) some shoulder fatigue at the end of the session. To avoid any chafing some foam pieces were provided to attach them in the contact parts of the robot that could cause the problem. This solution should be customized to the participant's arm/hand size. In the case of the shoulder fatigue, the sessions timing was adjusted to 20–30 minutes to all the participants with the aim of avoiding this adverse event.

Usability and acceptance results

The quantitative data obtained using SUS, QUEST and IMI questionnaires is summarized in figures below, which show the user acceptance and experience results. Usability perception has been rated with a mean score of 71.94% (SD = 16.38) on SUS scale (see Fig. 5), which means that the system usability is considered "Good" according to the Bangor et al. research (41).

In general, the motivation and satisfaction were positive, as reflected in the mean score on the IMI of 6.12 over 7 (SD = 1.36) (see Fig. 6 Right) and in the mean score on QUEST scale of 3.81 over 5 (SD = 0.38) (see Fig. 6 Left). In those both scales a higher score means higher that the participant is more motivated or satisfied, except for the pressure/tension which needs to be normalized to calculate the mean.

The results of the AA Questionnaire test are presented in Table 2. The participants rated the system with an average of 6 in a scale of 7, so, it can be concluded that they considered it easy to- learn, easy to use and intuitive. They also considered that the system can be positive for their treatment because it could allow them to train longer and they reported that this therapy could be more entertaining comparing to the regular therapy (6 out 7). All the participants agreed that they would recommend the system to other patients, but some improvements are proposed. Some examples of the participants' proposals can be found in next section (see *open-ended question)*

Table 2
Patients' results of the AA Questionnaire

Questions		P1	P2	P3	P4	P5	P6	P7	P8	P9	MEAN
1	It has been easy to learn how to use the system, both the hardware and the software.	7	7	7	5	7	7	3	7	7	**6.33**
2	I think I will often need the support of a technical person to be able to use this system.	2	4	5	5	1	1	6	2	6	**3.56**
3	Using this system, I need to spend a lot of time in non-training activities.	2	2	4	2	1	4	2	1	1	**2.11**
4	I can remember without problem how to use the system effectively.	7	7	4	3	7	7	3	7	7	**5.78**
5	It took a long time to be able to use the system without problems.	2	7	2	1	1	1	1	1	1	**1.89**
6	I think that I will benefit from using this system	7	7	7	1	7	7	7	7	7	**6.33**
7	Using this system I am motivated to train longer	7	6	7	1	5	7	4	7	7	**5.67**
8	I think that this system is uncomfortable to use.	5	3	5	7	4	5	4	7	2	**4.67**
9	I enjoyed training with this system	7	6	7	1	5	7	5	7	7	**5.78**
10	I would recommend other people to use this system.	7	7	6	4	7	7	6	7	7	**6.44**
11	I think that this system needs to be improved.	7	6	6	7	7	5	4	7	6	**6.11**
12	I had internet connection problems while using the system	4	2	5	6	1	3	2	6	1	**3.33**
13	I feel uncomfortable using a system like this, because I have no experience in using a pc.	1	1	4	1	1	1	6	1	2	**2.00**
14	I don't think using this system will make any change to my condition	2	1	2	7	1	1	5	1	2	**2.44**
15	I feel that the games are inadequate for the training.	2	1	1	4	6	1	1	1	2	**2.11**
16	I am familiar with this kind of technology.	6	4	2	2	4	4	1	7	2	**3.56**
17	I feel myself safe using this system	6	7	6	2	7	7	7	7	6	**6.11**
Note: On the scale 1 means 'Strongly disagree' and 7 means Strongly agree'											

Open-ended question

Participants were motivated to participate in the clinical trials and during the rehabilitation sessions. At the end of the trials all of them answered positively to the questions regarding using MERLIN system at home. Patients declared that they have enjoyed they participation and valued positively this different way of therapy for the rehabilitation of their affected arm. Some of them stressed about the aspects they liked most:

- *"It is a new attractive and motivating therapy"*
- *"MERLIN system is entertaining and easy to use therapy, which allows many repetitions"*
- *"We can decide the most convenient time for doing the therapy".*

Some of the negative aspects were repeated by some participants. The height and size of robot did not allow a completely relaxed posture for all of the patients. Regarding the serious games, some participants complained about the limited number of games and the simplicity of them. Participants, both patients and clinicians, proposed some future improvements:

- Improve robot design to allow a relaxed arm position.
- Adjust the dimensions, reduce the size and the area to better fit their home use.
- Include more games, and make them more attractive.
- Develop more complex games with cognitive involvement.

Finally, the participants were asked about their willingness to pay for a therapy using MERLIN system and the price they would be willing to pay. The 88.9% of the participants would be positive to pay for a system like MERLIN for more than 6 weeks and they would rent it by 40–60 € per month.

Clinical results

Although the aim of these trials was not to measure the effectiveness of the system, some measurements of the mobility status of the participants were also done before and after the use of MERLIN, with the aim of detecting not foreseen any negative effect on the patients. As it was previously explained, the scales Fugl-Meyer and MAS were used with this aim. The outcomes measures are shown in Table 3 and Table 4. From the data gathered it can be said that there was a visible improvement in the Fugl-Meyer scale after the rehabilitation using the system (T1) being more significative the changes in the upper limb and coordination ($p = 0.008$ and $p = 0.004$, respectively), and in the total score of motor function ($p = 0.002$).

Table 3
Fugl-Meyer Motor function outcomes. T0 = baseline and T1 = post-training sessions

	Upper limb (36*)		Wrist (10*)		Hand (14*)		Coordination (6*)		Motor function (66*)	
	T0	**T1**	**T0**	**T1**	**T0**	**T1**	**T0**	**T1**	**T0**	**T1**
P1	31	36	9	9	14	14	5	6	**58**	**63**
P2	23	28	7	10	10	11	4	4	**44**	**52**
P3	32	36	10	10	13	14	5	6	**60**	**66**
P4	30	31	9	9	13	13	4	4	**56**	**57**
P5	24	26	3	4	8	8	3	4	**38**	**42**
P6	26	30	7	9	14	14	5	6	**52**	**59**
P7	32	32	10	10	12	12	4	5	**58**	**59**
P8	9	10	3	3	6	7	3	3	**21**	**23**
P9	32	32	9	10	12	12	3	4	**56**	**58**
MEAN	26.56	29.00	7.44	8.22	11.33	11.67	4.00	4.67	**49.22**	**53.22**
SD	7.49	7.84	2.74	2.73	2.78	2.60	0.87	1.12	**12.84**	**13.25**
T-test	*t= -3.55; p = 0.008*		*t= -2.14; p = 0.065*		*t= -2.0; p = 0.081*		*t= -4.0; p = 0.004*		t= -4.54; p = 0.002	

Note: *Maximum score for each motor component of the assessment. Abbreviations: SD (standard deviation); P(Participant)

However, there were no significative changes in MAS outcomes (p = 0.169), so, this kind of therapy using a robot does not seem to influence the spasticity of the upper limb.

Table 4
MAS outcomes at T0 – T1.

	T0	T1
P1	0	0
P2	1	1
P3	1	0
P4	0	0
P5	1	1
P6	0	0
P7	0	0
P8	2	1
P9	0	0
MEAN	0.56	0.33
SD	0.73	0.50
T-Test	*t = 1.512; p = 0.169*	
Note: *Maximum score of the assessment = 5; P(participant)		

Discussion

The aim of this study was to analyse the user acceptance and usability of MERLIN system at home environment in patients with upper limb motor impairment after stroke. In this study it was also proposed to observe the possible changes in the clinical condition of the patients due to their participation on the trials, so some additional clinical measurements were also added. The final users' special needs and their mobility limitations must be considered when a new rehabilitation technology is developed, with the aim of guaranteeing that the design of the system will meet their real needs and requirements (42). As well, the usability of the system must be evaluated to build a system comfortable and motivational that patients are willing to use with the objective of generating treatment adherence in the future.

Numerous studies show the effectiveness and the advantages of using robotic systems for neurorehabilitation (43, 44, 45) and tele-rehabilitation (46, 47, 48). Other studies also demonstrated that the use of an exoskeleton with patient-driven control strategy for rehabilitation where patient is active during the therapy sessions more attractive and in consequence more effective in their treatment (49). In this study a robotic tele-rehabilitation system based on serious games has been brought to stroke patient's home to be tested. This is the first time that this system has been tested in a home environment, because previously it was tested in clinical setting (24, 18, 27).

The usability positive results obtained in this study agree with other home-based studies published in last years (5, 50, 51). 9 patients completed the study and rated positively the different scales. The mean for the SUS and

IMI scales were 71.94 and 6.06 respectively which show a positive evaluation of the usability and acceptance of the MERLIN system to be used for rehabilitation and obtained higher results than other similar studies (52, 53). Regarding the results on QUEST and AA Questionnaire indicate that participants perceived this of therapy as interesting and motivating, as well simple, intuitive and easy to use. However, P4 and P8, had a slightly more negative perception comparing to the rest. P4 was not used to new technologies and he felt frustrated when interact with the computer and games. P8 has severe motor impairment which implied much more effort to move the arm comparing with other participants. Despite of those inconveniences, both patients decided to complete the intervention.

Overall, all participants enjoyed the therapy with the MERLIN system, which indicates the potential of robotic systems based on serious games for involving stroke patients actively in their rehabilitation sessions. In addition, the use of feedback like games' scores or positive messages and the possibility of doing a follow-up of their own evolution checking the plots in the same system showed that motivate and engage the patients to train every day, thus increasing the adherence to the therapy.

It needs to be highlighted that the 100% of participants would recommend MERLIN system use to other patients, and the 88.9% would use it for more than 6 weeks. All participants reported low or no levels of stress when using MERLIN at home on their own. Despite the general positive perception, participants considered that MERLIN also would need some improvements which will be considered in further development of the system. The size and height of the device, as well as new games inclusion and design improvement are some examples of usability proposals done by the participants.

As it was stated before, the aim of this study was to evaluate the usability of the system, so the intervention timeline and the target of number of patients were very small to demonstrate the effectiveness of the therapy. However, clinical assessment showed moderated improvements in motor function on the upper limb that agree with results found in other studies done with similar robotic systems on home environment (54, 55). On individual level, the nine participants were classified on motor function as mildly (6 patients), moderately (2) and severely (1) impaired on the baseline measurements using Fugl-Meyer scale. Participants achieved a visible improvement which was evaluated using the motor function of Fugl-Meyer scale after the training. The intervention involves patients in the subacute, short-chronic and chronic phase according to the inclusion criteria. More changes were expected in patients considered subacute after training, as theoretically most recovery of specific impairments occurs during the 6 first months after stroke (56, 57), however no great differences have been found in the evolution of them. In fact, P6, a patient on chronic phase, experimented the greatest motor change. The most significant changes were experienced by P6, P2 and P3. Those patients were in different phases of evolution and with different baseline, as can be seen in Tables 1 and 3, respectively. Therefore, in this study, no relationship was found between motor function improvements and evolution.

Regarding MAS there were no significative changes ($p = 0.169$), so, it can be conclude that the use of this system does not have any influence on the upper limb spasticity. This result can be considered positive because in addition to the intrinsic factors that cause spasticity, it has been suggested that extrinsic factors (noxious triggers) may increase the spasticity. Those factors could include mental stress, physical contact, anxiety, pain, muscle fatigue, muscle contractures, certain body postures, jerky movements or changes of position, among others (58), which could induce or aggravate high tone and induce pain. None of the patients reported an

increase of the spasticity or reduction of the mobility after the use of the system, which demonstrates that MERLIN does not cause any noxious triggers.

According to the clinical results, none of the patients reported a reduction of the mobility after the use of the system, which demonstrates that the use of it is at least safe and in most of the cases beneficial.

Additionally, there were no serious adverse events during the study. Mild shoulder pain, mild fatigue and chafing in the skin are the only adverse effects noted. So, this study provides evidence that the MERLIN might be used safely in a home setting.

Future studies might consider incorporating greater number of participants and a higher training duration. Identifying different patients' factors like age, sex, severity, or evolution of stroke could be also helpful with the aim of identifying the target group. In addition, incorporating additional games and further range of movements in MERLIN system, probably could enhance motivation, which might stimulate a higher effective therapy.

Conclusion

This study demonstrates the usability of home-based MERLIN system in patients with upper limb motor function impairment after stroke in different stages. The usability analysis showed that almost 100% of the patients who participated found the system useful, safe and motivating, and all of them achieved moderate clinical improvement in motor function, according to the average score of Fugl-Meyer.

In this study participants trained 8 additional hours of upper limb rehabilitation at their home with an innovative approach of neurological rehabilitation, based on serious games using intensive, repetitive, interactive, and individualized practice. The results of this study reflects that home training with the MERLIN system with a therapist indirect supervision could be an interesting approach that includes the most important specific aspects in neurorehabilitation: high-intensity, task-specific, goal-setting, repetitive, functional, meaningful, and challenging for the patient.

Further research with larger sample of participants including a control group and longer intervention would help to explore the efficacy of the system and to identify the factors are associated with gathering better results on neurorehabilitation.

The feasibility of using this low-cost rehabilitation system, easy to learn, easy to use and easy to transport might suppose an important step towards for an intensive rehabilitation to be transferred to home. Nowadays, this aspect is very important, especially due to COVID-19 impact.

List Of Abreviations

AA	ArmAssist
ADL	Activities of Daily Living
ARAT	Action Research Arm Test
CFR	Code of Federal Regulations
FIBICO	Foundation for Biomedical Research in Cordoba; Fundación para la Investigación Biomédica de Cordoba in Spanish
Fugl-Meyer	Upper Limb Fugl Meyer Scale
GDPR	General Data Protection Regulation
HIPPA	Health Insurance Portability and Accountability Act
IMI	Intrinsic Motivation Inventory
IMIBIC	Maimonides Biomedical Research Institute (Instituto Maimónides de Investigación Biomédica, in Spanish)
MAS	Modified Ashworth Scale
P	Participant
QUEST	Quebec User Evaluation of Satisfaction with assistive Technology
REDCap	Research Electronic Data Capture
SD	Standard Deviation
SUS	System Usability Scale
T0	Evaluation measurement pre-intervention
T1	Evaluation measurement at post-training sessions

Declarations

Ethics approval and consent to participate

The experimental protocol has been approved on the 13/09/2019 (18/09/2019-Acta 20) by the Ethical Committee of Research with Drugs from Cordoba ref. num. 4237, and by the Spanish Agency of Drugs and Medical Devices (Agencia Española de Medicamentos y Productos Sanitarios – AEMPS in Spanish) on the 15/10/2019 according to the Directive 93/42 on medical devices in research.

The patients who participated in the research were informed about the implications of their participation and accepted voluntary participating, accepting the informed consent approved by the ethical committee, prior starting the trials.

Consent for publication

Informed consent for images publication was included in the patients' participation informed consent. The patients were explicitly informed about any image recording and consent was explicitly requested for this action and for the publication of them ensuring their privacy.

Availability of data and materials

The datasets used and analysed during the current study are available from the uicec@imibic.org on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Author's contributions

MNMA, FJMR, and MMR defined the study protocol. FJMR, PCA and MMR were responsible of participants' recruitment. SGC carried out the study and collected the patients' data. SGC y AG performed the data analysis and wrote the manuscript. FJMR participated in the study coordination and design. AG and JARR participated in the trials providing the technology that was used during the evaluation and gave technological support during the trials. The information regarding new technology in the manuscript was provided by them. The therapists that participated in the trials received also some training about the technology organized by TECNALIA.

All authors read and approved the final manuscript.

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Figures

Figure 1

AA system.

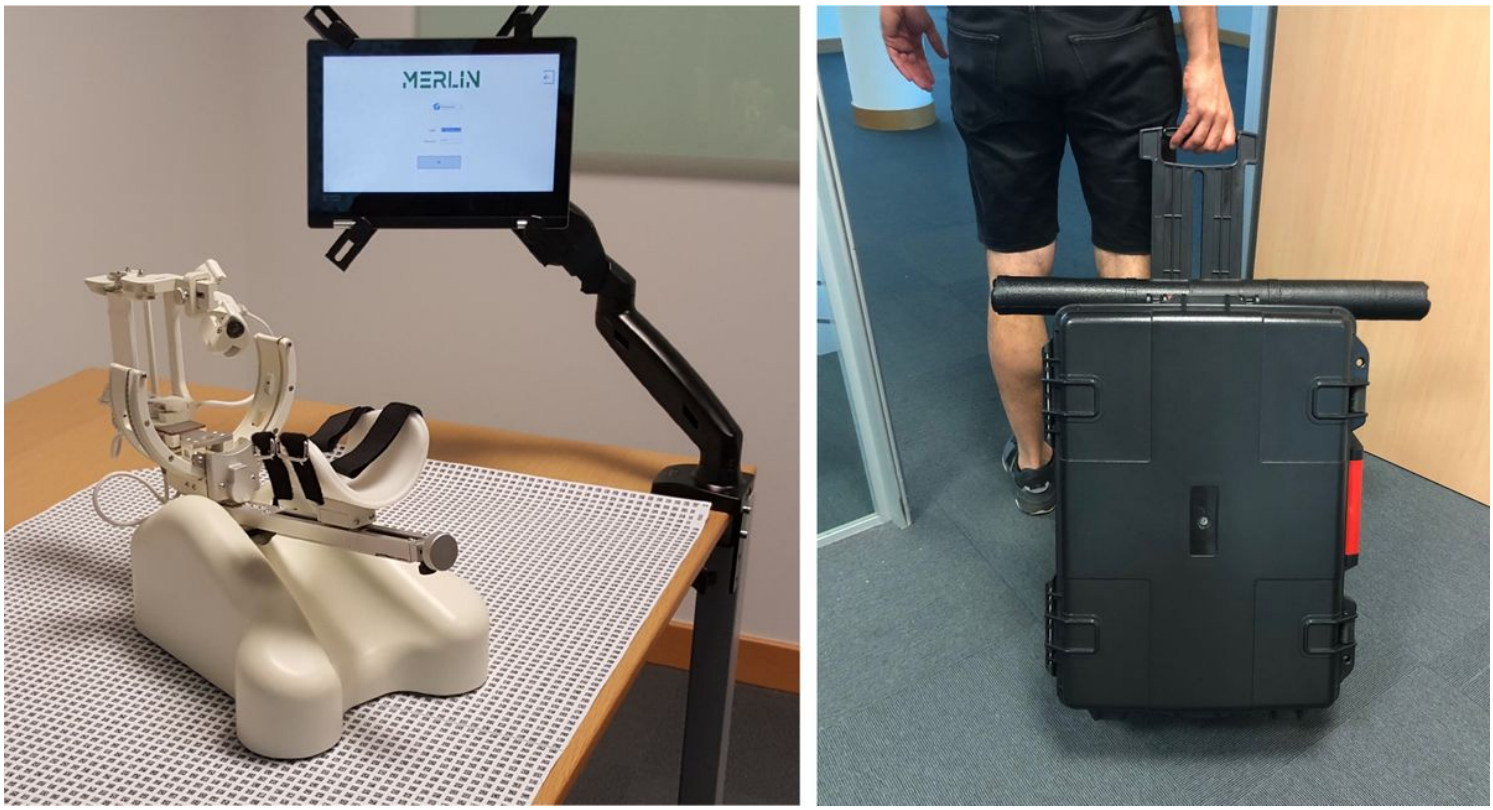

Figure 2

Adaptations made on the system for the home use. Left: mat adaptation. Right: package.

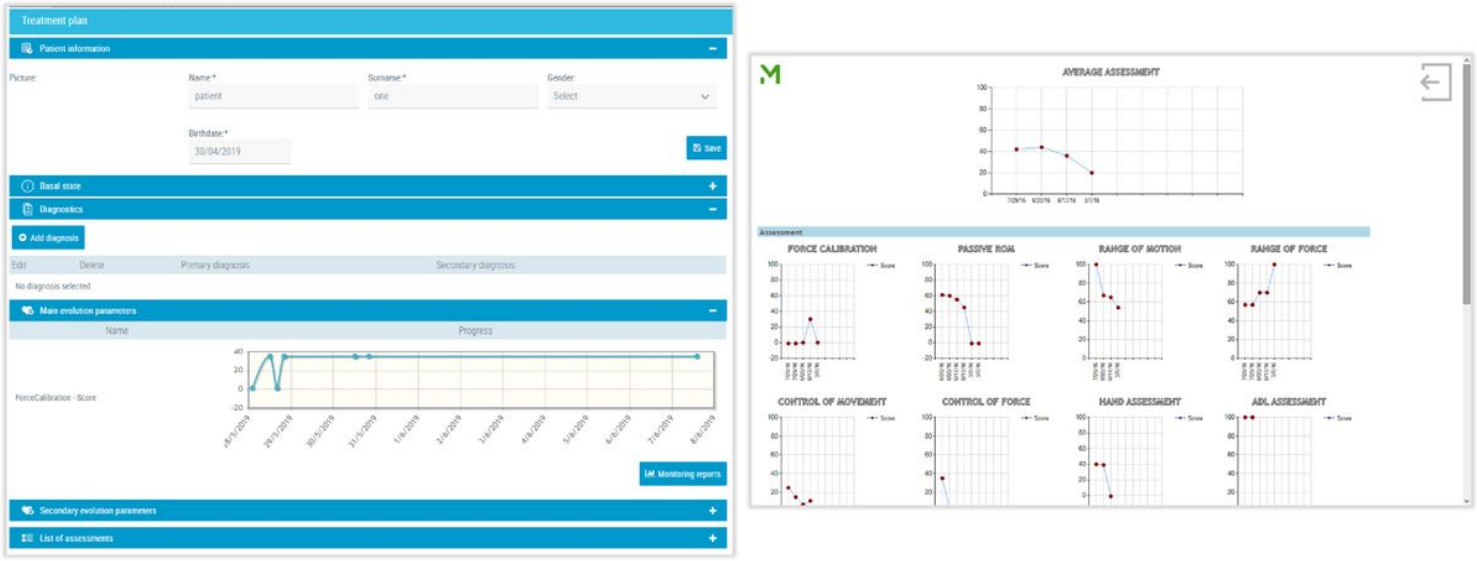

Figure 3

MERLIN system. On the right: See the results of the therapy on the therapist panel. On the left: see the evolution of the therapy on the patient panel.

Figure 4

Usability study pictures. Left: session at IMIBIC facilities. Right: session at home environment.

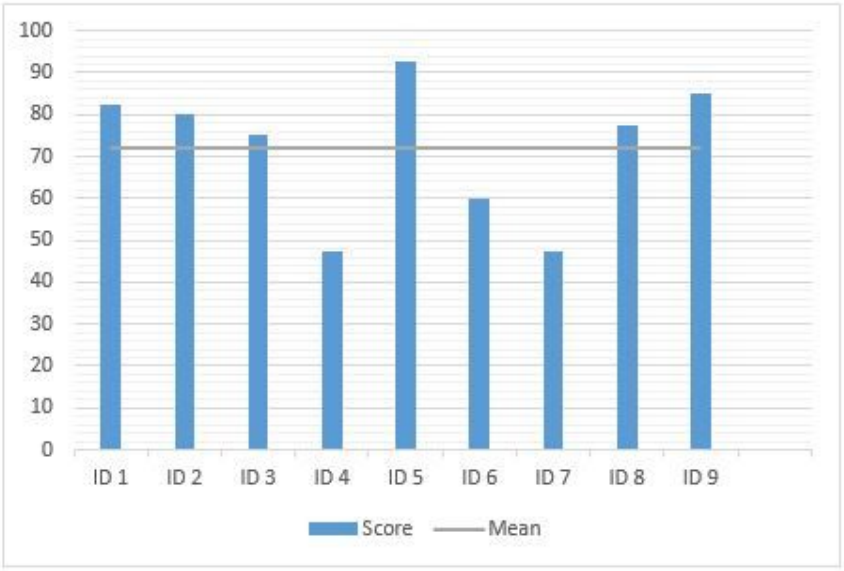

Figure 5

Individuals results in SUS Scale (0-100%).

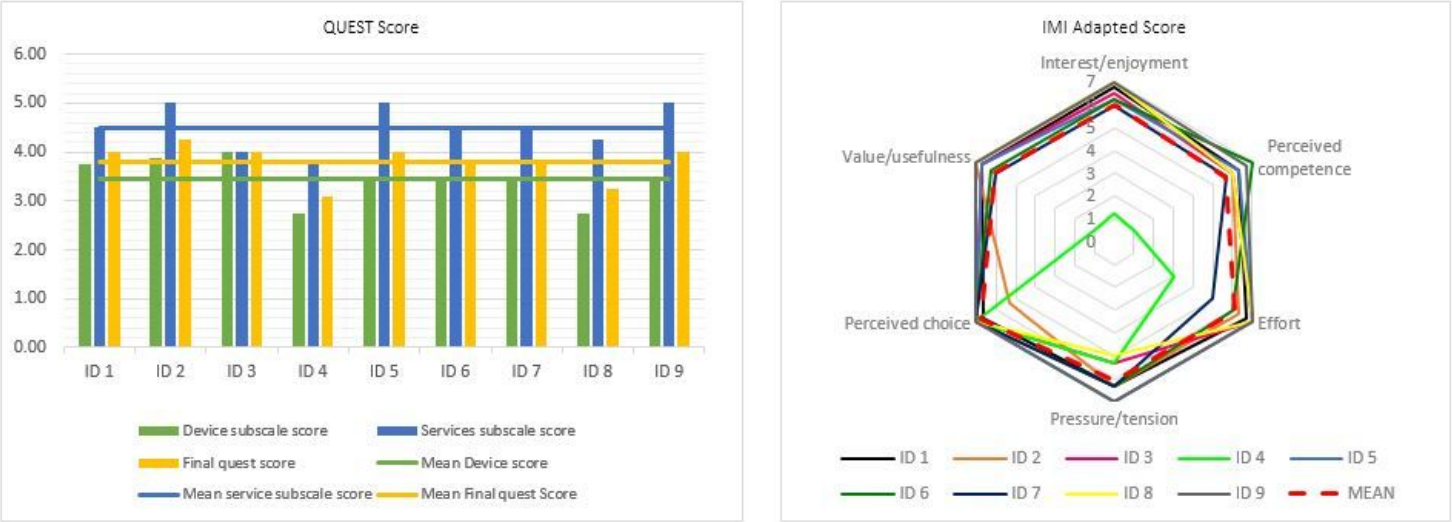

Figure 6

Individuals results. QUEST Scale (left) and IMI Adapted Scale (right).