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ORIGINAL ARTICLE

Effect of biofeedback cycling training on functional recovery and walking ability of lower extremity in patients with stroke

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Abstract This study aimed to investigate the effectiveness of biofeedback cycling training on lower limb functional recovery, walking endurance, and walking speed for patients with chronic stroke. Thirty-one patients with stroke (stroke onset >3 months) were randomly assigned into two groups using a crossover design. One group ($N = 16$; mean: 53.6 ± 10.3 years) underwent conventional rehabilitation and cycling training (30 minutes/time, 5 times per week for 4 weeks), followed by only conventional rehabilitation for another 4 weeks. The other group ($N = 15$; mean: 54.5 ± 8.0 years) underwent the same training in reverse order. The bike used in this biofeedback cycling training was the MOTOmed viva2 Movement Trainer. Outcome measures included the lower extremity subscale of Fugl-Meyer assessment (LE-FMA), the 6-minute walk test (6MWT), the 10-meter walk test (10MWT), and the modified Ashworth scale (MAS). All participants were assessed at the beginning of the study, at the end of the 4th week, and at the

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end of the 8th week. Thirty participants completed the study, including the cycling training interventions and all assessments. The results showed that improvements in the period with cycling training were significantly better than the noncycling period in the LE-FMA ($p < 0.05$), 6MWT ($p < 0.001$), 10MWT ($p < 0.001$), and MAS ($p < 0.001$) scores. No significant carryover effects were observed. The improvements on outcome measures were significantly different between the cycling period and the noncycling period after adjusting for potential confounding factors in the multivariate analysis of variance ($p < 0.001$). The study result indicates that the additional 4-week biofeedback cycling training could lead to improved LE functional recovery, walking endurance, and speed for patients with chronic stroke.

Introduction

Functional impairment of the lower extremity (LE) is one of the most common complications in patients with stroke [1—3]. The LE motor function plays a critical role in daily life such as transferring, standing, walking, or maintaining balance. Compromised walking ability may be due to abnormal patterns of muscle activity, abnormal muscle tone, or synergy patterns in the hemiplegic side. Research has shown that LE functional recovery for patients with stroke (onset >3 months) was still constrained, suggesting that a continuous rehabilitation program is necessary [4].

Compared with conventional training modes, cycling motion is a simple-to-use and low-cost rehabilitative training following stroke as well as an effective training program in clinical settings [5]. Subacute stroke patients receiving daily cycling training have gained significant improvements in their LE muscle strength, aerobic capacity, and balance ability [6]. Moreover, participants with chronic stroke who underwent 10—12-week cycling training have been reported to have improved cardiorespiratory fitness [7,8]. However, for the aforementioned outcome measures, there was a lack of immediate monitoring and quantifiable indexes for LE functional improvement; clinicians are therefore not provided with real-time information during cycling. A recent study investigated biofeedback cycling training using two-color bars in the bike panel during cycling, and demonstrated improvements of gait symmetry and walking speed in patients with stroke [9]. A study conducted by this research team recruited 40 patients with chronic stroke to evaluate kinesiological, kinematic, and kinetic aspect under conditions with and without visual feedback of cycling cadence, and found that cycling with visual feedback could improve neuromuscular control and overall performance, which may result from better control of rectus femoris muscle activations [10]. These studies supported the fact that biofeedback cycling training could improve LE functional recovery in patients with stroke. However, these studies suffered from the limitations of a very small sample size [9], or investigated only LE electromyography of rectus femoris muscle activation and coordination of both legs during a single cycling session [10]. No research has ever examined the treatment effect on walking ability by biofeedback cycling training intervention program for patients with chronic stroke.

The purpose of this study was to investigate the treatment effect of an additional biofeedback cycling intervention program for LE functional recovery and walking ability in patients with chronic stroke.

Methods

Participants

The study participants were stroke patients receiving regular outpatient rehabilitation in a university hospital. The inclusion criteria were: (1) first-ever stroke; (2) stroke onset >3 months and <3 years prior to the study enrollment; (3) unilateral hemiplegia; (4) between 18 years and 70 years of age; (5) ability to walk 10 m with or without assistance; and (6) scores of three levels of consciousness items in the National Institutes of Health Stroke Scale were zero [11]. The exclusion criteria were: (1) patients with aphasia who could not follow instructions; (2) blindness or severe visual impairments that prohibit seeing the faceplate; (3) musculoskeletal disorders (e.g., severe arthritis); (4) cardiac disorders (e.g., unstable heart diseases); and (5) peripheral neuropathy that could potentially interfere with this study. The research protocol was reviewed and approved by the ethics committee of the Kaohsiung Medical University Chung-Ho Memorial Hospital (KMUH-992314). All participants provided written informed consent prior to participating in the study.

Intervention

A crossover study design was used. Eligible participants who met the criteria and with an interval of at least 3 months after stroke onset were randomized into two groups by computer-generated random numbers held in sealed envelopes by an independent individual. All participants received their regular conventional outpatient rehabilitation (1-hour physical therapy and 1-hour occupational therapy). One group underwent an additional 30-minute cycling training with a stationary bike (MOTOmed viva, RECK-Technik, Betzenweiler, Germany) for 4 weeks (cycling period), followed by regular rehabilitation only in the next 4 weeks (noncycling period). The other group underwent the same 8-week training in the reverse order. The bike panel (11.3 cm × 8.4 cm) showed parameters of revolutions

per minute (rpm), symmetry of bilateral lower limb exertion (the best performance = 50/50), cycling distance (kilometer), performance (Watt), and resistance (0—20 grade). Data during cycling on these parameters were recorded in a bike chip. The biofeedback cycling training was provided by an independent, qualified physical therapist not involved in participants' rehabilitation.

The 30-minute biofeedback cycling training consisted of two bike sessions, including 15 minutes each of forward and backward cycling. The following protocols were adhered to in every training session: (1) preparation: participants were seated on a chair in front of the bike. For each participant, the distance from the seat to the crank axis was standardized by allowing their knee joint to have a maximum of 110—120° flexion throughout the entire pedaling cycle. Heart rate and blood pressure were measured; (2) passive warm up: 150-second passive cycling; the legs of the participant were passively moved by the bike with a constant speed of 25 rpm; (3) active pedaling: 10-minute training of active cycling; participants were required to maintain a pedaling speed of 60 rpm (range: 50—70 rpm) and focus on the visual feedback of load symmetry of their lower extremities to be 50/50 shown on the bike panel. The exercise intensity of active pedaling was set at Stage 13 of the Borg scale [12], which corresponds to "a little strenuous" intensity; (4) passive cool down: 150 seconds of passive cycling; the participants' legs were passively moved by the bike at a constant speed of 25 rpm; and (5) terminal step: the heart rate and blood pressure were measured and noted after each pedaling session.

Assessments

Outcome measures included the lower limb subscale of the Fugl-Meyer assessment (LE-FMA), the 6-minute walk test (6MWT), the 10-meter walk test (10MWT), and the modified Ashworth scale (MAS).

The FMA consists of two motor subscales, namely, 33-item upper limb movements and 17 lower limb movements [13]. Each item is scored on a 3-point scale, from 0 to 2, and therefore, the score of the LE-FMA has a range of 0—34. The LE-FMA was used to assess LE motor impairments; and the 17 items were administered in supine posture (hip flexion, hip extension, hip adduction, knee flexion, knee extension, ankle dorsiflexion, ankle plantarflexion, heel—shin speed, heel—shin tremor, and heel—shin dysmetria), prone posture (hamstring reflex test and ankle plantarflexor reflex test), sitting posture (knee extension, ankle dorsiflexion, and knee extensor reflex test), and standing posture (knee flexion and ankle dorsiflexion). The FMA had been shown to be reliable and valid for patients with stroke [14,15].

The 6MWT was used to measure maximum walking distance on a 20-m return track [16]. The 10MWT was used to measure walking speed. The time to perform walking 10 m on a 12-m walkway was measured. This was measured three times and the average of the three measurements was used [17]. The MAS is a 6-point scale (0—5) used to assess the spasticity of the knee extensor. The inter-rater reliability and reproducibility of the MAS have been well established in lower extremities of patients with stroke [18].

The set of bike parameters included symmetry of bilateral exertion, performance, and resistance; all these were retrieved daily from the bike chip. Twenty data sets were collected after completion of the 4-week (5 days/week) training. Symmetry stands for the exertion percentage of the affected limb to the sound limb, and the most symmetrical exertion of bilateral legs would be 50/50 (100%). The unit of performance is Watt, which is derived from multiplying the velocity by the moment, and represents average power output of the participant in active pedaling. For resistance, there are 21 grades from Grade 0 (without resistance) to Grade 20 (the maximal resistance). An increase of one grade is equivalent to an increase of 1 kg.

All outcome measures were administered by a blinded rater at the beginning of the study, at the end of the 4th week, and at the end of the 8th week.

Statistical analyses

Baseline characteristics of patients in the two groups were compared using Chi-square test or Fisher exact test for categorical variables, independent *t* test for continuous variables, and Mann—Whitney *U* test for ordinal variables. Paired *t* test was used to compare the change values of cycling period with the noncycling period in outcome measures within Group A and Group B, respectively. The overall efficacy was defined as follows [19]:

$$\text{Formula} = 1/2 \times \{[(\text{change value of cycling} - \text{change value of noncycling}) \text{ within group A}] - [(\text{change value of cycling} - \text{change value of noncycling}) \text{ within group B}]\}$$

Moreover, to estimate treatment effect and carryover effect, data of the cycling period and the noncycling period of the two groups were pooled. The significance of treatment effect was tested by multivariate analysis of variance (MANOVA) after adjusting for sex, age, onset time after stroke, stroke type, affected side, and baseline scores. Statistical analyses were performed using JMP version 9.0 (SAS Institute Inc., Cary, NC, USA). The significance level was set at $p < 0.05$.

Results

Forty patients were interviewed from August 2011 to May 2012. Nine of them were excluded after preliminary screening, including transportation problems ($n = 5$), cognition and comprehension disorders ($n = 2$), and LE fracture ($n = 2$). Thirty-one patients gave their consent to participate in the study; they were then randomly assigned into Group A ($n = 16$) and Group B ($n = 15$). However, one participant dropped out from Group A because of falling at home after agreeing to participate. Finally, 30 participants completed the study interventions and all assessments (Group A = 15; Group B = 15). The flowchart of this randomized trial is shown in Fig. 1. Demographic and clinical characteristics of both groups were comparable at baseline and there were no significant differences in Table 1. Most participants in this study had mild to moderate disability according to the Barthel Index score. No adverse event or side effect was reported

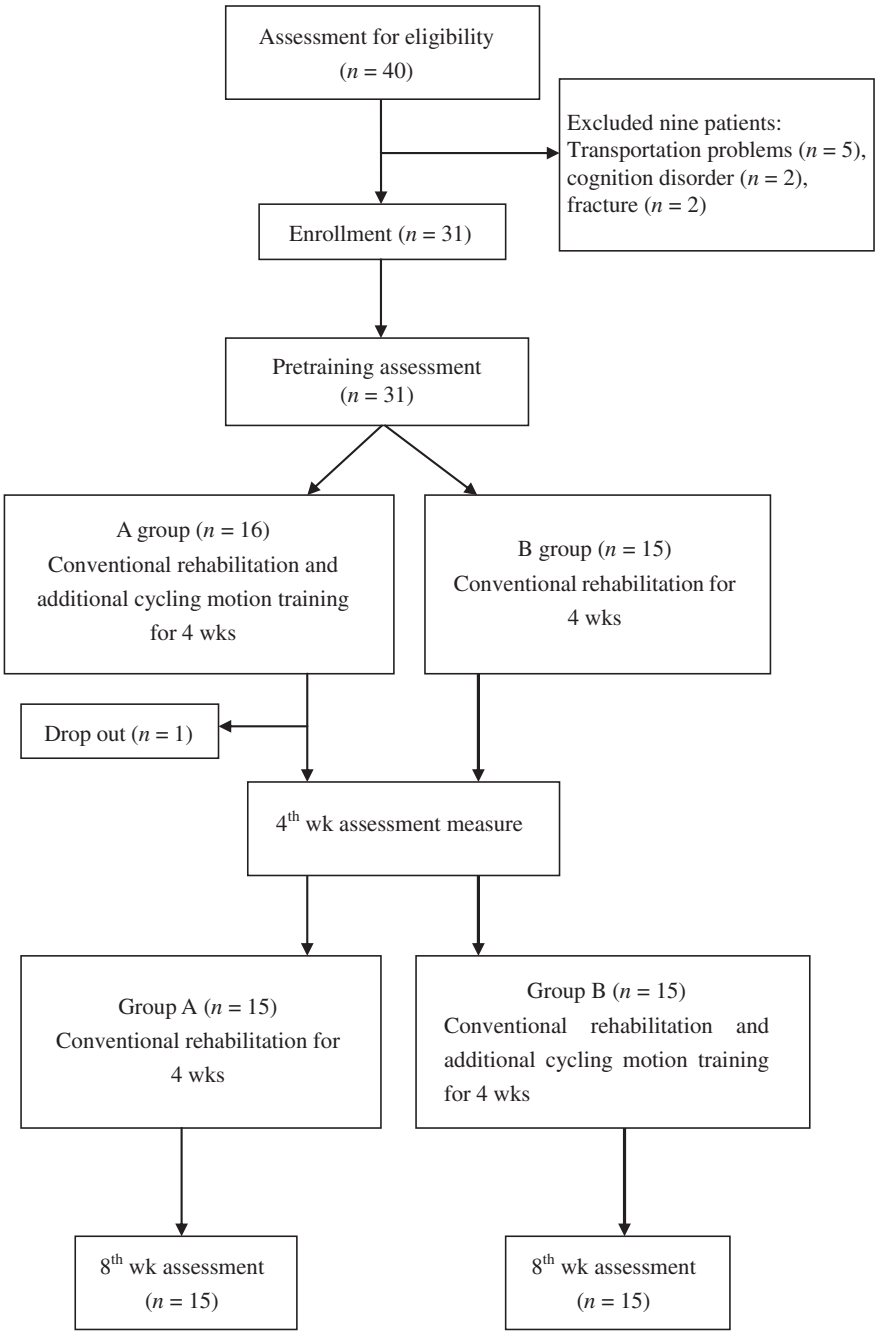

Figure 1. Flowchart of the design and conduct of the study.

during the study period. The symmetry of bilateral legs was maintained at 76.5—81.1% in active pedaling. Performance improved from 19.9 Watt to 32.7 Watt and resistance increased from 6.5 kg to 9.6 kg after the 4-week intervention period.

Table 2 presents the paired *t* test results of changed values during the cycling and noncycling period within each group. The results show that for all parameters measured, a significant difference was observed between the cycling training period and the noncycling period: LE-FMA ($p < 0.05$), 6MWT ($p < 0.001$), 10MWT ($p < 0.001$), and MAS ($p < 0.001$). Moreover, the absolute value of the changes was always greater in the cycling period and without any significant carryover effect.

Results of the adjusted MANOVA show that the improvements in the outcome measures were significantly different in the cycling period than in the noncycling period in Table 3. Treatment effect of each outcome measure was significant ($p < 0.001$); more specifically, the overall efficacy was 3.9 [95% confidence interval (CI): 3.6—4.2], 44.9 (CI: 32.9—56.9), 0.16 (CI: 0.11—0.19), and −1.1 (CI: −0.91 to −1.4) for LE-FMA, 6MWT, 10MWT, and MAS, respectively. None of the carryover effect was significant.

Table 1 Characteristics and baseline measures in the two groups.

Variables	Group A (n = 15)	Group B (n = 15)	p
Sex (male/female)	9/6	13/2	0.22
Type of stroke (H/I)	6/9	7/8	0.71
Side of hemiplegia (left/right)	4/11	7/8	0.45
Brunnstrom stage of L/E	4.4 ± 0.8	4.2 ± 1.2	0.45
Age (y)	53.9 ± 10.5	54.5 ± 8.0	0.88
Time since stroke (mo)	11.1 ± 8.1	11.1 ± 9.7	0.98
Barthel index (0—20)	17.4 ± 2.2	16.5 ± 3.8	0.41
LE-FMA (0—34)	24.1 ± 7.2	20.5 ± 10.2	0.28
6MWT (m)	216.4 ± 107.4	193.1 ± 127.3	0.59
10MWT (m/s)	0.68 ± 0.36	0.60 ± 0.40	0.53
MAS (0—5)	1.1 ± 0.64	1.2 ± 0.68	0.78

Data are presented as mean ± SD.
6MWT = 6-minute walk test; 10MWT = 10-meter walk test; H = hemorrhage; I = ischemic; LE-FMA = lower extremity subscale of the Fugl-Meyer assessment; MAS = modified Ashworth scale; mo = months; y = years.

Discussion

This is the first study to adopt a randomized crossover design to compare the effects of cycling and noncycling training on LE functional recovery, walking endurance, walking speed, and muscle spasticity in patients with a first-ever stroke. Our results suggested that for patients with stroke (onset > 3 months), combining biofeedback cycling training (five 30-minute sessions per week for 4 weeks) with conventional rehabilitation therapy could lead to additional improvement on LE functional recovery, walking endurance, walking speed, and muscle spasticity using clinical evaluation parameters (the LE-FMA, 6MWT, 10MWT, and MAS scores) without noticeable adverse effects. In addition, improvement or maintenance of their functional ability in the noncycling period was also observed; therefore, conventional rehabilitation therapy plays an important role for patients with chronic stroke.

Evaluated using the LE-FMA, it was previously reported that 3 weeks of cycling training (5 times per week) could improve functional and movement recovery of LE in patients with subacute stroke <30 days [20]. In the present study, the LE-FMA was also used to assess the changes on functional recovery among chronic stroke patients (onset >3 months) receiving cycling training, and significant improvements were observed. An overall increase of 44.9 m on walking endurance was also observed, which is higher than the smallest real difference of 6MWT [21]. For the 10MWT results examined in the present study, the overall effect was increased by 0.16 m/s, and this value reached the commonly suggested minimal clinically important difference [22]. It is worth noting that although the improvement for 6MWT was 258.4 m and that for 10MWT was 0.8 m/s after cycling training, the improvements for stroke participants were still lower than those of healthy elders aged 60—69 years [23].

Data from the bike chip demonstrated improvements of muscular control and muscle activation after cycling training. The effectiveness of this cycling training was also demonstrated in the maintenance of symmetry as well as an increase on performance and resistance. In short, this study found that a 4-week biofeedback cycling training could lead to improvement on functional recovery and walking ability in patients with chronic stroke.

Previous studies have shown that intrinsic and extrinsic feedback about movement or movement performance can provide sensory information for stroke patients to enhance motor control or learning [24—27]. Using visual feedback provided in the bike panel, stroke patients learned movement adjustment and bilateral LE control by themselves, and then were able to enhance the load symmetry of their reciprocal motion. The patterns of muscles activation

Table 2 Values of measures at baseline (T1), 4th week (T2), 8th week (T3), and changed values in the cycling and noncycling period.

Measures	Group	T1	T2	T3	Cycling period[a]	Noncycling period[b]	Paired t
LE-FMA	A	24.1 ± 7.2	28.3 ± 5.7	28.6 ± 6.0	4.2 ± 3.4	0.3 ± 1.8	0.002
	B	20.5 ± 10.2	20.7 ± 10.0	24.7 ± 9.4	4.1 ± 2.5	0.1 ± 1.2	0.00*
6MWT (m)	A	216.4 ± 107.4	275.4 ± 137.9	284.5 ± 139.3	59.0 ± 38.1	9.1 ± 7.0	0.00*
	B	193.1 ± 135.3	197.5 ± 128.4	241.4 ± 146.0	44.3 ± 29.5	4.4 ± 12.8	0.00*
10MWT (m/s)	A	0.68 ± 0.36	0.85 ± 0.41	0.85 ± 0.42	0.17 ± 0.15	−0.01 ± 0.05	0.00*
	B	0.60 ± 0.40	0.61 ± 0.41	0.75 ± 0.45	0.14 ± 0.11	0.01 ± 0.02	0.00*
MAS	A	1.1 ± 0.64	0.20 ± 0.41	0.27 ± 0.46	−0.93 ± 0.46	0.07 ± 0.26	0.00*
	B	1.2 ± 0.68	1.5 ± 0.52	0.60 ± 0.51	−0.93 ± 0.26	0.33 ± 0.49	0.00*

Data are presented as mean ± SD; paired t is the comparison between the cycling and noncycling period within each group.
6MWT = 6-minute walk test; 10MWT = 10-meter walk test; LE-FMA = lower extremity subscale of the Fugl-Meyer assessment; MAS = modified Ashworth scale; T1 = pretraining; T2 = 4th week; T3 = 8th week.
*$p < 0.001$.
[a] Cycling period: the patients underwent conventional rehabilitation and cycling training. Value of cycling period: Group A was (T2—T1), Group B was (T3—T2).
[b] Noncycling period: the patients underwent only conventional rehabilitation. Value of noncycling period: Group A was (T3—T2), Group B was (T2—T1).

Table 3 Overall efficacy, treatment effect, and carryover effect of primary and secondary outcome measures.

Measures	Group	Difference[a]	Overall efficacy (95%CI)	Treatment effect (t value)[c]	p	Carryover effect (t value)[c]	p	MANOVA adjusted p[b]
LE-FMA	A	3.9 ± 3.9	3.9 (3.6–4.2)	6.39	0.00*	0.26	0.80	0.00*
	B	4.0 ± 2.3						
6MWT (m)	A	50 ± 36.1	44.9 (32.9–56.9)	7.67	0.00*	1.48	0.15	0.00*
	B	39.9 ± 24.8						
10MWT (m/s)	A	0.18 ± 0.10	0.16 (0.11–0.19)	7.50	0.00*	0.50	0.62	0.00*
	B	0.13 ± 0.10						
MAS	A	−1.0 ± 0.53	−1.1 (−0.91 to −1.4)	10.36	0.00*	1.30	0.20	0.00*
	B	−1.3 ± 0.59						

Data are presented as mean ± SD.
6MWT = 6-minute walk test; 10MWT = 10-meter walk test; CI = confidence interval; LE-FMA = lower extremity subscale of the Fugl-Meyer assessment; MAS = modified Ashworth scale.
*$p < 0.001$.
[a] Difference: value differences between the cycling and noncycling period of Table 2. Cycling period: the patients underwent conventional rehabilitation and cycling training. Noncycling period: The patients underwent only conventional rehabilitation.
[b] MANOVA adjusted p: factors adjusted in the MANOVA included sex, age, onset time after stroke, stroke type, affected side, and baseline score of respective measure.
[c] t statistic.

during cycling and walking are similar; both required reciprocal flexion and extension movement, and needed a well-alternated use of agonist and antagonist muscles [28,29]. Previous research suggested alternating flexion and extension movements of the LE during locomotion produced by central pattern generator (CPG) can be regulated by peripheral sensory inputs [30]. The CPG is in the central neuron system and is able to produce stereotyped and reproducible pattern of rhythmic output even without sensory input or orders of the higher central neuron system [31]. Thus, a possible explanation for the positive treatment effects observed was that the CPG responds to the visual feedback provided in the bike panel during cycling training [32], which could be beneficial to neuromuscular control and muscle activations of the affected LE. The findings supported the hypothesis that cycling training with visual feedback could improve LE functional recovery and walking ability in patients with chronic stroke.

The present study also demonstrated that the knee extensor tone was decreased after the 4-week cycling training, and the result was similar to a couple of previous studies [33,34]. The 30-minute biofeedback cycling training consisted of two bike sessions (forward 15 minutes and backward 15 minutes), which might increase the activities of monosynaptic corticospinal inhibition pathway and decrease the monosynaptic connections stimulated from neurons to muscles. This reaction could normalize the relationship between muscle activities and monosynaptic motoneurons [35,36]. Significant improvements in the muscle tension in the affected knee extensor suggested that the present cycling intervention is safe and could reduce muscle spasticity.

In the clinical setting, extrinsic feedback is useful for patients with stroke to enhance motor control or learning [24–26]. A previous study has examined the effect of extrinsic feedback on the facilitation of cortical plasticity during upper limb functional tasks in patients with stroke [37]. Recently, a near-infrared spectroscopy method has been used to detect the hemodynamic changes resulting from neuronal activity during the pedaling exercise [38]. Enhanced premotor cortices (PMCs) activation of the unaffected side with improved cycling performance was observed during active cycling with visual feedback, compared with that observed without feedback. The finding suggests that extrinsic visual feedback improved cycling performance with additional PMC activations in patients with stroke. The PMC has been proposed to be engaged in information processing for the planning and execution of motor tasks and to arbitrate the complex motor skills [39,40]. However, limited information about the effect of cycling motion training with extrinsic feedback on the induction of brain activation is available, especially in long-term follow-up studies; this could be explored by functional magnetic resonance imaging in future studies.

The limitations of this study may affect the generalizability and applicability of the results found. For example, the average age of the sample was not very old. Moreover, most participants were patients with chronic stroke and the impairment was mild to moderate, and therefore, results of this study were not suitable to patients with severe dysfunction.

In summary, results of this study suggested that conventional rehabilitation with an additional 4-week biofeedback cycling training could improve LE functional recovery and walking ability in patients with chronic stroke. It was recommended that biofeedback cycling training could be used as a clinical protocol in rehabilitation or as home exercise for patients with chronic stroke.

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