Effects of functional electrical stimulation of bi-manual activation-based therapy combined with the training of electromyographic biofeedback on the upper limb motor function in subjects with stroke.

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Introduction: *Stroke is the leading cause of death and disability in Chile. More than 85% of patients suffer from hemiplegia, and more than 69% functional motor disability of the upper extremities. This disturbance impacts the use of the upper limbs, affecting people's daily lives. No studies combine electromyographic biofeedback therapy and bi-manual activation with functional electrical stimulation in subjects with stroke. Therefore, there is interest in determining the effect of a training protocol based on Functional Electrical Stimulation (FES) with bimanual activation and biofeedback therapy on the function of the upper limb.* ***Methodology:*** *15 subjects with stroke between 40 and 85 years recruited in the outpatient neurorehabilitation program of Clínica Dávila, randomized in an experimental group and two control groups of 5 subjects. In each session, the experimental group will train fifteen minutes of bi-manual activation with functional electrostimulation and then a ten-minute biofeedback training program. The control 1 and control 2 group trained under the same conditions but with placebo FES and placebo BF-EMG, respectively.* ***Results:*** *There were significant changes in the experimental group after the intervention.* ***Conclusion:*** *This study suggests the electrical stimulation works and biofeedback as a tool for the rehabilitation of upper limbs in subjects with stroke*

Keywords: *Stroke, Neurofeedback, Rehabilitation*

INTRODUCTION

In recent years, our country has experienced a significant change in its age composition, positioning itself as one of the countries with the highest aging population in Latin America. In turn, this has changed the healthcare situation of Chileans; the cerebrovascular accident (CVA) is the leading cause of death with 9,004 deaths in 2013 —that is — one person per hour. It is estimated that there are 24,964 new cases per year (69 cases per day)[(1)].

More than 85% of CVA patients have hemiplegia and more than 69% experience a functional motor disability of the upper extremities [(2)]. Furthermore, it is the first specific cause of disability-adjusted life years in people over 74 years old. For all these reasons, CVA is a criti-

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cal public health concern[1].

According to the latest AUGE clinical practice guideline of ischemic cerebrovascular accident, 14% of Chilean patients with severe paresis, with little or no active movement upon admission, experienced complete recovery, while 30% had a partial recovery. This deficit impacts on the use of the upper limbs for reaching, grasping, handling, balance, and the exploration of surroundings, thus affecting various daily activities[1]. Despite all interventions, functional motor disability frequently appears in the upper limbs rather than the lower limbs. One of the reasons why this happens could be the high frequency with which the middle cerebral artery (MCA) or its branches, whose territory includes cortical areas that are associated with the upper extremities motor functions, are affected by the CVA (75% of the extension of the territory affected by the CVA). Lang et al. showed that upper extremity motor disability significantly affects CVA patients' daily activities such as eating, dressing, or washing their faces [2, 3]. These upper extremities functions have been emphasized as important elements in human beings [4]. From this perspective, this disease is the source of important and diverse sequelae both in the motor and cognitive spheres, which significantly interfere with the quality of life of those who have it. There are various therapeutic interventions for upper extremity motor recovery, from neurodevelopmental techniques, bi-manual training, constraint-induced movement therapy, strength training, mirror therapy, mental practice, biofeedback, virtual reality technology, and movement therapy assisted by robotic devices (Table 1) [1].

Multiple previous studies have been conducted using different combined techniques. Hyun Seok [3] compared two groups of subjects with subacute stroke sequelae. The experimental group received restrictive therapy combined with visual biofeedback. The latter consisted of a device that projected different games on the screen connected to a dynamometer and a pinch meter, without using EMG. The control group only received visual biofeedback therapy. No significant differences were found between both groups regarding all the variables evaluated: Purdue Pegboard test, JAMAR test of grip strength, Wolf Motor Function Test, Fugl-Meyer Assessment for upper extremity, motricity index, and Korean version of the modified Barthel index. To date, there are no studies that combine electromyographic biofeedback therapy with EPS in subjects who have subacute stroke sequelae.

Biofeedback

In this technique, biological signals are presented to the user through a visual stimulus. The use of visual biofeedback is recommended to improve upper limb functions and motor performance in CVA patients with sequelae[5, 6, 7], although the biofeedback dosage is a parameter that has not been studied yet[8]. In a meta-analysis, Moreland and Thomson found a small increase in the upper limb functionality using biofeedback when compared to conventional therapy[8].

For this study, the EMGOne device was used, a Chilean device based on low-cost electromyographic biofeedback (BF-EMG) that detects muscle activity, amplifies it, and displays it as feedback in a video game viewed on a tablet. This improves proprioception[9] and motivation [7], enhances motor learning, attention[5] and both the upper[1, 3, 8] and lower[10, 11, 12] limbs, with better results in less time[13, 14, 15], though it is possible to detect compensatory movement strategies[17].

Functional electrical stimulation (FES): It is a muscle stimulation technique that uses electrical current applied by a system of external electrodes, which induces an immediate muscular contraction of the skeletal muscles to generate functional movements[18]. It increases the post CVA active movement and has better evidence in the subacute stage[19, 20, 21]. It reduces spasticity and improves activation, range, and function in a hemiparetic wrist[22]. However, there is a need for further research to reach conclusive results[23]. TrainFes was used in this study, an EPS device created by the Chilean company TrainFes®, which provides different treatment modalities. In this study, a positional recording of the healthy limb will be carried out. Upon detecting the wrist extension movement, the healthy limb will trigger the same movement in the paretic limb through direct stimulation of the involved muscles. The waveform is square

symmetric biphasic, compensated, and with current control. Intensity ranges from 0-130mA, with 1mA steps, a frequency: 1-60Hz, and a pulse width: 20-400uS per phase. All these specifications guarantee the safety of the tissues with compensated waves, which means that the sum of applied charges (Q) is 0, so it must have two polarities, and the sum of the positive phase charges and the ones of the negative phase must be equal so that they are canceled. This allows that there is no net accumulation of charge in the tissues. Without this, the accumulated net charge would generate chemical effects on the tissues. Moreover, TrainFES® standards are international and comply with ISO13485 and IEC606001.

Functional electrostimulation is widely applied with substantial evidence, although we believe it could be complemented with other types of therapies. It is important to conduct this research, since, currently, there are no studies that combine conventional therapy, functional electrical stimulation, and electromyographic biofeedback in subjects with CVA sequelae. In addition to this and to the upper limb function impact on the subjects' quality of life, there is an interest in determining the effect of a training protocol based on conventional therapy, functional electrical stimulation (FES) with bi-manual activation and biofeedback therapy in upper limb function.

HYPOTHESIS

The association of the training protocol with conventional therapy, functional electrical stimulation, and electromyographic biofeedback produces favorable results in the activation and opening function of the paretic hand in subjects with subacute CVA sequelae.

OBJECTIVE

To demonstrate the efficacy of an intervention protocol of conventional therapy, functional electrostimulation, and biofeedback in subjects with subacute CVA sequelae in the paretic upper-limb function.

METHODOLOGY

Design

The procedures of this quantitative and longitudinal research of the randomized controlled trial-type followed the Declaration of Helsinki (1975) ethical standards, in their 2008 update. This study and its informed consent were approved by the ethics committee of the northern metropolitan health service and of Clínica Dávila, where the research was conducted.

Sample

According to studies that used biofeedback and functional electrical stimulation, a minimum of 30 subjects are needed[2][3]. Considering that it is a pilot study, 15 subjects were studied between March and October 2019.

Inclusion criteria: Cooperating subjects age between 40 and 85 years old with ischemic supratentorial subacute CVA sequelae, between seven days and six months of evolution, with sequelae of upper limb hemiparesis, with activation in the manual muscle test for all muscle groups of the hand, with 0 and 1+ on the modified Ashworth scale and that they maintain a seated position. The exclusion criteria were: Visual alterations, undamaged upper limb sensorimotor, previous CVA, musculoskeletal alterations, surgeries, or functional impotence due to VAS 8/10 pain that prevents the paretic hand movement.

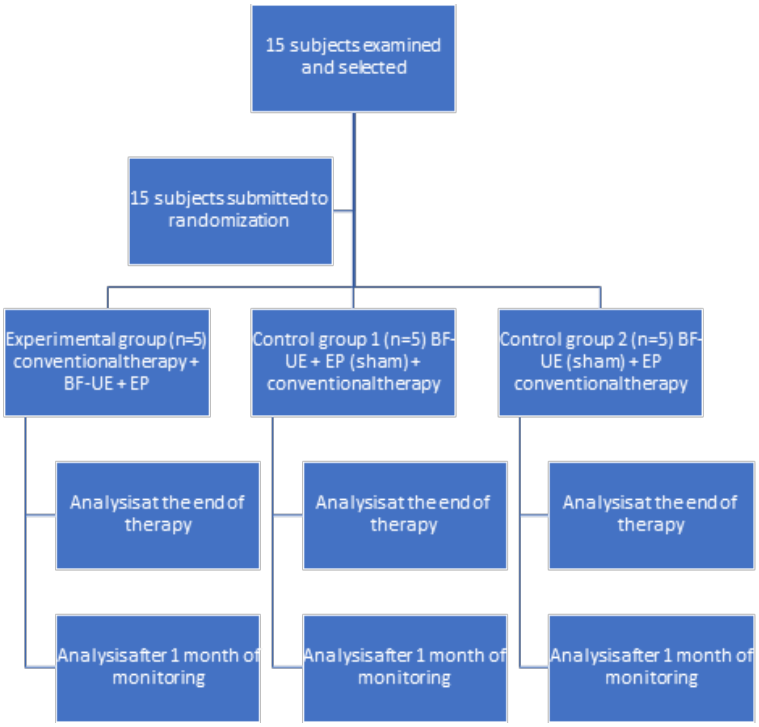
Randomization

Randomization was made using a pool, sorted into three groups: Experimental, Control 1 and Control 2. Five subjects were assigned to each group. (Figure 1)

Blinding

This is a double-blind study. The examiner was blinded at the beginning, at the end of the second week, and in the fourth week. After one month of monitoring, he was blinded for the following measurements of the most affected upper limb: manual muscle testing (MMT) together with the Ashworth scale modified for the wrist flexor extensors, and the upper extremity Fugl-Meyer scale[25] (FMA-UE). Subjects were also blinded. Data analysis was also performed by a blinded statistician at the end of the thera-

Figure 1. Flow diagram of the study



py and at the end of the monitoring. Only the therapist, who applied the therapy, was not blinded.

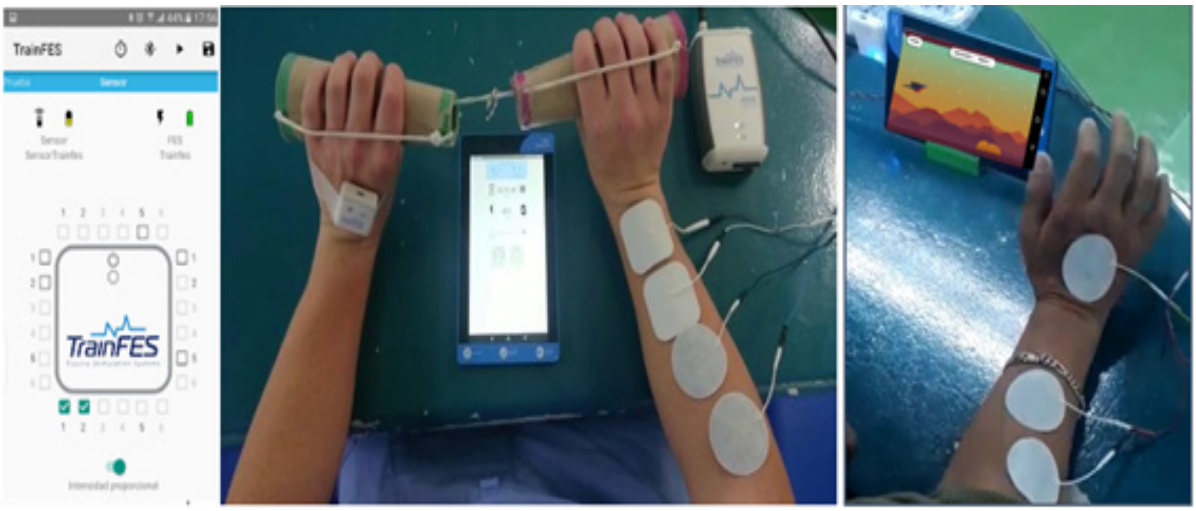
Intervention

It had a four-week duration, three times a week. Each subject was seated in front of a table in a chair with backrest. Their arms were flexed at fifteen degrees at the shoulders, at ninety degrees at the elbows, and zero degrees at the wrists. In each session, the experimental group first did a 30-minute conventional therapy training, which consisted of 75% of the neuromuscular activation time and two exercises per muscle group; the first one without resistance, the second one with moderate resistance. Fifty repetitions were done per exercise. The trained muscle groups were flexion and extension of the wrist and fingers and pronosupination. The remaining 20% of the therapy consisted of maintained 20 seconds flexion for each muscular group: flexors, extensors, pronators, and supinators. In the final 5% of the therapy practice, protopathic and epicritic sensory stimulation was conducted in the forearm, wrist, and fingers with four elements: a brush, a ball with plastic spikes, a sponge, and a vibrator, each one with 20 repetitions.

Then, they had a fifteen-minute bi-manual activation training with electrostimulation, where each subject did twenty repetitions of bi-manual extension within one minute, holding two cones with a ring in the middle which they had to keep in that position throughout the extensor movement, with one-minute breaks in resting position without activation. Finally, they went through a 10-minute EMGOne biofeedback training program, which consisted of overcoming obstacles located at the bottom of the tablet screen, at a speed of 0.5 in the application, with a normal gravity of 1.0x in the settings, with obstacles that appeared every five seconds, and with a size of 50 cm.

Regarding the control groups, control group 1 trained under the same conditions. However, the electrostimulation was a placebo with suboptimal intensity, while control group 2 also received the same treatment as the experimental group but with the administration of placebo electromyographic biofeedback with a previous submaximal calibration. (Figure 2).

Figure 2. Therapy based on the use of functional electrostimulator with electromyographic biofeedback.



RESULTS

Statistics

The Willcoxon test was used to compare the results between the groups and the values before and after treatment for all subjects. The results were expressed as medians with minimum and maximum value. The statistical significance level of $p<0.05$ was considered for the comparison of the variables before and after treatment and between the three study groups. (Table1).

Fugl-Meyer test

In the experimental group, there is a median difference of 13 points. There were no significant changes for this test in the two control groups.
In total, eleven subjects increased their score on the scale; all subjects from the experimental group (100%), four subjects from the control group 2 (80%), and only one from control group 1 (20%). (Figure 3).
There were only two outliers, one for control group 1 and another for control group 2.
Figure 3. Comparison of the changes for the Fugl-Meyer test of the paretic upper limb in the different groups before and after the intervention.

TMM

Regarding the wrist extensors group, there were statistically significant changes only in the experimental group and control group 2. Regarding control group 1, there were no significant changes. This same phenomenon occurred in the wrist flexor groups (Figure 4). There were only two outliers, one in the experimental group and another in control group 1.
Figure 4. Comparison of the changes in the manual muscle test for the wrist extensors in the paretic upper limb in the different groups before and after the intervention

Ashworth

There were no significant changes in tone in any of the muscular groups. All subjects completed the research protocol with Ashworth 0 in all muscle groups.

CONCLUSION

The combination of the three interventions suggests a more significant impact on the hand function in subjects with CVA sequelae.
Nevertheless, there were no changes in sensitivity. Thus, only the changes in the function of the upper limb can be correlated with the changes at the motor level.
It is necessary to incorporate new technological elements in rehabilitation that facilitate its updating and that are affordable and low-cost so that the subjects could train longer, and better treatment protocols could be created, thus enhancing the hand function due to its importance in daily activities.
The non-significant difference of the two con-

Table 1. Analysis of intergroup results

	Exp	min-max	Control 1	min-max	Control 2	min-max
Fugl-Meyer						
Before	32	14-58	64	55-66	60	40-63
After	51	32-66	64	Dec-66	65	51-66
Difference	13	Aug-27		-17	6	-12
P value	*(p=0,04)		(p=0,7)		(p=0,078)	
Sensitivity						
Before	7	10-Dec	9	3-Apr	10	8-Dec
After	10	9-Dec	12	10-Dec	12	11-Dec
Difference	2	0-6	3	2-Jun	2	0-3
P value	(p=0,1)		*(p=0,04)		(p=0,06)	
Range						
Before	15	15-24	24	21-24	24	21-24
After	24	15-24	24	24-24	24	21-24
Difference	7	0-9	0	0-3	0	-6
P-value	(p=0,1)		(p=0,3)		(p=1)	
Pain						
Before	13	Oct-23	19	15-23	19	15-23
After	20	15-24	23	20-24	24	20-24
Difference	3	Jan-13	4	-12	5	0-6
P value	*(p=0,043)		(p=0,138)		*(p=0,066)	
TMM FM						
Before	3	3-May	4	3-May	3	3-Apr
After	4	3-May	5	4-May	5	4-May
Difference	1	0-1	0	0-2	1	1-Feb
P value	*(p=0,046)		(p=0,180)		*(p=0,034)	
TMM EM						
Before	3	3-Apr	4	3-Apr	3	3-Apr
After	4	4-May	5	4-May	5	4-May
Difference	1	0-1	1	0-2	1	1-Feb
P value	*(p=0,046)		(p=0,102)		*(p=0,034)	
Ash FM						
Before	0	0-1	0	0-1	0	0-1
After	0	0-0	0	0-0	0	0-0
Difference	0		0		0	
P value	(p=0,157)		(p=0,317)		(p=0,317)	
<Ash EM						
Before	0	0-1	0	0-1	0	0-1
After	0	0-0	0	0-0	0	0-0
Difference	0		0		0	
P value	(p=0,317)		(p=0,317)		(p=0,317)	

Figure 3. Comparison of the changes for the Fugl-Meyer test of the paretic upper limb in the different groups before and after the intervention.

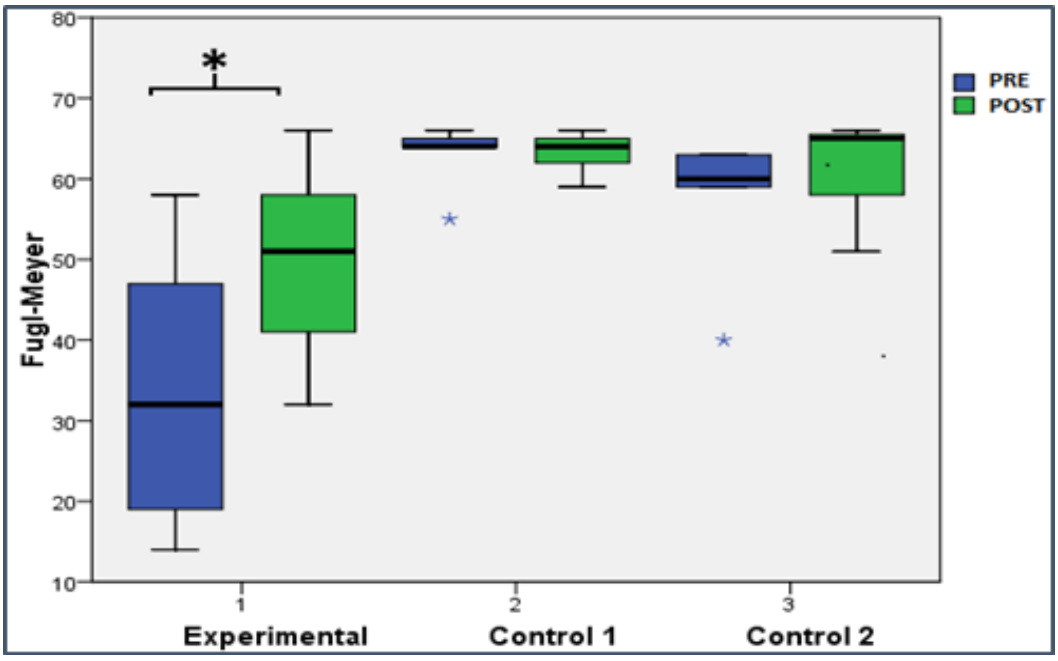
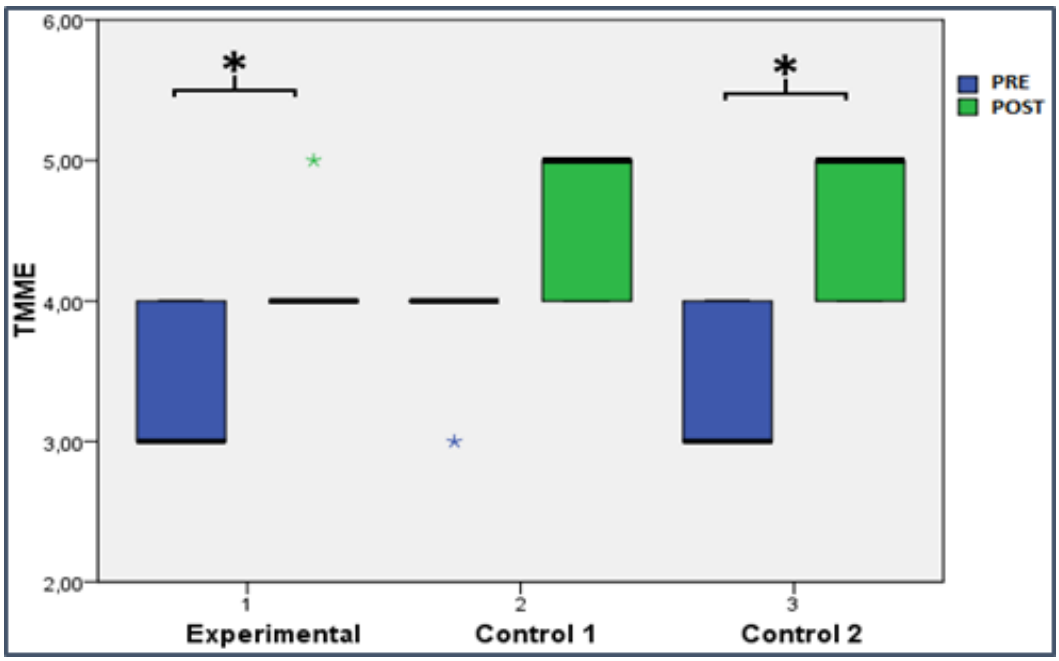


Figure 4. Comparison of the changes in the manual muscle test for the wrist extensors in the paretic upper limb in the different groups before and after the intervention



trol groups is attributed to a ceiling effect due to the median of the initial value for all tests, which was very high. One way to avoid this in future studies is to also use different scales such as the ARAT scale.

The analysis of the data concerning subjects who are currently being monitored is still pending. For this reason, in addition to the small sample size and the lack of greater sample homogeneity, it is only possible to suggest that the combined application of functional electrical stimulation and biofeedback can be an excellent complement to conventional therapy, although more research is needed in this area.

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