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A robotic rehabilitation intervention in a home setting during the Covid-19 outbreak: a feasibility pilot study in patients with stroke

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Abstract

Background Telerehabilitation allows patients to engage in therapy away from healthcare facilities, often in the comfort of their homes. Studies have suggested that it can effectively improve motor and cognitive function. However, its applicability may be limited to patients with severe impairments who require physical assistance. The proposed study aims to evaluate the feasibility and effects of a home-based rehabilitation program for post-stroke patients, based on the use of a planar robot, able to overcome the limitations posed by the COVID-19 pandemic.

Methods We enrolled 20 patients with stroke (11 men, aged 66.1 ± 9.2 years). Patients underwent 20 one-hour robotic upper limb rehabilitation sessions, consisting of the execution of planar point-to-point reaching exercises, using a robotic device in their own home, with the remote supervision of a physical therapist. We assessed the feasibility of this intervention by examining adverse events, patient satisfaction (measured on a Likert scale), usability (using the System Usability Scale, SUS), acceptability (evaluated through the Technology Acceptance Model questionnaire, TAM+), and pain onset (measured with the Numeric Rating Scale). To gauge the clinical effects of the treatment, we analyzed changes in the motor and sensory components of the Fugl-Meyer Assessment for Upper Extremity (FMA-UE) before and after the intervention.

Results The approach was safe, as we did not observe any adverse events, and patients did not experience an increase in pain levels. Patients expressed their appreciation for the treatment, providing an average Likert scale score of 8 out of 10. The usability of the treatment received high marks, with an average SUS score of 78 ± 12. Similarly, the treatment acceptability was favorable, with all examined domains scoring above 4, indicating a positive attitude towards the proposed solution. Moreover, we observed a statistically significant improvement in the motor part of the FMA-UE ($p < 0.001$).

Conclusion Our results demonstrate the feasibility, safety, and effectiveness of employing a rehabilitation robot for upper limb rehabilitation in post-stroke patients within a home-based environment. These findings mark a significant step in advancing innovative and easily accessible rehabilitation options for stroke survivors, ensuring uninterrupted care and creating new opportunities to enhance their functional abilities.

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Trial registration clinicaltrial.gov (NCT05250934).
Keywords Rehabilitation, Telerehabilitation, Stroke, Upper extremity, Robotics, Covid-19

Background

Stroke is globally recognized as the second most prevalent cause of mortality and the foremost cause of physical impairment in adult subjects [1]. Over the last few years, there has been an increase in the number of stroke survivors, which has raised the demand for rehabilitation services [2]. Six months after a stroke, only 12% of survivors achieve full upper limb functional recovery [3]. For the remaining 88%, upper limb motor deficits persist with a negative impact on their level of activities [4–6] and participation [7], as defined by the International Classification of Functioning, Disability, and Health [8].

It is well-known that high dosages of activity-based rehabilitation therapy improve outcomes after stroke [9]. However, many patients received this therapy only within the first 3 months from onset [10] and, sometimes, they do not receive this therapy, for a variety of reasons (inadequate access, transportation issues, and low compliance [11]). This situation was dramatically exacerbated by the COVID-19 pandemic. The limitations imposed by the pandemic on healthcare facilities around the world resulted in the early discharge of patients, the suspension of new patient admissions, and a reduction of in-presence activities. In Europe alone, COVID-19 has impeded access to rehabilitation services for approximately 2 million people [12]. As a result, a pressing demand emerged for the swift reconfiguration of rehabilitation services to cater to individuals with concurrent physical and cognitive impairments, alongside those afflicted by chronic comorbid medical conditions, as well as other patients requiring physical therapy during the pandemic [13]. These individuals encountered restricted or entirely unavailable access to hospital and rehabilitation facilities. Some authors, during COVID-19, underlined that, given the constraints imposed by social distancing measures and stay-at-home directives, individuals confronting challenges in reaching top-tier rehabilitation facilities and services could have found cost-effective and high-quality therapeutic interventions offered through home-based rehabilitation programs [

Telerehabilitation had already been promoted and implemented in the field of physical medicine and rehabilitation before the COVID-19 outbreak [14]. It refers to therapeutic interventions that are administered outside of a hospital environment, often at home or community setting. This approach enables individuals to be engaged in tailored programs of therapeutic activities [13]. After the COVID-19 outbreak, home-based technology has been proposed as a way to provide flexibility in terms of time and place for rehabilitation therapy, as well as to receive feedback from therapists remotely. Several studies have been conducted in patients with stroke, suggesting that telerehabilitation for stroke patients can improve motor functions, cognitive functions, and abilities in daily living activities, supporting its efficacy and feasibility. According to a meta-analysis on the topic [15], telerehabilitation may serve as a viable substitute for conventional rehabilitation therapy in individuals recovering from stroke, particularly in regions with limited access to healthcare services. Nevertheless, implementing telerehabilitation services for individuals with significant impairments presents some challenges. This is primarily because these services typically rely on specialized telehealth platforms or software designed to support virtual rehabilitation, or wearable sensor-based devices to monitor a patient's movements, progress, and vital signs. Therefore, these approaches cannot offer physical assistance or support to the weakened arm, thereby restricting their applicability to patients with only mild to moderate deficits.

Robotic therapy has been suggested as an effective approach for the rehabilitation of the upper limb [16]. It enables highly intensive treatment in tasks specifically tailored to the patient's characteristics over extended periods, with adequate patient involvement [17–19], enhances the amount and intensity of therapy [20], standardizes the course of the treatment [21], and provides complex but controlled multisensory stimulation [20]. Furthermore, thanks to their integrated sensors and actuators, robotic devices are capable of providing precise quantification of patient's movements, allowing for a highly detailed analysis of her/his dexterity [22, 23]. Besides clinic-based applications, there is a growing need and interest in the development of robotic systems able to provide home-based interventions, able to overcome the limitation previously reported for the current telerehabilitation services and providing high-quality, highly technological rehabilitation services to patients with severe impairment. However, it is worth noting that robotic systems might provide challenges in terms of their setup and procedure, and are not designed to be used autonomously by patients. These devices need the presence of a skilled operator and lack mobility, rendering them impractical for use inside a patient's home. Finally, their software typically lacks cloud-based functionality, rendering them inaccessible remotely to clinicians and physical therapists. Very few studies have administered robot-assisted therapy in the home environment by using robotic devices such as end-effectors [24–26], exoskeletal robots [27, 28], and robotic orthosis [29, 30]. However, none of these studies guaranteed constant monitoring of

the patient, even if remotely, as it occurs in a healthcare setting, to ensure the feasibility of the treatment.

The proposed study aimed to test the feasibility of a home-based rehabilitation treatment for neurological patients based on a teleconsulting, telemonitoring, and robotic telerehabilitation system using a planar robot for upper limb rehabilitation and integrated sensors to overcome the limitations imposed by the COVID-19 pandemic. The objective of the protocol is to evaluate: (1) the feasibility of the treatment; and (2) the effects in terms of motor recovery.

Methods

Participants

In this non-randomised, feasibility pilot study, we recruited a sample of consecutive subjects with stroke, among those previously admitted to our rehabilitation center. We included patients with (a) a diagnosis of ischemic or hemorrhagic stroke, verified by Magnetic Resonance Imaging or Computed Tomography, occurred at least three months before the study; (b) age between 18 and 85 years; (c) upper limb hemiparesis (Fugl-Meyer Assessment Upper Extremity (FMA-UE) ≤ 58); (d) availability of a caregiver who could support and supervise the patient during telerehabilitation sessions. Exclusion criteria were: (a) fixed contractions in the affected limb (ankylosis, Modified Ashworth Scale equal to 4); (b) cognitive deficits that could interfere with the understanding of rehabilitation instructions (Mini-Mental State Examination < 22); (c) behavioral disorders that could interfere with therapeutic activity; (d) other orthopedic or neurological complications that could interfere with the rehabilitation protocol; (e) inability or unwillingness to provide informed consent. All participants gave written informed consent before study participation. The study was approved by the Ethics Committee "Comitato Etico Lazio 1" on May 6, 2021 (610/CE Lazio 1). The research has been recorded on ClinicalTrials.gov under the identifier code (NCT05250934). A preliminary description of the study was reported elsewhere [31].

Fig. 1 The robot Icone

Device

The intervention was performed using the Icone robot (CE Class IIA medical device, developed by Heaxel), shown in Fig. 1. It is a planar robot that allows the administration of neurorehabilitation protocols for the upper limb, based on the intensive repetition of point-to-point reaching exercises defined by the clinical operator for a specific patient. Specifically, Icone is an all-in-one, plug-and-play, cloud-connected, and transportable robot. These features have allowed them to obtain a CE mark for use in any environment, such as a patient's home or other non-hospital settings.

The therapy is set up by a clinical operator and can also be supervised by a non-clinical operator, as a family member of the patient. The device integrates a computer with a multi-touch screen and dedicated management software, thanks to which interactive games are offered to the patient that require coordination of the shoulder and elbow joints for the execution of planar reaching movements. In these exercises, the patient moves the end-effector of the robot at specific points, shown on the monitor in the form of a simple videogame, and receives visual feedback on the position of the end-effector in real-time Several scenarios are available, but the patient is always asked, by moving the handle of the robot, to move an object shown on the screen (such as a ball, or a spacecraft) to reach a target, clearly identified (Fig. 2).

During all the exercises, the robot acquires kinematic (position, speed) and dynamic (force) parameters of the exercise, useful for assessing the state of motor skills and for regulating the degree of interaction of the robot with the patient in a safe manner. The patient is informed about his/her performance with graphic and numerical indicators, periodically shown on the monitor, reporting, in percentage, the number of movements initiated independently by the patient, the amplitude of movement in the direction of the target, the patient's active power, the patient's ability to anticipate the movement, and the accuracy of the movement in reaching the desired target while following a straight trajectory. Icone is designed to work in passive, assistive, adaptive, resistive, or transparent modes, to best adapt to the patient's characteristics; at the same time, it offers the possibility of objectively evaluating the degree of recovery of patients, using ad-hoc tasks. A complete instrumental evaluation report is automatically generated following the execution of a session of ad-hoc evaluation exercises (described below). Data collected by the robot, processed in the form of synthetic indicators (described below), allows the clinical operator to be provided with quantitative information

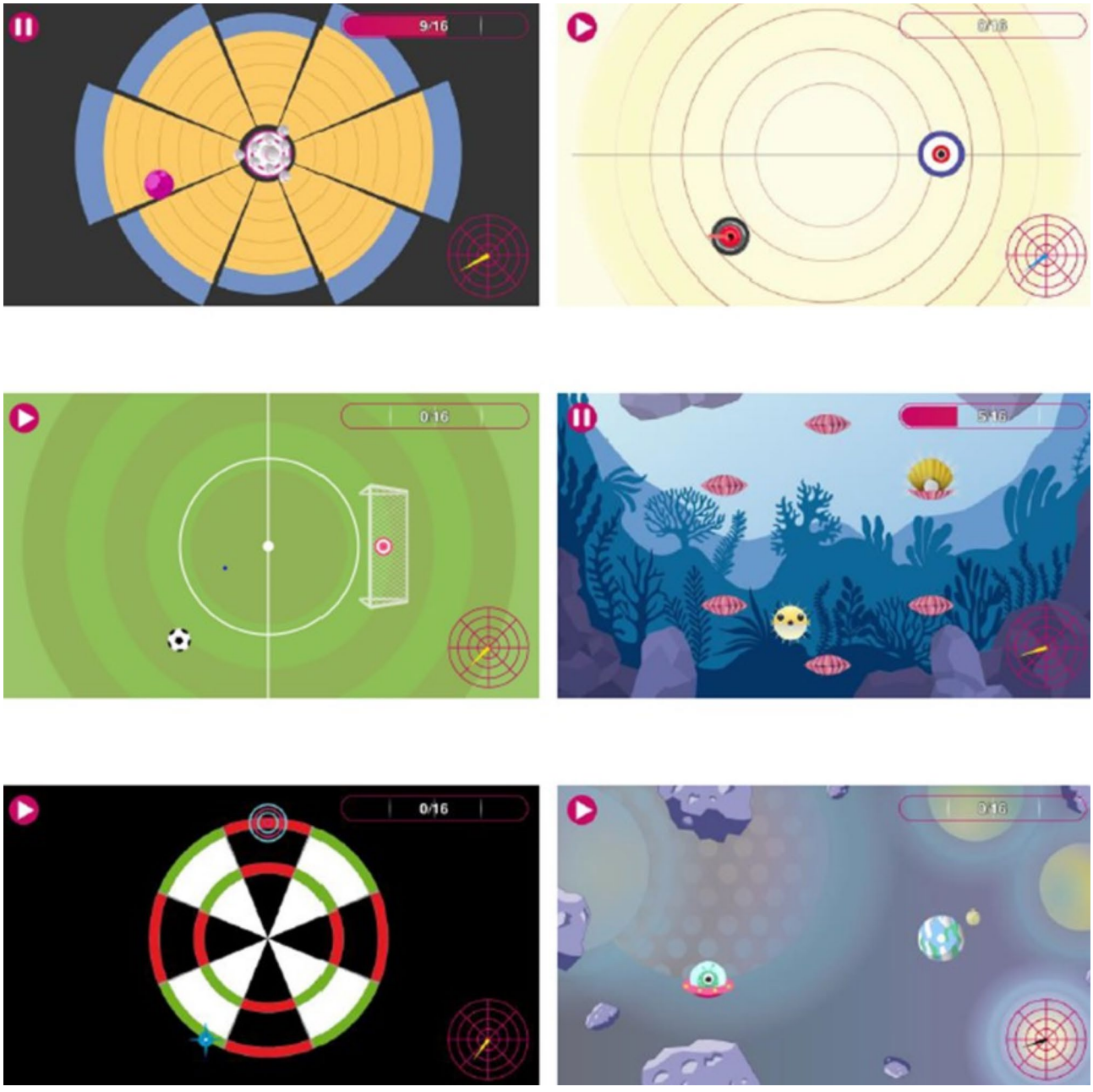

Fig. 2 Some of the serious games of Icone

on the patient's status. Icone requires an internet connection: the Icone cloud architecture is, in fact, the user interface of the robot. This cloud provides the possibility of remotely carrying out all the operations of patient data and reporting, and of the operators' data, thus allowing the consultation of the reports, the management of the therapy, and the population of the database remotely.

For this study, we provided patients with height-adjustable table and chair, which were configured during the robot installation process to ensure their comfort throughout the treatment. Moreover, to ensure patient safety, all the experimental rehabilitation sessions were supervised remotely by a physical therapist (Fig. 3), using three webcams showing the frontal and the sagittal plane of the patient, as well as the monitor of the robot. A specific tool for teleconsulting was used (Maia connected care, ab medica, Italy).

Experimental protocol

Rehabilitation treatment

Patients underwent 1-hour daily robotic upper limb treatments for a total of 20 sessions, consisting of the

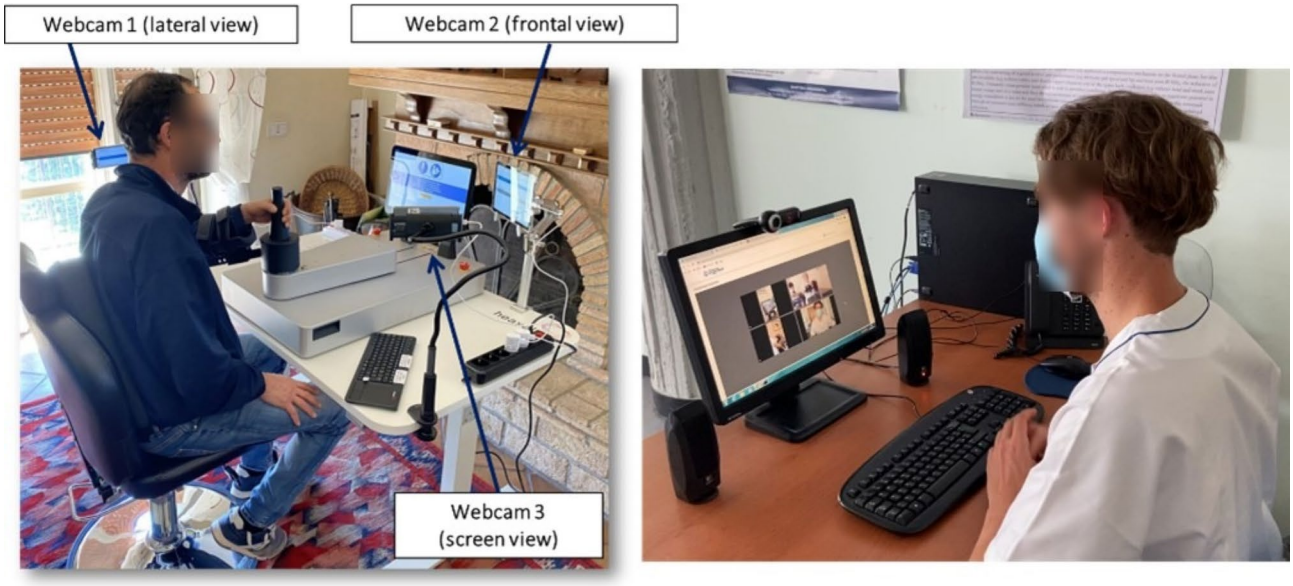

Fig. 3 Home-based set-up with remote supervision

execution of planar point-to-point reaching exercises, involving the shoulder and the elbow joint, using a paradigm widely reported in the Literature [32]. As the medical staff had already pre-set the exercises to be performed, the patient was only required to initiate the treatment from the device, with the assistance of a caregiver. During the treatment, two specifically positioned webcams (one for the patient's sagittal plane and one for the frontal plane) allowed for the observation of the patient while performing movements, ensuring that correct postures were maintained and that potentially unlikely hazardous situations did not occur. A third webcam was also used to display the screen, enabling monitoring of the patient's activities and the feedback displayed on the screen.

After an initial assessment (described below), based on the score obtained on the FMA-UE scale, patients were divided into three groups based on upper limb deficit: severe deficit when the FMA-UE score was between 0 and 28 points; moderate deficit when the FMA-UE score was between 29 and 42 points; mild deficit when the FMA-UE score was greater than 42 points. This screening phase was important for defining the treatment protocol to be applied, at least for the first sessions. For patients with severe disability, exercises with assistance ≥ 5 were set up to allow the patient to complete the exercise or be fully assisted in it. For patients with moderate disability, exercises were set up without assistance or with minimal resistance (≤ 3). For patients with mild disability, exercises with resistance > 3 were set up. Another important factor that influenced the proposed rehabilitation path was the pain parameter (measured using the NRS scale). When the patient reported pain greater than 3, even with a moderate or mild deficit on the FMA-UE, the therapeutic approach was made less intense, favoring assisted exercises over resistance exercises in order to avoid increasing pain. According to the patients' feedback, as well as his/her observations, the physical therapist team modulated the robotic treatment in terms of assistance level, number of repetitions, and several parameters linked to the patient-robot interaction. This was made possible through the continuous supervision provided by the clinical staff.

Assessment

The study included both in-person assessment (initial and final assessment) and remote assessment (teleconsultation), as shown in Fig. 4: (a) an initial in-person enrollment session required to assess the eligibility of the patient, obtain the informed consent, and train the patient and the caregiver in the use of the device; (b) two in-person evaluation sessions (at the beginning and the end of treatment); (c) three teleconsultations during which medical staff assessed the patient's progress, clinical condition, and adherence to the rehabilitation program, to select the most suitable rehabilitation program for the patient. During the initial session, the training on the use of the device took approximately one hour.

In-person evaluations

In-person evaluations were conducted at the beginning (T0) and the end (T1) of the intervention and included both a clinical and an instrumented evaluation. The clinical assessment included the upper extremity portion of the Fugl-Meyer Assessment (FMA-UE) [33], to evaluate upper limb motor performance, and the Numerical Rating Scale (NRS) [34], to assess pain. In addition,

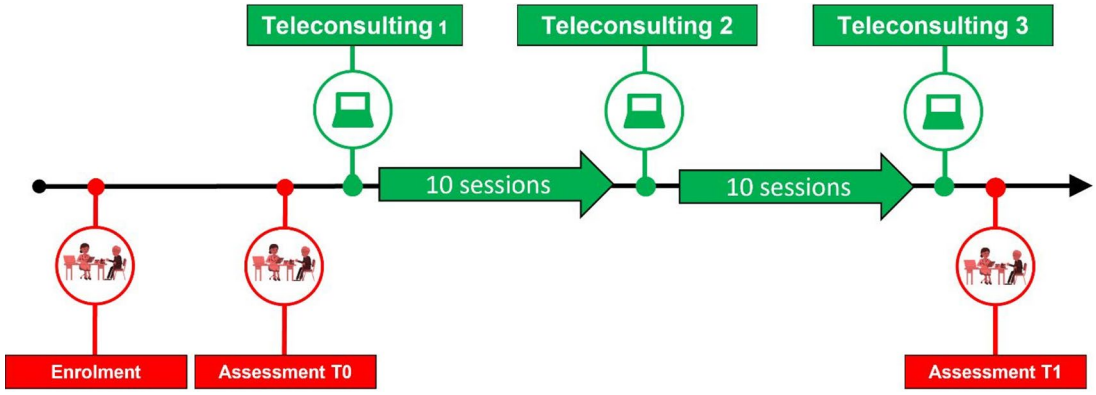

Fig. 4 Study timing (red, in-presence phases; green, remote phases)

Table 1 Quantitative indices provided by the robot

Task	Index	Definition
Circle Drawings	Independence	The ratio between the minor and major axes of the ellipse best fits the hand path
	Area	The area of the ellipse best fits the hand path
Point to point	Path error	The average distance of each point of the patient's trajectory from the theoretical path
	Reach error	The average value of the distance between the maximum distance reached by the patient and the target position
	Speed metric	The average value of the ratio between the mean speed and the maximum speed for each point-to-point movement. It is a measure of smoothness
	Peak speed	Maximum speed
	Mean speed	Mean speed
	Movement duration	Average time required to perform a point-to-point movement
Playback static	Hold	The average deviation from the center
Round Dynamic	Displacement	Average distance traveled against resistance

an instrumented assessment was performed, consisting of planar reaching tasks (reaching targets shown on the screen), planar drawing tasks (drawing a circle) and force assessment tasks (moving the robot handle against resistance). In detail, the evaluation sessions consisted of the following 4 exercises:

1. *Circle Drawings*: the task consists of drawing 4 sets of 5 circles, differentiated by starting point (3 o'clock or 9 o'clock) and direction (clockwise or counterclockwise);
2. *Point to Point*: the patient performs planar reaching movements, starting from a central target and reaching 8 targets arranged along a circumference, and follows the feedback shown on the screen.
3. *PlayBack Static*: the task consists of holding the end-effector of the robot, while the robot tries to move its hand toward each of the 8 peripherals targets.
4. *Round Dynamic*: the patient moves the robot's end-effector towards the targets while the robot tries to hold its hand steady at the center.

Specifically, in the first two exercises the robot exerted no force and acted only as a measuring tool, while in exercises 3 and 4 it opposed to patients' movement, to measure the patient's force. From the above-mentioned task, several quantitative indices are obtained, as reported in Table 1.

Moreover, at T1 evaluation only, the usability and the acceptance of the treatment were evaluated using the System Usability Scale (SUS) [35] and the Technology Acceptance Model questionnaire [36], respectively. For the latter, we considered an extended version (TAM+) [37] to explore the following domains: Enjoyment, Aesthetics, Control, Trust in Technology, Perceived Usefulness, Ease of Use, Intention to Use, and Attitude. Finally, the satisfaction was measured using an 11-point (0–10) Likert scale. The exact question was: "How satisfied are you with the robotic treatment?", where 0 means "not satisfied at all" and 10 is "extremely satisfied". These questionnaires (SUS, TAM + and Likert Scale) were administered to both patients, and the two physical therapists involved in the study.

The possibility of adverse events was systematically recorded throughout all sessions. This included physical risks, such as the onset of unusual pain or excessive fatigue; technical risks, such as device malfunctions, electrical issues, or connectivity problems; and any additional concerns reported by the patient that might be associated with using the robotic system. This comprehensive documentation ensured thorough tracking and analysis of potential complications related to the intervention.

Teleconsultation sessions

Teleconsultation sessions were provided before the first rehabilitation session (teleconsultation 1), after 10 sessions (teleconsultation 2), and at the end of the intervention (teleconsultation 3), to enable clinical personnel to comprehensively monitor the patient's clinical status, set up and update the treatment, and provide motivation to ensure the continuity of treatment.

Statistical analysis

The software SPSS was used for statistical analysis (IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp). To assess the feasibility of the intervention, the number of adverse events, and subjective ratings of treatment usability, acceptability, and satisfaction were reported using descriptive statistics. To evaluate the treatment's effects in terms of motor recovery and sensitivity, data related to the FMA-UE scale at T0 and T1 were compared using non-parametric tests for paired samples (Wilcoxon Signed Rank Test). Finally, we analysed any potential correlation between the Likert, SUS or TAM + questionnaires with demographic/clinical characteristics of the patients, as well as their upper limb motor changes, to identify any patient characteristics that might interfere with the feasibility of the treatment, using the Spearman rank correlation coefficient (for ordinal and numeric data) and the Mann-Whitney U test (for categorical data). For all the analyses, a p-value lower than 0.05 was considered significant.

Results

Between May and July 2021, a cohort of 30 individuals received a comprehensive assessment to ascertain their suitability for treatment, by the eligibility criteria. Subsequently, twenty participants were selected to participate in the research study. Out of the total number, two participants did not adhere to the prescribed treatment regimen due to clinical complications unrelated to the research project. Hence, by August 2021 a total of 18 participants successfully concluded the prescribed regimen of 20 therapy sessions and underwent evaluation at completion of the treatment protocol. Since this was a pilot study, a sample size calculation was not performed. However, the recruited sample was deemed sufficient for the

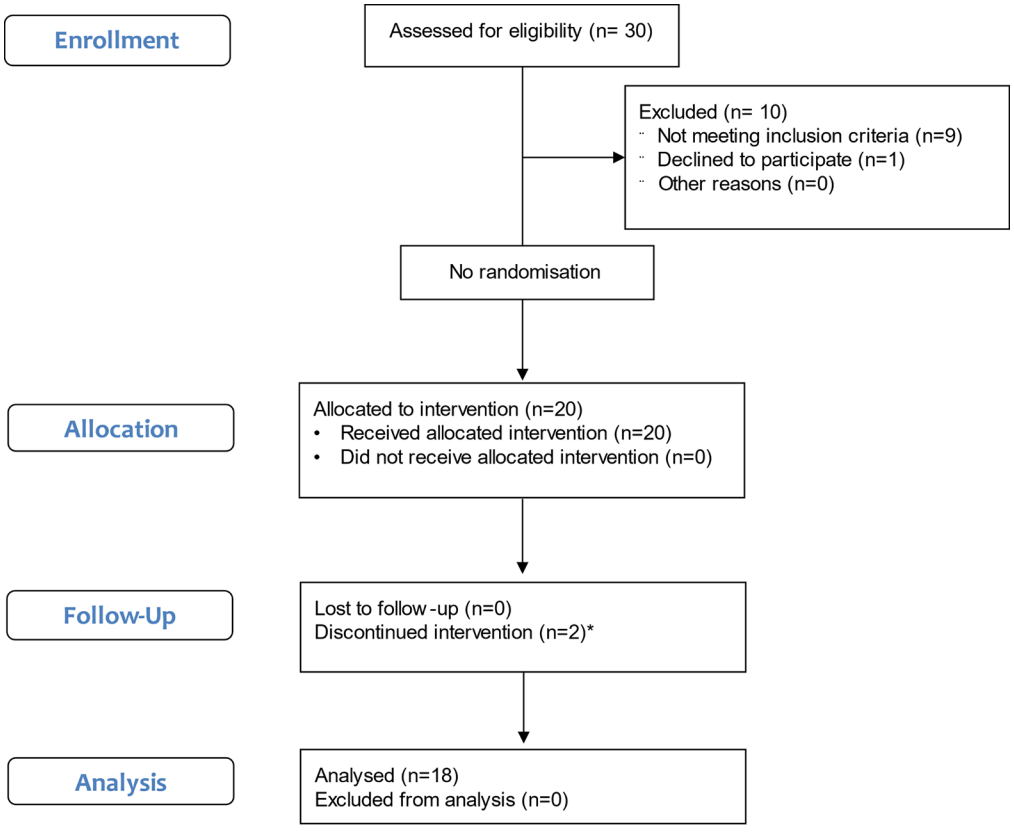

Fig. 5 Flow-chart of the study

Table 2 Demographic and clinical characteristics of the sample ($N = 20$). Data are mean ± sd (min-max), or N (%), as appropriate. FMA-UE: Fugl-Meyer assessment of the upper extremity

Variable	Value
Age (year)	66.0 ± 9.2 (52–82)
Sex	
men	11 (55%)
women	9 (45%)
Dominant side	
right	18 (90%)
left	2 (10%)
Education (years)	11.5 ± 5.5 (5–18)
Time from acute event (months)	11.4 ± 12.7 (3–39)
Stroke aetiology	
ischemic	14 (70%)
hemorrhagic	6 (30%))
Affected side	
right	10 (50%)
left	10 (50%)
Aphasia	1 (5%)
Neglect	3 (95%)
FMA-UE *motor function* (0–66)	32.9 ± 17.4 (4–59)
FMA-UE *upper extremity* (0–36)	18.6 ± 8.7 (4–31)
FMA-UE *wrist* (0–10)	3.9 ± 3.4 (0–10)
FMA-UE *hand* (0–14)	7.7 ± 4.8 (0–14)
FMA-UE *coordination/speed* (0–6)	2.6 ± 2.3 (0–6)
FMA-UE *sensation* (0–12)	9.3 ± 3.0 (1–12)
Numerical rating scale (0–10)	2.6 ± 3.1 (0–8)

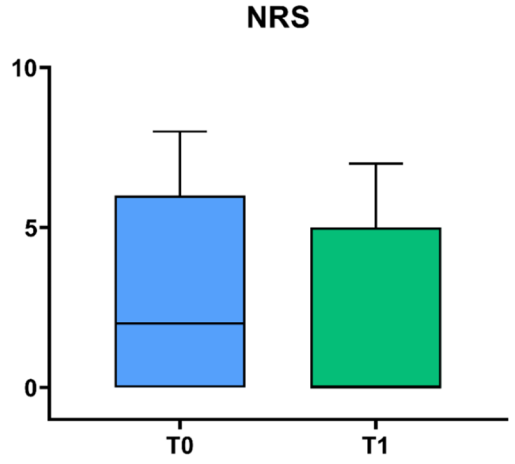

Fig. 6 Numeric rating scale (NRS) for pain before (T0) and after (T1) the treatment

aims of the study. The participant flowchart is reported in Fig. 5.

The demographic and clinical characteristics of the recruited patients are shown in Table 2.

Satisfaction, usability, and acceptability– patient perspective

Subjective assessment of treatment usability and satisfaction by patients was performed at the end of treatment by detecting any adverse events, pain monitoring (NRS), the System Usability Scale (to assess the usability of using the device at home), the Technology Acceptance Model (to assess the acceptability of using the device at home), and the Likert scale (0–10 to assess satisfaction with home treatment). No adverse events were observed during the treatment sessions. Patients did not report experiencing unusual or excessive pain or fatigue, either during or after the intervention, and no issues related to device malfunction were identified. Concerning pain, patients did not show a statistically significant increase in pain after the treatment (Fig. 6).

The feasibility measures of usability, satisfaction, and acceptance are reported in Fig. 7. Concerning patient satisfaction, the mean of the responses was 8 ± 2 out of 10, indicating very good patient satisfaction. The usability of the proposed solution received a score of 78 ± 12; this score indicates usability grade B (good usability). Acceptance of the proposed telerehabilitation solution was evaluated using the TAM+, and all domains examined showed an average score above 4 (neutral score), indicating a positive attitude towards the proposed solution.

Satisfaction, usability, and acceptability - physical therapists' perspective

In the study, two therapists —a 28-year-old and a 32-year-old men, both with experience in robotic rehabilitation—were involved in the treatments and completed the questionnaires. Treatment satisfaction, as rated by the Likert scale, obtained an average rating of 7.3/10. The average score of the SUS was 80.8; this score indicates usability level A (excellent usability). Finally, all mean scores in the TAM + were above 4, indicating a good acceptance by practitioners.

Clinical outcomes

As shown in Fig. 8, the statistical analysis showed a statistically significant improvement in upper extremity motor performance, as indicated by a mean increase of 7 points on the motor portion of the FMA-UE scale ($p < 0.001$). There was also evidence of improvement on the sensory portion of the FMA-UE scale, although not statistically significant. Notably, 11 over 18 patients showed an improvement that exceeded the minimal clinically important difference of the motor portion of the FMA-UE (equal to 5.25 points). Investigating the subscores of the FMA, we detected a statistically significant improvement in the "upper extremity" ($p < 0.001$) and "hand" ($p < 0.01$) subscores (Fig. 9).

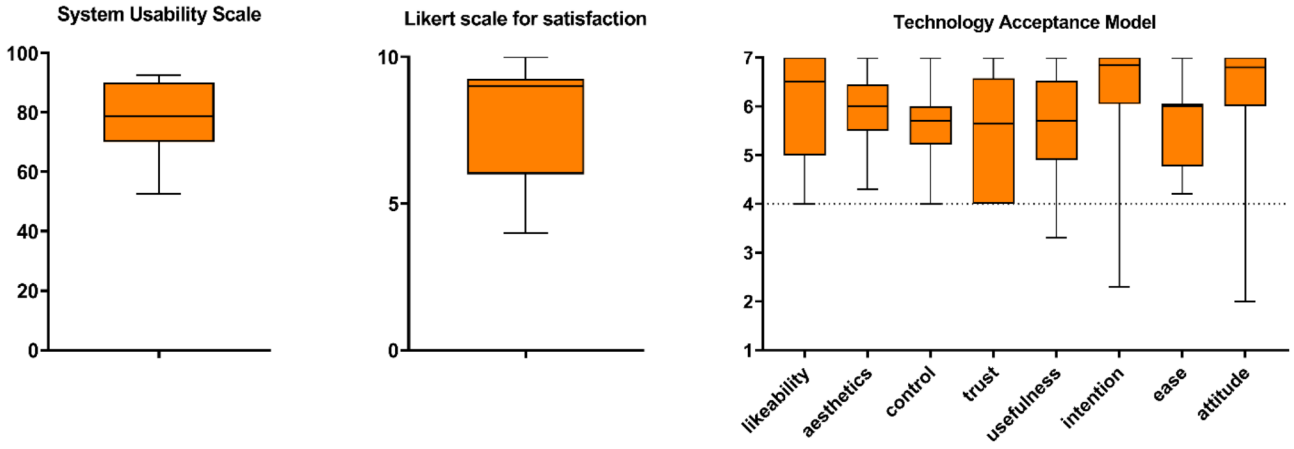

Fig. 7 Feasibility measures of usability, satisfaction, and acceptance of the home-based rehabilitation intervention

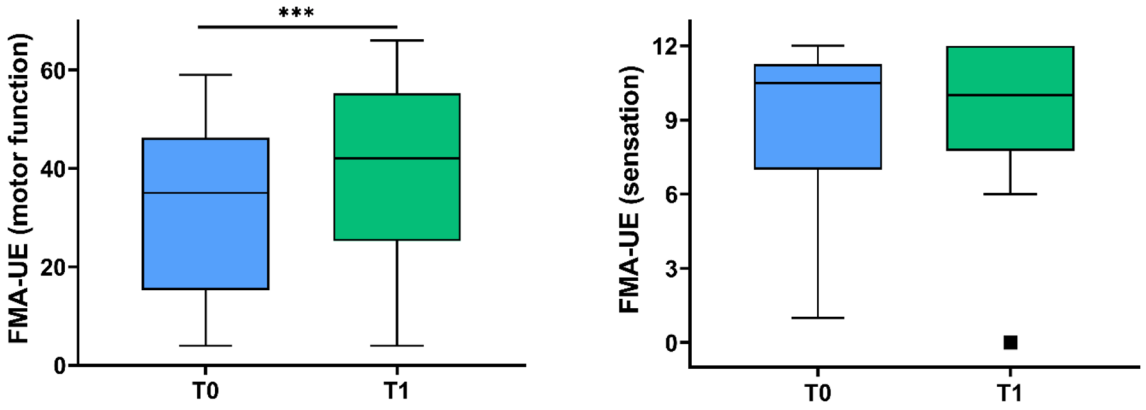

Fig. 8 Clinical evaluation before (T0) and after (T1) the rehabilitation treatment, using the Fugl-Meyer Assessment for upper extremity (FMA-UE) score. The symbol *** indicates a $p < 0.001$, according to the Wilcoxon Signed Rank test

Instrumented outcomes

Instrumented scoring data using Icone are shown in Table 3: 5 out 10 the indicators used showed a statistically significant change in performance after treatment. Specifically, we detected an improvement in the following indices: *independence* (Circle Drawings task), *movement duration*, *mean* and *peak speed* (point-to-point task) and *hold* (Playback static).

Identification of patient characteristics that most influence the feasibility of the proposed solution

To identify any patient characteristics that might interfere with the usability and satisfaction with the treatment, potential correlations between the Likert, SUS, and TAM + questionnaire with age, gender, education, time since the event, hemiparetic side, and stroke type were evaluated. According to the *TAM + ease to use* data, men found the treatment easier, compared to women (men: 6.0 ± 0.8, women: 5.2 ± 0.7; $p = 0.034$). Concerning categorical data, no other statistically significant differences were found for stroke type, or side of hemiparesis. Concerning numerical/ordinal data (age, time since the event, education level, motor and sensory deficits, pain, and improvement after treatment), the results are shown in Table 4.

Patients with better upper limb performance were the ones who most enjoyed the treatment. Meanwhile, according to the items of the TAM + questionnaire, patients' pain levels were inversely related to the ease of use, but directly related to trust.

Discussion

In this study, we assessed the feasibility of using a rehabilitative robot in a home-based setting for upper limb rehabilitation in post-stroke patients. The treatment proved to be safe, well-received by both patients and physiotherapists and effective in improving patients' performance. Our results demonstrated that the proposed treatment is feasible, as no adverse events were recorded. Specifically, patients did not report the onset of unusual pain or fatigue during or after the rehabilitation sessions, nor were any malfunctions of the robotic system observed. The two dropouts from the study were due to clinical complications unrelated to the proposed

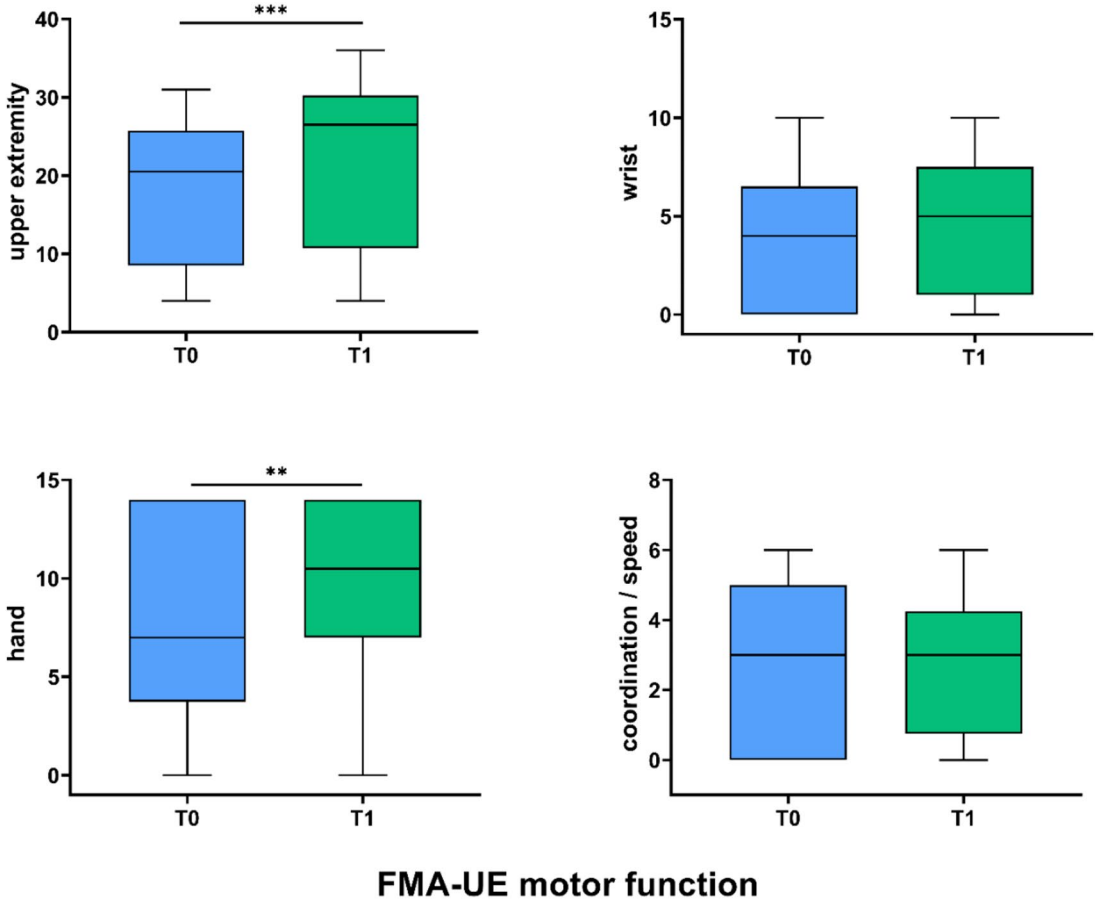

Fig. 9 Subscores of upper extremity motor function section of the Fugl-Meyer Assessment. Changes before (T0) and after (T1) the treatment are reported, together with the statistical analysis (** $p < 0.01$, *** $p < 0.001$, according to the Wilcoxon Signed Rank test)

Table 3 Instrumented assessment

Task	Indicator	Mean T0 (SD)	Mean T1 (SD)	*P* (Wilcoxon Test)
Circle Drawings	Independence	0.750 (0.268)	0.851 (0.124)	**0.016**
	Area (m^2)	0.05 (0.07)	0.06 (0.015)	0.133
Point to point	Movement duration (s)	4.6 (2.4)	2.7 (1.9)	**< 0.001**
	Path error (mm)	14.7 (9.7)	12.1 (6.5)	0.154
	Reach error (mm)	19.2 (22.6)	10.8 (5.9)	0.199
	Mean speed (m/s)	0.06 (0.02)	0.09 (0.04)	**< 0.001**
	Peak speed (m/s)	0.11 (0.04)	0.16 (0.06)	**0.002**
	Speed Metric (smoothness)	0.51 (0.10)	0.57 (0.07)	0.102
Playback static	Hold (m)	0.091 (0.045)	0.058 (0.037)	**0.002**
Round Dynamic	Displacement (m)	0.090 (0.035)	0.106 (0.047)	0.063

treatment. Moreover, the NRS scale did not evidence pain onset during the rehabilitation intervention, and the usability and acceptability were judged positively by both patients and physiotherapists. Finally, according to the Fugl-Meyer Assessment, we demonstrated that in our sample the intervention was able to significantly improve upper limb motor function.

These results support the use of telerehabilitation in stroke patients, in accordance with the latest systematic reviews and meta-analyses on the topic [38, 39], especially if mediated by augmented technologies, such as virtual reality [40, 41]. Concerning robot-based telerehabilitation experience, most of the retrieved studies were preliminary feasibility studies [25, 42–45]; this observation highlights the need for conducting additional studies that can shed light on the clinical prospects and potential applications that these technologies hold. A recent systematic review and meta-analysis aimed at identifying the effect size of home-based rehabilitation using robotic, virtual reality, and game devices on physical function for stroke survivors retrieved only 4 studies using robot-mediated telerehabilitation [46], claiming additional studies on the topic.

Analyzing the specific results obtained in our study, the absence of adverse events is consistent with the current literature about the use of robotics in clinical rehabilitation practice in hospital settings. In fact, according to the Cochrane Review of Mehrholz et al. [16] on

Table 4 Correlations between feasibility measures and demographic/clinical characteristics. In the table, spearman rank correlation coefficients are reported. Values in bold indicate statistically significant correlation (* $p < 0.05$; ** $p < 0.01$; *** $p < 0–001$)

	Age	Time since stroke	Education level	FMA-UE motor score	FMA-UE sensation	NRS	ΔFMA-UE
Likert scale	−0.048	0.076	−0.332	**0.621****	0.135	−0.416	−0.002
SUS	0.155	−0.272	−0.213	−0.058	0.014	−0.298	0.218
TAM + enjoyment	−0.001	−0.001	−0.156	0.339	0.372	0.01	0.071
TAM + aesthetic	−0.117	0.046	−0.047	0.097	−0.05	0.251	−0.129
TAM + control	0.164	0.178	−0.052	0.147	−0.066	0.018	0.134
TAM + trust	0.149	0.003	−0.163	−0.084	0.063	**0.476***	−0.289
TAM + perceived usefulness	−0.25	−0.092	−0.233	0.112	−0.11	−0.09	−0.127
TAM + intention to use	−0.331	0.236	0.112	0.316	0.202	−0.128	−0.11
TAM + ease of use	−0.158	0.067	0.002	0.182	−0.179	**−0.634****	0.345
TAM + attitude	−0.1	0.27	−0.137	0.31	0.333	−0.116	0.072

SUS: System Usability Scale; TAM+: extended version of Technology Acceptance Model; FMA-UE: Fugl-Meyer Assessment for Upper Extremity

electromechanical and robot-assisted arm training in post-stroke patients, the identified adverse events in the 45 analyzed trials were rare. Considering home-based application, in the study of Bressi et al. [25] investigating a rehabilitation intervention home-based using the same device investigated in our study, no adverse events were recorded either during the evaluations or the home-based treatment. This finding is particularly important, as safety is a fundamental prerequisite in any rehabilitation setting, and it gains additional significance when the treatment takes place in the home environment, often characterized by limited clinical supervision. Moreover, we observed a high level of satisfaction and acceptability from both patients and involved physiotherapists. These findings are notably congruent with the prevailing literature, which consistently reports a markedly elevated level of patient satisfaction with robotic interventions [47], but also with telerehabilitation, as reported by Xing et al. [48]. This data reflects the positive perception of the robot-based rehabilitation approach in a home-based setting and suggests that its implementation is well-received by all parties involved. To further comprehend these results, it is important to underscore that the patients in our experimental group received their rehabilitative care in a home-based setting after their discharge from the rehabilitation facility. The paradigm of the 'continuum of care' is of paramount significance in this context, as individuals with disabilities necessitate a continuum of care that is oftentimes not seamlessly provided, leading to a discontinuation of essential treatments post-discharge. This discontinuation, driven by financial and logistic constraints, regrettably results in the potential forfeiture of the gains achieved during the inpatient phase. The matter of the continuum of care has recently garnered significant attention [10]. This emerging discourse calls for a re-evaluation of healthcare policies and strategies to address the challenge of ensuring that patients with disabilities receive uninterrupted and comprehensive care, thereby preserving and optimizing their therapeutic outcomes. The consideration of this element is of utmost importance, particularly in the context of upper limb rehabilitation, since it is widely recognized that this segment tends to exhibit slower and less complete recovery. Consequently, ensuring the provision of a continuum of care is imperative to facilitate optimal functionality of the patient's upper limb.

In assessing the feasibility of our study, particularly about adverse events, it is crucial to acknowledge the context in which our research was conducted. We utilized a device that was appropriately certified for use in an extra-hospital environment, all while being supervised by a caregiver. This aspect undeniably worked in favor of the feasibility of the treatment. The use of a certified and established device ensured a higher level of safety and reliability for patients, minimizing the potential for adverse events. Moreover, the presence of a caregiver further enhanced the safety net, providing an additional layer of support and oversight, which is vital in remote healthcare scenarios. These considerations not only bolstered the feasibility of our treatment but also underscored the importance of utilizing established and certified technologies when implementing remote healthcare interventions. Furthermore, before the deployment of the robot, both the patient and their designated caregiver were required to visit the clinical center for specialized training on the device's operation. In our opinion, this preparatory step significantly contributed to the overall success of the treatment. It ensured that both the patient and the caregiver had a comprehensive understanding of how to use the device effectively and safely. This training not only empowered the patient with the necessary skills to operate the equipment but also provided the caregiver with the knowledge and confidence to offer assistance when needed. This training was crucial in mitigating potential risks and emphasized the importance of comprehensive patient and caregiver education in the successful implementation of remote healthcare solutions.

Arguably, the preeminent achievement of our investigationis the improvement in upper limb functions after the therapeutic interventions, as assessed by a statistically significant increase in the FMA-UE scores. This outcome underscores the efficacy of robot-assisted rehabilitation, as it led to a clinical benefit for the patients. The fact that such improvements were observed in patients in subacute to chronic phases suggests that robotic therapy can be effective even in a later stage following a stroke, thereby extending the therapeutic intervention window. Of particular note, 11 patients exhibited substantive improvements surpassing the threshold of the Minimal Clinically Important Difference on the FMA scale, which was found to be greater than 5.25 in patients with chronic stroke [49]. It is imperative to underscore the temporal dimension of our study population, with an overarching mean latency period of 11.6 months, and a notable subset of 6 patients experiencing a latency exceeding one year. This observation underscores the compelling rationale for the provision of rehabilitative interventions, especially focused on upper limb function, even several months following the occurrence of the acute event. This improvement contrasts with the findings reported in Bressi et al. [25], the only known study that utilized the same robotic device we employed, in a home environment. In this research, patients failed to obtain a statistically significant improvement in FMA scores. This discrepancy in outcomes can likely be attributed to the difference in treatment duration, with our study comprising 20 sessions compared to their 10 sessions. A very recent study [26], in which participants were instructed to engage in daily home-based robotic training for 30 days (starting with 20 min per day and increasing to 120 min per day) reported significant gains in FMA scores among stroke patients (an average increase of 2.4 points from baseline). Additionally, a minimal detectable change (MDC) greater than 5.25 was observed in 2 out of 12 participants at T1. It is noteworthy that our prior research has provided insight into the dynamic nature of rehabilitative progress, as evidenced by our prior work revealing that, in a 30-session rehabilitative protocol, the most substantial FMA score increments were consistently realized between the tenth and twentieth sessions [50]. Furthermore, the influence of treatment dose on the therapeutic outcomes is aligned with the current literature [9, 51].

An outcome that is, to some extent, unanticipated pertains to the analysis of the subscores within the Fugl-Meyer Assessment scale. Notably, we have discovered that, despite administering a treatment protocol primarily targeting the shoulder and elbow joints of the upper limb, we observed not only improvements in the upper limb domain but also within the hand subscore, which was not a direct focus of the therapeutic intervention. This outcome may potentially find an explanation by postulating that enhancements in upper limb function could have led patients to engage their upper extremities more comprehensively in their activities of daily living, some of which inherently encompass manual dexterity. However, it is important to underscore that this remains a hypothesis necessitating further empirical substantiation, perhaps through the utilization of inertial sensor technology throughout the entire treatment period, which can effectively capture the extent of real-world patient movements beyond the scheduled treatment sessions [52].

A result that was largely anticipated in our study pertains to the statistically significant improvement observed in the instrumental indicators derived through the employment of robotic assessments. This finding aligns extensively with the established literature [53], reinforcing the utility of robotic assessments as a rapid means of evaluating patient progress, thereby facilitating the ability to tailor and adjust the rehabilitation trajectory based on individual patient needs. Notably, this outcome is corroborated by the work of Bressi et al. [25], wherein an improvement in these instrumental metrics was observed in patients, even in the absence of concurrent enhancements on the Fugl-Meyer Assessment (FMA) scale, thereby underscoring their heightened sensitivity. In particular, we observed in the point-to-point task, a statistically significant improvement in hand mean and peak speed, a hallmark of motor recovery after stroke [54]. Furthermore, we observed an increase in a metric assessed in tasks not explicitly trained during the robotic therapy sessions (independence in circle drawing task and hold in playback static task), thus suggesting that the observed outcomes may be interpreted as genuine instances of learning rather than mere task adaptation [55]. This resonates with the concept that the benefits of robotic rehabilitation extend beyond the realm of task-specific adaptation, encompassing the broader domain of skill acquisition and motor learning. The absence of statistically significant changes in the smoothness metric may be attributed to the specific metric used (the speed metric). In fact, several studies have reported improvements in smoothness when measured using metrics based on jerk [56], or the Spectral Arc Length [57]. It is worth noting that several metrics have been proposed, and the debate regarding the most effective one is ongoing [58].

Regarding the exploration of factors potentially impacting the acceptance, usability, and satisfaction with the proposed solution, our initial findings reveal that, as per the System Usability Scale (SUS), patients evaluated the device's usability positively, irrespective of their clinical characteristics.

Moreover, with respect to the acceptability, our analysis revealed that men found the treatment easier, compared

to women. This observation underscores a gender-related nuance in the acceptance of technological innovations, which holds significance for our understanding of how individuals, particularly across gender lines, interact with and embrace technological solutions. The topic is not so well investigated and literature data lead to opposite results. In the study of Gallimore et al. [59], including 200 participants viewing a video depicting a robot interacting with humans, females were found to be more trusting of the robot compared to males. Nertinger et al. [60], assessed the user acceptance of assistive social robots in telemedicine and telerehabilitation scenarios and found, among other results, that being a male is a factor that positively affects acceptance. These results accentuate the importance of considering gender-related factors when implementing and designing technology-based interventions, including robotic systems, and emphasize the need for gender-sensitive approaches to enhance the overall usability and acceptance of such solutions. Further research in this area could yield valuable insights into gender-related differences in technology adoption and trust, and the possible interaction with cultural sensitivity.

A third noteworthy outcome pertains to the association between upper limb performance and user satisfaction. This result, to some extent, aligns with our expectations, as we posit that it is linked to the fact that patients with lesser impairment tend to derive more substantial benefits from the treatment. This could be attributed to their heightened ability to perceive clinically significant improvements compared to patients with more severe deficits. However, it is essential to underscore that this relationship may not necessarily extend to usability, as there was no correlation between the SUS scores and the FMA scores at admission.

Additionally, an aspect that appears to be correlated with treatment feasibility is the presence of pain. Patients experiencing higher levels of pain encountered greater difficulties in employing the robotic device; however, they also exhibited a higher degree of trust in the technology. Pain constitutes a pivotal facet within the context of stroke rehabilitation, as extensively corroborated by scientific literature [61]. Numerous studies have specifically highlighted the profound influence of pain, particularly shoulder pain, on the rehabilitation trajectory [62, 63]. This could elucidate the observed challenges in device utilization. Nonetheless, along with pain, there may also exist a heightened motivation to overcome these challenges, which could contribute to the elevated trust demonstrated by these individuals. Nevertheless, it should be acknowledged that these findings, drawn from a relatively limited sample, should be considered preliminary and warrant further validation in larger-scale studies. It is noteworthy that pain levels did not increase following the treatment, thus aligning with the pre-existing body of literature that attests to the safety and effectiveness of rehabilitative robotic technologies in mitigating any potential exacerbation of pain [64].

In our research, we integrated a comprehensive approach to patient monitoring by utilizing three webcams. This multi-camera setup played a pivotal role in our study, as it allowed us to maintain a continuous and detailed observation of the patient's movements and interactions during the course of their treatment. These webcams served a dual purpose. Firstly, they provided us with real-time feedback on the patient's posture, which was crucial for ensuring that they maintained correct alignment and minimized the risk of adopting improper postures that could potentially lead to further health issues. Secondly, the webcams enabled us to monitor the feedback displayed on the screen, which played an important role in motivating the patient throughout the therapy. Furthermore, the consistent presence of a trained therapist during the sessions had a calming and reassuring effect on the patient. It offered a sense of security and ensured that the patient felt supported and guided throughout the therapy, ultimately leading to improved compliance and a more positive overall experience. These elements, when considered collectively, likely had a substantial impact on the outcomes of our study. Not only did they enhance the feasibility, usability, and acceptability of the therapy, but they also contributed significantly to motor improvement and, crucially, the prevention of any increase in discomfort or pain. In this perspective, a scoping review conducted by Forbrigger et al. [65] of designs for at-home upper limb stroke rehabilitation mechatronic devices highlights the limits of the actual generation of robotic devices for home-based rehabilitation, citing, among them, the need for supplemental sensors, as Inertial Measurement Units, or cameras, in addition to those embedded in the robot, to obtain information about patients' body pose and prevent, for example, compensation and help the therapist to track patients' progress. In summary, our holistic approach to patient monitoring, including the use of webcams and the presence of a therapist, was instrumental in achieving positive results in our study. However, incorporating this comprehensive approach to patient monitoring also raised an important consideration: the sustainability of continuous monitoring over the long term. While the use of webcams allowed for remote monitoring and eliminated the need for patients to travel to a clinic, maintaining constant surveillance is not practical or sustainable in most clinical settings, since it would place a substantial burden on healthcare providers. However, we hypothesize that scheduled monitoring sessions, when combined with instrumental continuous assessments, can strike a balance between providing an effective and safe

treatment and ensuring sustainability. For this reason, future, larger trials should be conducted without constant supervision from the physiotherapist, including an assessment of the economic feasibility and sustainability of the intervention to ensure broader applicability.

The principal limitations of our study encompass the small sample size, the lack of a follow-up assessment to gauge the persistence of achieved outcomes, at least in the short term, the lack of a specific outcome to assess the impact of the provided intervention on activity of daily living tasks and Quality of Life, and the absence of a control group. Regarding the latter, it is crucial to underscore that usual care in the home-based setting often does not incorporate any form of rehabilitative intervention; therefore, it would be hard to define "usual care" to compare it with our approach. Nevertheless, the outcomes of the study should be interpreted within the scope of these inherent limitations, given that this is a pilot study, and are thus best considered as preliminary findings warranting further substantiation through more extensive and comprehensive investigations, including long-term follow-ups to ascertain the sustainability of observed improvements.

Conclusion

In conclusion, our findings indicate that the use of a rehabilitative robot in a home-based setting for upper limb rehabilitation in patients with post-stroke outcomes is feasible, safe, and effective. These discoveries represent a milestone in promoting innovative and accessible rehabilitation solutions for stroke patients, guaranteeing the continuum of care and opening new possibilities for improving their performance and quality of life. However, it is important to note that further research and long-term investigations are required to validate these observations fully and to fully understand the potential of this approach in post-stroke rehabilitation.

Abbreviations

SUS	System Usability Scale
TAM	Technology Acceptance Model questionnaire
FMA-UE	Fugl-Meyer Assessment for Upper Extremity
NRS	Numerical Rating Scale

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Author contributions

I.A., M.G. and L.Z. conceptualized the research. I.A., L.Z. and L.V. coordinated the study. M.G. and F.S.L. collected and analyzed the data. M.G., M.C.M. and F.F. prepared the initial draft. All authors reviewed the manuscript.

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Data availability

Data are available from the Corresponding Author upon reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics Committee "Comitato Etico Lazio 1" on May 6, 2021 (610/CE Lazio 1). All recruited participants provided written, informed consent to participate in this study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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