

## Effectiveness of a sensor-based technology in upper limb motor recovery in post-acute stroke neurorehabilitation: a randomized controlled trial

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Sensor-based technological therapy devices could be a possible neurorehabilitation strategy for motor rehabilitation in patients with stroke during the post-acute hospitalization, especially for treating upper extremities function limitations. The audio-visual feedback devices are characterized by interactive therapy games with that allows training the movement of shoulders, elbows, and wrist, measuring the strength and the active range of motion of upper limb, registering data in an electronic database to quantitatively monitoring measures and therapy progress. This study aimed to investigate the effects of sensor-based motor rehabilitation in add-on to the conventional neurorehabilitation for improving the upper limb functions in patients with subacute stroke. Thirty-seven patients were enrolled in the study and randomly assigned to the experimental group and the control group. The training consisting of twelve sessions of upper limb training compared with twelve sessions of upper limb sensory-motor training, without robotic support. Both rehabilitation programs were performed for 40 minutes three times a week, for 4 weeks, in addition to conventional therapy. All patients were evaluated at the baseline (T0) and after 4 weeks of training (T1). The within-subject analysis showed a statistically significant improvement in both groups in all clinical scales. The analysis of effectiveness revealed that, compared with baseline (T0), the improvement percentage in the MBI was greater in the experimental group than the control group. The use of a sensor-based training with audio-video-feedback could be a useful complementary strategy for improving upper limb motor functions in patients with stroke during post-acute neurorehabilitation

Stroke is a major cause of disability worldwide and the second cause of death (1). Its global burden is growing, because of lower mortality and higher incidence (1). Upper limb motor impairment is the most frequent stroke consequence (2). Stroke rehabilitation plays a key role in reducing motor impairment and disability (3). It can include a wide variety of therapeutic options, but their efficacy on motor functions is still unclear (4). Upper limb rehabilitation of stroke patients represents one of the main aims of rehabilitative process for its functional and social participation implications. Functional

recovery after stroke is driven by affected harm use in a task-oriented manner, leading to axonal sprouting and novel neuronal connections (5). It is known that task-oriented exercises are effective in improving upper limb functions (6). While intensity and task-oriented characteristics of the training are clearly important, the engagement, motivation, the involvement of adequate neural infrastructure provide increased resource to allow the recovery process (7).

Technological devices can help the therapist in this kind of training, providing enriched and top down (8) therapy over a longer period, indeed they

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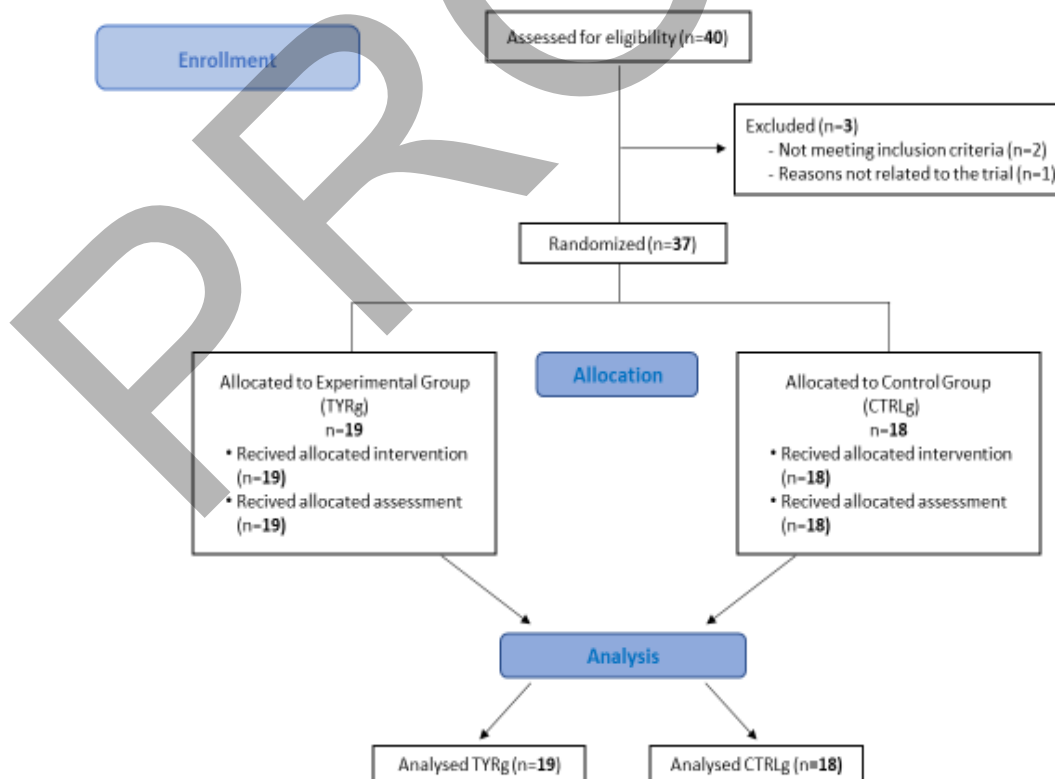
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are often integrated in clinical practice for stroke patients (9). Moreover, they can help understanding individual needs (giving quantitative measures of impairment) and optimizing learning strategies, by adapting rehabilitation “as needed” (10). Despite their use in stroke rehabilitation, there is still an evidence gap regarding optimal treatment dose and frequency, and characteristics of patients that could benefit from this treatment in terms of severity, latency from stroke event and type of robot. These details are important to guide clinicians to improve therapeutic decision making and define technology application field in upper limb neurorehabilitation.

The PABLO® Upper Extremity is a sensor-based device product by Tyromotion for upper limb unilateral and bilateral training (12, 13). It allows interactive therapy games with audio-visual feedback, training upper limb movements at the three joints (shoulder, elbow and wrist) and measuring the strength of hand functions and the active range

of motions of the upper extremity. Three sensors allow to detect movement accelerations in the three dimensions of the space and one sensor detect the hand’s strength applied during the movements. These quantitative measures may be used to monitor individual data and therapy progress. PABLO®-Tyromotion is considered a neurocognitive task-oriented approach of rehabilitation and required an active participation of patients.

Based on these considerations, our hypothesis is that an audio-visual feedback and hand training performed with a sensor-based technology (PABLO®-Tyromotion) in addition to the conventional neurorehabilitation, may increase the effect of conventional therapy in upper limbs functions of patients with stroke. For that purpose, the study aim was to evaluate the effects of a sensor-based technology on the upper limbs motor recovery in patients with stroke during post-acute neurorehabilitation.



**Fig. 1.** Flow Chart. *TYRg*= Experimental Group; *CTRLg*= Control Group.

## MATERIAL AND METHODS

### Trial design

This was a two-arm single-blind randomized controlled trial (Fig 1). The guidelines for Good Clinical Practice, and the Consolidated Standards of Reporting Trials (CONSORT), were followed. The trial was approved by the Local Ethics Committee with the number CE/PROG.631. All participants gave their written informed consent for the participation in the study. A researcher who was not involved in the intervention sessions assessed the patients' eligibility to participate, based on the inclusion and exclusion criteria. Participants were randomly assigned to one of two groups: experimental (TYRg) or control group (CTRLg).

### Participants

Thirty-seven patients (27 males, mean age 58.46 years) with a diagnosis of stroke in sub-acute phase (<6 months after stroke) were recruited and enrolled on the basis of consecutive sampling from January 2018 to February

2020 at the Fondazione Santa Lucia (FSL), Institute for Research and Health Care.

Inclusion criteria were as follows: hemiplegia/hemiparesis in the subacute phase caused by a first-ever stroke, lesions that were confirmed by computed tomography or magnetic resonance imaging, and age between 25 and 80 years, with Mini-Mental State Examination (MMSE)  $\geq 24$  (14) and Medical Research Council (MRC) scale (15, 16) ranging from 1 to 4. Exclusion criteria were: Modified Ashworth Scale (MAS) (17)  $>3$  at the upper limb; cognitive deficits affecting the ability to understand task instructions (MMSE  $<24$ ) (14); MRC scale (15, 16) with score 0 or 5; presence of clinically evaluated severe comorbidities; pregnancy; subjects with artificial pacemaker; subjects involved in other studies. Demographic characteristics of the sample are reported in Table I.

### Interventions - The experimental group's intervention

TYRg performed twelve sessions of upper limb training with PABLO®-Tyromotion. For each session, the

**Table I.** Demographic characteristics at baseline.

	TYRg (n=19)	CTRLg (n=18)	p value
Age (years)* $\pm$ SD	56.8 $\pm$ 9.2	60.2 $\pm$ 14.9	0.438
Sex n (%)#			0.463
Male	15 (78.95)	12 (66.67)	
Female	4 (21.05)	6 (33.33)	
Disease subtype n (%)#			1.000
Ischemic	10 (52.63)	9 (50.00)	
Hemorrhagic	9 (47.37)	9 (50.00)	
Time since stroke (months)* $\pm$ SD	4.79 $\pm$ 0.79	4.89 $\pm$ 0.66	0.684
MRC	64.7 $\pm$ 21.5	73.3 $\pm$ 15.1	0.265
MBI	75.5 $\pm$ 24.1	72.0 $\pm$ 29.3	0.831

Mean  $\pm$  standard deviation. **TYRg**= Experimental Group; **CTRLg**= Control Group; **MRC**=Medical Research Council Scale for muscle strength, upper limbs, ranging from 0 (most affected) to 110 (least affected); **MBI**= Modified Barthel Index, ranging from 0 (most affected) to 100 (least affected); #: Chi-square test; \*: t-Student test.

training consisted in interactive-games based on virtual reality which allowed a task-oriented approach and a neurocognitive feedback. The proposed exercises required precision tasks and one-dimensional and bidimensional reaction, allowing to train the attention, the strength control and movement control, the coordination, and the movement precision. All the proposed tasks required the full collaboration and motivation of the patient. The interactive games were chosen from those proposed by the Tyromotion PABLO® System (13).

#### Control group's intervention

CTRLg performed twelve sessions of upper limb sensory-motor training, without robotic support. Subjects performed specific exercises aimed to recovery global upper limb functions, to control hand grasp and to improve hand's fine movements. Both groups performed the training three times a week for 4 weeks. Each session lasted 40 min and was performed in addition to the conventional neurorehabilitation (18-20) in comments. Both trainings were carried out by physiotherapists with experience in neurorehabilitation.

#### Outcomes

At enrolment, clinical and demographic data were collected. A blinded examiner assessed primary and secondary outcomes. All patients were evaluated at baseline (T0) and after 4 weeks of training (T1). The primary outcome were the changes in functionality of the upper limb measured in 9 Hole Peg Test (9HPT) (21), at 1 month. Secondary outcome measures were the Modified Barthel Index (MBI) (22). Moreover, the measurement of exerted force for pinch, lateral grip, three-point grip and interdigital grip was performed using the evaluation

system of the Tyromotion PABLO® device. All clinical scale scores were collected by a researcher not aware of the allocation group and not involved in the intervention sessions.

#### Sample size

The sample size complied with the minimum number of participants recommended by a power analysis performed on preliminary data ( $\alpha=0.05$ ;  $\beta=0.8$ ;  $ES=0.5$ ) for nonparametric between group comparisons (23). This sample-size estimation procedure recommends that at least 15 patients be included in each group (24).

#### Blinding

A researcher, not involved in the intervention sessions, carried out the randomization. Block randomization was performed with a computer-generated randomization list using a block size. Allocation concealment was ensured by using an automatic random number generator ([www.random.org](http://www.random.org)). The researcher responsible for the randomization process, deposited the list in a secure web-based storage.

#### Statistical Analysis

All the statistical analyses were carried out with the IBM SPSSS Statistic Software version 23, IBM Corp. Armonk, NY, U.S.A. Data were reported in terms of means and standard deviations. The paired T-test and the Wilcoxon signed ranks test were used for the within-subjects comparison for both groups at times T0-T1. The Mann-Whitney U-test and the unpaired t-test was used to compare data between groups at T0 and T1. The significance was considered for  $p<0.05$ . The descriptive

**Table II.** Results of within subject analysis and of the percentages of effectiveness.

	TYRg				CTRLg			
	T0 mean $\pm$ SD	T1 mean $\pm$ SD	p-value (T1- T0)	Increase T1vsT0 (%) $\pm$ SD	T0 mean $\pm$ SD	T1 mean $\pm$ SD	p-value (T1-T0)	Increase T1vsT0 (%) $\pm$ SD
9-HPT	294.5 $\pm$ 220.6	166.9 $\pm$ 132.7	0.000*	NA	229.6 $\pm$ 232.5	196.1 $\pm$ 199.9	0.016*	NA
MBI	75.5 $\pm$ 24.1	92.2 $\pm$ 9.0	0.000*	73.3 $\pm$ 20.9	72.00 $\pm$ 29.3	83.39 $\pm$ 21.8	0.001*	60.0 $\pm$ 27.8

Mean  $\pm$  standard deviation; **TYRg** = experimental group; **CTRLg** = Control Group; **9-HPT**=9 Hole Peg Test; **MBI**=Modified Barthel Index; **NA**= not applicable; The Effectiveness is the percentage of improvement and was calculated as follow:  $[(T1 \text{ score} - T0 \text{ score} / \text{maximal score} - T0 \text{ score}) \times 100]$  \* = significant for  $p<0,05$  in the subjects' analysis.

analysis was performed using  $[(T1 \text{ score} - T0 \text{ score} / \text{maximal score} - T0 \text{ score}) \times 100]$  (25) to calculate the percentages of effectiveness in the two groups.

## RESULTS

Thirty-seven patients met the inclusion criteria and were enrolled in the study. None of the enrolled subjects left the study before the end. The statistical analysis was performed using the data of thirty-seven subjects (TYRg=19, CTRLg=18). There were no significant between-group differences in demographics and clinical data in outcome measures at baseline (T0).

Both groups showed a statistically significant

improvement along time in the within subjects' analysis, in 9HPT and MBI; no significant differences were found in the between analysis. The analysis of effectiveness revealed that, compared with baseline (T0), the improvement percentage in the MBI was greater in the TYRg than the CTRLg (Table II).

Regarding the MRC scores, both groups show a significant improvement for the within group analysis, in all the assessed items (Table III). Significant differences in the between-subjects' analysis were found for the elbow extension, forearm supination and forearm pronation MRC scores in the TYRg with respect to the CTRLg (Table IV).

The PABLO®-Tyromotion scores show a statistically significant improvement in 13 out of the

**Table III.** MRC scale Scores.

	TYRg			CTRLg		
	T0 mean $\pm$ SD	T1 mean $\pm$ SD	p-value (T1-T0)	T0 mean $\pm$ SD	T1 mean $\pm$ SD	p-value (T1-T0)
Shoulder Flex	2.9 $\pm$ 1.0	3.7 $\pm$ 1.0	0.001*	3.4 $\pm$ 0.8	3.8 $\pm$ 1.1	0.035*
Shoulder Ext	3.1 $\pm$ 1.0	4.1 $\pm$ 0.9	0.000*	3.4 $\pm$ 0.8	3.8 $\pm$ 1.1	0.035*
Shoulder Abd	3.1 $\pm$ 0.9	3.9 $\pm$ 1.1	0.000*	3.2 $\pm$ 1.0	3.6 $\pm$ 1.1	0.005*
Shoulder Add	3.6 $\pm$ 1.0	4.4 $\pm$ 0.9	0.001*	3.6 $\pm$ 0.9	4.1 $\pm$ 0.9	0.005*
Shoulder Lat.Rot	2.9 $\pm$ 0.9	3.7 $\pm$ 0.8	0.000*	2.9 $\pm$ 0.9	3.4 $\pm$ 1.1	0.007*
Shoulder Med.Rot	3.3 $\pm$ 0.9	4.1 $\pm$ 0.8	0.001*	3.3 $\pm$ 0.8	3.9 $\pm$ 0.8	0.002*
Elbow Flex	3.4 $\pm$ 0.8	4.5 $\pm$ 0.8	0.000*	3.6 $\pm$ 0.8	4.0 $\pm$ 1.0	0.005*
Elbow Ext	3.6 $\pm$ 1.1	4.5 $\pm$ 0.9	0.001*	3.4 $\pm$ 0.9	3.8 $\pm$ 1.0	0.008*
Forearm Sup	3.2 $\pm$ 0.9	4.3 $\pm$ 0.9	0.000*	3.1 $\pm$ 0.8	3.6 $\pm$ 1.0	0.005*
Forearm Pron	3.3 $\pm$ 1.0	4.4 $\pm$ 0.8	0.000*	3.6 $\pm$ 1.0	3.2 $\pm$ 0.8	0.014*
Wrist Flex	2.8 $\pm$ 1.2	3.7 $\pm$ 1.0	0.001*	3.3 $\pm$ 0.8	3.7 $\pm$ 1.0	0.008*
Wrist Ext	2.8 $\pm$ 1.2	3.7 $\pm$ 1.1	0.001*	3.3 $\pm$ 0.8	3.6 $\pm$ 0.9	0.025*
Metacarpophalangeal joints Flex	2.8 $\pm$ 1.3	3.8 $\pm$ 1.1	0.000*	3.3 $\pm$ 0.8	4.0 $\pm$ 1.0	0.001+
Metacarpophalangeal joints Ext	2.8 $\pm$ 1.2	3.7 $\pm$ 1.2	0.000*	3.3 $\pm$ 1.0	3.6 $\pm$ 1.0	0.0014*
Interphalangeal joints Flex	2.6 $\pm$ 1.4	3.7 $\pm$ 1.2	0.000*	3.3 $\pm$ 0.9	3.9 $\pm$ 1.1	0.002*
Fingers Abd	2.4 $\pm$ 1.3	3.3 $\pm$ 1.1	0.000*	3.2 $\pm$ 0.9	3.4 $\pm$ 0.9	0.046*
Fingers Add	2.5 $\pm$ 1.3	3.7 $\pm$ 1.0	0.000*	3.4 $\pm$ 0.8	3.8 $\pm$ 1.0	0.008*
Metacarpophalangeal and Interphalangeal joints of Thumb Flex	2.7 $\pm$ 1.3	3.8 $\pm$ 1.0	0.000*	3.6 $\pm$ 0.7	4.1 $\pm$ 0.8	0.002*
Metacarpophalangeal and Interphalangeal joints of Thumb Ext	2.7 $\pm$ 1.2	3.7 $\pm$ 1.1	0.001*	3.4 $\pm$ 0.7	3.7 $\pm$ 1.0	0.025*
Thumb Abd	2.7 $\pm$ 1.1	3.7 $\pm$ 1.1	0.001*	3.5 $\pm$ 0.7	3.9 $\pm$ 0.8	0.008*
Thumb Add	2.9 $\pm$ 1.3	4.1 $\pm$ 1.1	0.000*	3.6 $\pm$ 0.7	4.1 $\pm$ 0.9	0.003*
Opposition of Thumb and little finger	2.6 $\pm$ 1.3	3.5 $\pm$ 1.2	0.000*	3.1 $\pm$ 0.9	3.6 $\pm$ 1.0	0.002*

Mean  $\pm$  standard deviation. **TYRg**= Experimental Group; **CTRLg**= Control Group; **Abd**=abduction; **Add**=adduction; **Ext**=extension; **Flex**=flexion; **Pron**=pronation; **Sup**=supination; **Lat**=lateral; **Med**=medial; \* = significant for  $p < 0,05$  in the subjects' analysis.

**Table IV.** MRC statistically significant values for the between analysis.

	TYRg		CTRLg		p-value (T0-T0)	p-value (T1-T1)
	T0 mean $\pm$ SD	T1 mean $\pm$ SD	T0 mean $\pm$ SD	T1 mean $\pm$ SD		
<i>Elbow Ext</i>	3.6 $\pm$ 1.1	4.5 $\pm$ 0.9	3.4 $\pm$ 0.9	3.8 $\pm$ 1.0	0.392	0.028*
<i>Forearm Sup</i>	3.2 $\pm$ 0.9	4.3 $\pm$ 0.9	3.1 $\pm$ 0.8	3.6 $\pm$ 1.0	0.558	0.036*
<i>Forearm Pron</i>	3.3 $\pm$ 1.0	4.4 $\pm$ 0.8	3.6 $\pm$ 1.0	3.2 $\pm$ 0.8	0.745	0.013*

Mean  $\pm$  standard deviation. **TYRg**= Experimental Group; **CTRLg**= Control Group; **Ext**=extension; **Flex**=flexion; **Pron**=pronation; **Sup**=supination; \*= significant for  $p < 0.05$  in the between subjects' analysis.

**Table V.** PABLO®-Tyromotion scores.

	TYRg			CTRLg		
	T0 mean $\pm$ SD	T1 mean $\pm$ SD	p- value (T1- T0)	T0 mean $\pm$ SD	T1 mean $\pm$ SD	p-value (T1-T0)
<i>Hand grip-extension force</i>	7.1 $\pm$ 6.2	9.6 $\pm$ 7.8	0.01*	7.3 $\pm$ 6.0	9.1 $\pm$ 7.4	0.20
<i>Precision pinch thumb- forefinger</i>	2.0 $\pm$ 1.5	2.7 $\pm$ 1.5	0.00*	2.4 $\pm$ 1.7	1.8 $\pm$ 1.7	0.06
<i>Precision pinch thumb- middle finger</i>	1.9 $\pm$ 1.6	2.6 $\pm$ 1.3	0.01*	2.1 $\pm$ 1.5	2.5 $\pm$ 1.3	0.03*
<i>Precision pinch thumb- ring finger</i>	1.5 $\pm$ 1.3	2.0 $\pm$ 0.8	0.01*	1.5 $\pm$ 1.0	2.1 $\pm$ 1.1	0.00*
<i>Precision pinch thumb- Little finger</i>	1.1 $\pm$ 1.3	1.3 $\pm$ 0.6	0.20	1.2 $\pm$ 0.9	1.5 $\pm$ 1.1	0.15
<i>Lateral pinch thumb- forefinger</i>	3.0 $\pm$ 1.9	3.7 $\pm$ 1.6	0.00*	3.7 $\pm$ 2.2	3.8 $\pm$ 2.0	0.07
<i>Interdigita pinch forefinger- middle finger</i>	1.0 $\pm$ 1.0	1.8 $\pm$ 1.2	0.00*	1.7 $\pm$ 1.5	1.6 $\pm$ 1.1	0.60
<i>Interdigita pinch middle finger - ring finger</i>	1.0 $\pm$ 1.2	1.8 $\pm$ 1.3	0.00*	1.2 $\pm$ 1.2	1.4 $\pm$ 1.2	0.07
<i>Interdigita pinch ring finger - Little finger</i>	0.8 $\pm$ 1.2	1.3 $\pm$ 1.2	0.00*	1.0 $\pm$ 1.0	1.4 $\pm$ 1.5	0.04*
<i>Pinch thumb- forefinger- middle finger</i>	1.9 $\pm$ 1.1	3.1 $\pm$ 1.2	0.00*	2.6 $\pm$ 1.6	3.1 $\pm$ 1.6	0.15
<i>Shoulder Abd/Add</i>	127.2 $\pm$ 53.1	140.6 $\pm$ 50.2	0.41	131.9 $\pm$ 52.3	141.6 $\pm$ 51.6	0.17
<i>Shoulder Flex/Ext</i>	154.8 $\pm$ 46.7	177.9 $\pm$ 47.9	0.00*	151.8 $\pm$ 45.2	160.0 $\pm$ 45.2	0.16
<i>Elbow Flex/Ext</i>	154.2 $\pm$ 51.7	165.6 $\pm$ 49.1	0.03*	162.9 $\pm$ 42.4	158.6 $\pm$ 46.6	0.67
<i>Forearm Sup/Pron</i>	102.4 $\pm$ 48.6	130.4 $\pm$ 40.2	0.01*	107.3 $\pm$ 35.3	127.0 $\pm$ 42.6	0.04*
<i>Wrist Flex/Ext</i>	105.2 $\pm$ 32.1	124.8 $\pm$ 33.5	0.00*	105.6 $\pm$ 30.0	108.1 $\pm$ 36.6	0.71

Mean  $\pm$  standard deviation. **TYRg**= Experimental Group; **CTRLg**= Control Group. **Ext**=extension; **Flex**=flexion; **Pron**=pronation; **Sup**=supination; \*=significant for  $p < 0.05$  in the within subjects' analysis.

15 evaluated districts for TYRg and 4 out of the 15 for CTRLg, considering the within subjects' analysis (Table V); no significant differences were found in the between subjects' analysis. No side effects were reported.

## DISCUSSION

The aim of this study was to evaluate the effects of a sensor-based training performed with PABLO®-Tyromotion on the upper limb motor recovery in patients with stroke during post-acute neurorehabilitation. Both groups showed significant improvements in terms of arm motor recruitment and functional recovery. However, the percentage of functional improvement in MBI was greater for TYRg than CTRLg, while between groups differences were not significant.

Consistently, Tyromotion instrumental scores improved more in TYRg than CTRLg, in functions directly involved in exercises. We can hypothesize that these results are related to the strength of PABLO®-Tyromotion training, as the possibility to gain a stronger and lasting intrinsic motivation (26) and the visual feedback allowing greater awareness of upper limb abilities and improvements over time. Moreover, this sensor-based motor rehabilitation provides intensive and motivating task-oriented training (27) and might increase cognitive network involvement as for example attentional and executive resources (28, 29). It is noteworthy that most of the researches published in literature on the technological devices for upper limb regards robot or electromechanical assisted machines introduced more than 20 years ago (30) while sensor based technology has been only recently introduced with few research studies most of which regards chronic subjects.

Tiemmermans and colleagues are finding feasible and usable sensor-based task-oriented training, in a small sample of chronic stroke patients, treated for eight weeks (31). The same research group compared sensor-supported versus robot-supported task-oriented arm training for highly functional chronic stroke patients, highlighting possible best treatment option with sensor-based training in this specific stroke population (32). Our results are in accordance with previous studies regarding upper

limb sensor-based training in subjects with stroke. A recent review stated that robot and sensor assisted training ensures high-quality therapy to the largest possible patient group with lower health care costs (12). In addition, sensor-based technology might be a good option to measure training parameters as frequency, intensity, amount, and dose and as an outcome to quantify in a lab and in the real world for improvement ability (33).

The present study has some limitation. Firstly, the small study sample included different types of stroke (i.e. haemorrhagic and ischemic, right and left hemiparesis), resulting in a heterogenous group. Second, although the patients have shown themselves available and pleasantly satisfied with the training with PABLO®- Tyromotion, we did not use any validated scale to measure enjoyment and intrinsic motivation (34). In addition, future instrumental assessments (35, 36) of muscles' activity, and training parameters as frequency and intensity may be considered. In conclusion the use of a sensor-based training with audio-video-feedback could be a useful complementary strategy for improving upper limb motor functions in patients with stroke during post-acute neurorehabilitation. Future studies on larger populations are needed to better understand the clinical value of the achieved results.

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