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Medication by Physical Exercise of the Upper Limb in Deforming Spastic Paresis (Stroke); Conventional Physiotherapy Versus Supervised Self- rehabilitation: A Multicentre Prospective, Controlled and Randomized, Single-blind Study over a Period of One Year

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ABSTRACT

Background: Some patients who have had a stroke develop paresis. With time it can become spastic and even distorting. Spastic deforming paresis is often accentuated in the upper limb. It is a real brake in the performance of daily activities, with a psychological impact. The physical therapy of the upper limb today, appears like a real sea snake. Hence the strategies of physical medication must be thought out, studied and developed on a daily basis to overcome this unsightly condition.

Objective: Is conventional physiotherapy more effective than supervised self-rehabilitation, in terms of functional recovery in deforming spastic paresis after stroke of the upper limb? This was the major question / objective of this study.

Methods: Our study was a multicenter, prospective, interventional, controlled, and randomized, single-blind study. Comparing conventional physiotherapy versus supervised self-rehabilitation over a 12-month period. We recruited 37 patients in France and Spain more than 6 months after their stroke. The judgment tool used during all phases (1st day; 6 months; 9 months and 12 months) of the assessment was the modified Frenchay scale (MFS).

Results: The mean age of our cohort was 69 ± 7 years and the mean mounts after stroke was 11,9 ± 5 months. Supervised self-rehabilitation was significantly superior to conventional physiotherapy during the three evaluations carried out on the modified Frenchay scales. At 6 months: 5.99 ± 4.7 Vs 6.97 ± 2.1 (P <0.5). At 9 months: 6.71 ± 9.4; against 7.83 ± 4.1 (P <0.5). Three months after the follow up, we reassessed the patients to see the residual effect, the retention of acquired knowledge and behavioral adaptation after the protocol: 6.57 ± 11, Vs 7.9 ± 6 (P= 0,14).

Conclusion: Supervised self-rehabilitation is more effective than conventional physiotherapy. Because from 6 months, and 9 months, a statistically significant difference is demonstrated. this difference persists even 3 months after stopping the follow-up. For the techniques used in the supervised self-rehabilitation group: learning a motor skill could strengthen the circuits of spinal interneurons that facilitate movement. We realized that learning a simple and reciprocating movement, associated with activo-dynamic stretching, done several times a day on target muscles (antagonists were more significant than traditional physiotherapy which, it was rather holistic and nonspecific) would produce an influence in the spinal cord. And, over time, would promote reciprocal inhibition between antagonist and agonist muscles. All the same, further studies with a larger cohort must be carried out in order to conclude on this mentioned neurophysiological hypothesis.

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Keywords: Stroke, Deforming Spastic Paresis, Upper Limb Rehabilitation, Supervised Self-Rehabilitation, Activo-Dynamic Stretching, Reciprocating Movement Of Maximum Amplitude.

Introduction

One of the major consequences after a stroke is Spastic Deforming Paresis (SDP), because more than 76% of patients who have had a stroke end up at one time or another by developing paresis [1,2]. One of the physical and even psychological problems of these patients who have had a stroke is the body deformity [3]. These patients are more comfortable with having reduced motor skills and functionality than having a deformed body [3]. They do not consult because of the spasticity, but they come to complain of stiffness, deformities, functional limitations, discomfort, or pain [3]. Spasticity can be helpful in compensating for loss of motor force while walking, running or posture, but can also become harmful with loss of function and contractures [4]. The SDP is therefore one of the frequent consequences of stroke [5,6]. It is increased by the phenomenon of under / underuse [7]. Pathological spasticity is a motor disorder characterized by a speed-dependent increase in the tonic stretch reflex, and by an increase in osteotendinous reflexes, resulting from hyperexcitability of the stretch reflex in the context of pyramidal syndrome [3,8]. It is clinically defined by agonist paresis and antagonist hyperactivity [3,9,10]. The main goal of stroke rehabilitation is to restore patients' independence in their activities of daily living. However, while it is true that stroke leaves a context of paresis-type motor vulnerability, it is also true that underuse worsens this condition. And, initiates another underlying local pathology, spastic myopathy [3,5,6]. It sometimes appears from the first days post-stroke at the central level: neuronal degeneration by a reorganization of the afferent fibers (poorly adaptive plasticity) and increases the primary motor deficiency and on the periphery; by atrophy and micro structural degradation of the biomechanical component of muscle tissue [3,8]. The SDP is reversible from the moment you start to actively use the injured side [3,11,12]. Treatments with exercise or physical therapy are more effective than pharmacological treatments when it comes to motor recovery, maintenance or adaptations of the functional capacities of people in general, and brain injuries in particular [3,7]. This study aims to compare two techniques / strategies of physical treatments (conventional physiotherapy versus supervised self-rehabilitation) for the functional recovery of the upper limb (MS) of patients who have developed SDP after their stroke. And, the clinical measurement tool employed is the modified Frenchay scale (MFS) [13,14].

Materials and Methods

Design: This was a clinical, multicenter, prospective, single-blind, controlled, randomized and comparative study, aimed at evaluating which strategy was most effective in Upper Limb (UL) recovery. The study ran from October 2019 to January 2021 (duration 14 months). This took place in two countries; France (Paris) and Spain (Madrid), out of 37 patients definitively retained, (see figure 1).

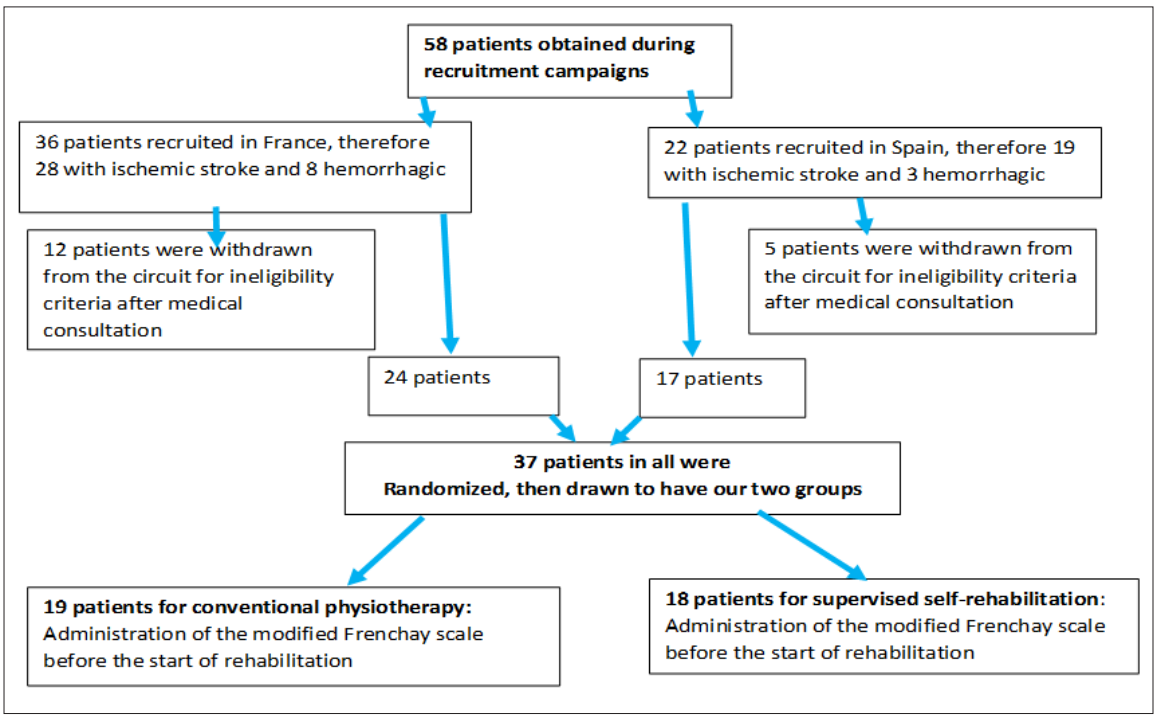

Figure 1: design of the study; period of recruitment, selection, randomization in the two countries

Our protocol was interventional: conventional physiotherapy versus supervised self-rehabilitation.

Conventional physiotherapy techniques were left to the choice of therapists, they had their traditional large panels that they are used to offer to stroke patients. Among others, the mixed techniques of (Bobath, Kabath, Perfetti) and other techniques like cardiovascular, ergo-cyclometry, stretching, walking rehabilitation and reinforcements. The doctors encaged in this study had made a letter to each physiotherapist asking him to focus more on upper limb rehabilitation. This was in order to match the odds in each group. The sessions were 3 to 4 times a week (for rehabilitation time, we noted in our protocol the time provided by Social Security for stroke, 45 min to 1 h per session), as recommended by the Social Security of the two countries. And, we make sure to just encourage the patients of both groups and reassure ourselves if they were actually in their traditional physiotherapy care or were doing their supervised self- rehabilitation sessions. The city physiotherapists of the two caged countries were not aware of our study, because we wanted to reduce the

skew as much as possible. For the intervention group, supervised self-rehabilitation techniques Which were prescribed to patients, were specific techniques targeting antagonistic muscles [15]. After evaluation, we precised and selected the muscles to be treated: the antagonists. This intervention group received a supervised self-rehabilitation program. Two techniques were taught: alternative movements 3 to 6 times a day and activo-dynamic stretching whenever the subject was free. The number of times the subject was required to do every day 4 stretches of 2 to 8 min per stretching session, per muscle. Stretching should be gentle, but progressive to the point of causing pain on a visual analogy scale (VAS), between 3 and 5/10 during extreme periods of stretching. In order to give the soft, deep tissue a chance to experience spinal excitation on the Gamma reflex loop. An Activo-dynamic stretch means maintaining the stretch for at least 30 seconds. By keeping an increase in the area of the stretched muscle when still possible. The combination of the two techniques (stretching and eccentric movement of maximum amplitude) had to be a minimum of two hours per day. This was the minimum requested in the verbal contract made with this group. The therapist would meet with the patient just once every two weeks and make sure the patient completed his exercise log between physical visits. We made two phone calls every 15 days to patients in this group, against one call per week and 3 to 4 meetings per week for conventional physiotherapy group. In this supervised self-rehabilitation group, other muscles or joints were prescribed to be treated (depending on the assessment made beforehand during the meetings) by the two techniques after each physical meeting of 15 days. These techniques were taught to patients each time the muscles to be treated were changed.

Inclusion criteria having had a single stroke; stroke more than 6 months ago; be under 80 years old; have an ambulation greater than 0.4 m / sec at a comfortable speed; voluntarily accept the protocol of physiotherapy or self-rehabilitation sessions depending on the group chosen at random; not be caged in another neurological rehabilitation protocol; not have neurocognitive disorders.

Non-inclusion criteria have already had more than one stroke; have a stroke <6 months; be> 75 years old; have a walking speed <0.4 m / sec; have joint comorbidities in the upper limbs; pain> 6/10 on the analogue pain scale with passive flexion of the arm or fingers; suffer from neurocognitive disorders; refuse to engage in the study.

Judgment criteria: The modified Frenchay scale (MFS) [16,17] is the tool that allowed us to measure the active function of the UL [18]. It is a simple scale and close to the active function of the UL in relation to the activities of daily living. The MFS is reliable, reproducible with little inter and extra examiner variations [19]. It has ten tasks that must be performed by the hemiparetic patient (see figure 2). So, four uni-manual tasks and six two-hand tasks. These tasks are rated on a video basis by a clinician on a visual analogy scale (VAS) from 0 to 10 (benchmarks being: 0, no movement; 5, barely accomplished performance; 10, normal performance, accomplished with ease, without difficulty). The clinician videotapes the completion of the ten tasks to facilitate subsequent scoring. To get out of the straightness offered by rating 0; 5 or 10, we used half points between intervals for some movements. We noted 0 (zero) for no movement; 1 for initiated movement ≥ 1 movement component - e.g., tasks 2,3,4 (figure 2): onset of shoulder flexion/abduction; 2 for ≥ 2 movement components initiated - e.g., tasks 2, 3, 4: onset of shoulder flexion, elbow extension and supination; overall, task midway between being achieved and not; 3: ≥ 4 components initiated but incomplete - e.g., tasks 2, 3,4: onset of shoulder flexion, elbow extension, elbow supine and hand opening; overall, task closer to being achieved than not to 3.5: ≥ 3 movement components incomplete - e.g., tasks 2, 3, 4: elbow extension, supination and hand opening; 4: ≥ 2 movement components incomplete - e.g., tasks 2, 3, 4: supination and hand opening 4.5: 1 movement component incomplete e.g., tasks 2, 3, 4: hand opening; 5: Task barely accomplished; 6: Sense of difficulty but "security": task could not be missed, secured but with difficulty, slowly; 7: Sense of smoothness: task accomplished with some smoothness but still slow; 8: Sense of speed: task completed fastly, while still clearly different from normal; 9: Almost normal; 10: Normal performance, M. Baude et al [19].

For the data analysis of the work of this study, we used two main software (Excel and Rstudio). For significant data, we will retain for all parts of our results when it is necessary from the statistical data, <0.5 as significant data.

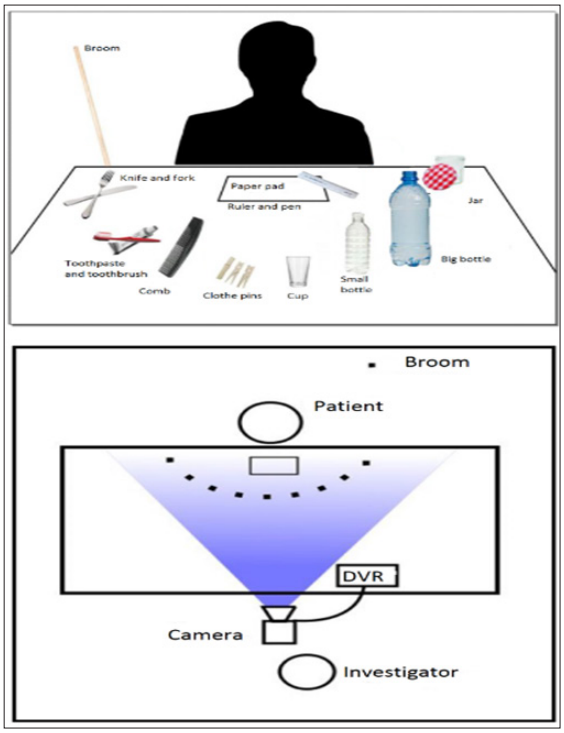

Figure 2: Description of the ten tasks and summarize instructions given to patients before the start of the assessment (pink: one-manual tasks and blue: two-handed tasks) performed according to the modified Frenchay scale : 1) : Open and close jam jar with two hands ; 2) : draw line one paper using ruler, with two hands; 3): Big bottle, with affected hand (pick up and release); 4): small bottle, with affected hand (pick up and release); 5): glass, with affected hand (pick up and bring to mouth); 6): clip clothes pins on paper pad, with two hands; 7): comb, with affected hand (pick up and mimic combing); 8): put toothpaste onto toothbrush, with two hands; 9): knife and fork, with two hands (pick up and mimic cutting on paper pad); 10): broom with two hands (sweep the floor).

Results

At the start of this study, we recruited 37 patients after eliminating profiles that did not meet our baseline criteria. So, 31 male and 6 female, or 83.78% of men and 16.21% of women recruited in this study. Thus representing 28 ischemic and 9 haemorrhagic strokes; (75.67% of ischemic stroke versus 24% of haemorrhagic stroke). The mean age of our cohort was 69 ± 7 years (with an end

between 56 years for the youngest and 80 years for the senior of this cohort) and the mean time after stroke was 11.9 ± 5 months (with an end between 7 months for the most recent stroke, against 2 years 3 months for the oldest stroke).

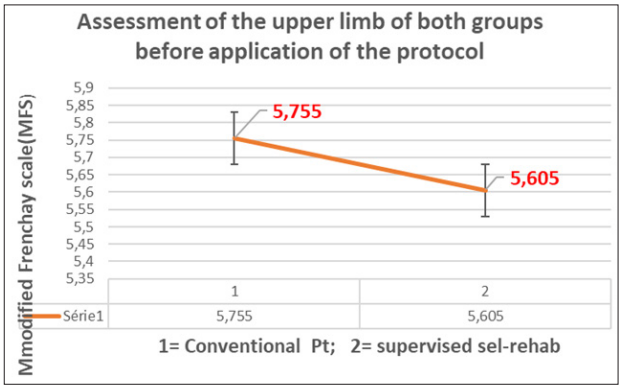

Figure 3: assessment before beginning of the training for both groups

This graph shows all the data collected from our population immediately after randomization and before the start of planned physical treatments. For the conventional physiotherapy group, we noted in the 10 tasks of the modified Frenchay scale: 5.75 ± 1.32 versus 5.60 ± 1.9 for the supervised self-rehabilitation group.

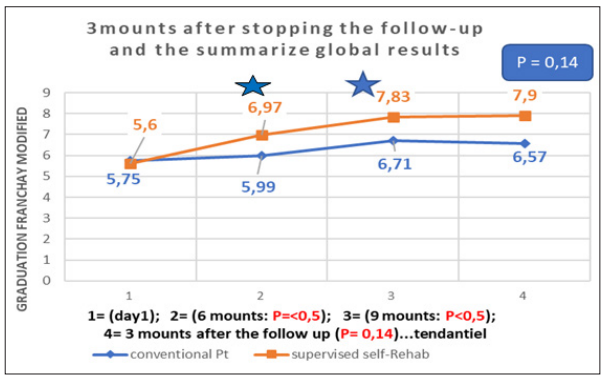

Figure 4: full study results, Day 1; at 06 months; at 9 months, and 03 months after stopping the protocol:

At 6 months; 5.99 ± 4.7 for the traditional physiotherapy group, against 6.97 ± 2.1 for the intervention group (self-rehabilitation, supervised rehabilitation). P = 0.5 *
At 9 months: for traditional physiotherapy, we obtained 6.71 ± 9.4; against 7.83 ± 4.1 for the supervised self-rehabilitation group. P = <0.5 *
On this last graph, we summarize globally all the results of this study, with the last clinical measurement performed in our patients three months after stopping the protocol. We note for the traditional physiotherapy group (within group) 6.71 ± 9.4 at the 9-month evaluation, then a slight decline to 6.57, 3 months after stopping the follow-up protocol. While in the supervised self-rehabilitation group, we have intra-group data, after three months of stopping the protocol 7.9 ± 6, against 7.83 ± 4.1 at the nine-month evaluation, a certain pace seems to be maintained. In intergroups, after the follow-up stop, we have: 6.57 for traditional physiotherapy versus 7.9 for supervised self-rehabilitation.

Discussion

This study was supposed to last 12 months, the conditions of the international health crisis pushed us to lengthen four months, in order to recover certain periods when we were in status quo, at the peak of the first two waves of COVID 19. During the study, we lost three patients in wave 1 of COVID-19. Six patients lost to follow-up (therefore two in the conventional physiotherapy group and four in the supervised self-rehabilitation group). We also lost five patients (3 supervised self-rehabilitation and two from conventional physiotherapy) during the resurgence of the second wave of COVID-19, but this last loss was during our last assessment, the one taken three months after stopping of the protocol. However, three patients in the supervised self-rehabilitation group returned to conventional physiotherapy after the 6-month assessment, which no longer allowed us to include their data in the nine-month assessment.

The first observation made at the first evaluation (D1), the data of the clinical parameters collected seemed homogeneous, but the individuals within group and even extra groups were not homogeneous in each of their data obtained with the MFS. The patients during the tests seemed a little more relieved with the six bimanual tasks than the four manual united tasks, which can obviously be explained by the controlateral hand which can psychologically mimic the movement to be performed by the patient or create a kind of positive reinforcement about the task at hand. The clinical results obtained at six months show the efficiency of the supervised self-rehabilitation group over the conventional physiotherapy group. First, intra-group, since the subjects in the intervention group themselves broke their own records. This can also be explained by the importance of the repetition alternative movement and the stretching done by this supervised self-rehabilitation group, associated with which had also been requested by us, which was perhaps not the case in conventional physiotherapy [22-23]. They may have understood that they themselves had to contribute to their functional restoration. It was also observed in both groups, that people did not all evolve in the same way. Since some were evolving from a distance although others, especially the young, and those whose brain damage was not massive. And, again, the subjects with the bleeding stroke progressed less than the ischemic strokes. Subjects in poor recruiting condition did not perform as well as those who were less poor in recruiting, a similar situation had also been observed by Kwakkel et Taub [12,24].

For the traditional physiotherapy group, at 9 months we observe a change progressive and positive (although not enough to compete with the supervised self-rehabilitation group, see figure 6 & 7). We note all the same that traditional physiotherapy is important and far better than the absence of rehabilitation. However, in this conventional physiotherapy group, several things were observed during phone calls to motivate them to go to physiotherapy (so that the motivations were matched to limit possible bias). As a result, the patients were not satisfied with their rehabilitation time and their care, as 9 of them complained to us, which makes almost the more than 30% of people in this group. Those who complained were not only the youngest, but the most motivated of this group.

The last clinical data received 3 months after stopping the protocol, was not only the maintenance of prior learning in both, but also a higher positive increase in the supervised self-rehabilitation group than in the conventional physiotherapy group. This could perhaps be explained by a transformation of the daily (positive) self-training habits acquired, this time which could be actively manifested without supervision after stopping the follow-up protocol [15].

We observed during this study that people were prone to functionally recover even 1 year after their stroke. Since, we have observed (data from the Frenchay scale) the personal self-

progressions of some of our patients who were more than two years away from their strokes. Which effectively shows that behavioral plasticity is lifelong [7, 3, 23]. And, that we must also count on the motivation and monitoring to have a good result [25, 26].

We believe that one of the major problems of conventional physiotherapy lies in the time spent on rehabilitation activities granted to patients. The actual working time granted by city physiotherapists to patients is very poor. According to a recent study done by Maude Pradine, Jean-Michel Gracies and al, this time was 12 minutes per day [27, 15]. Which cannot bring about such significant changes after the period of plasticity induced by the lesion itself [3, 7]. Other problems are the plurality of passive movements performed by physical therapists in town, and the lack of intensity, repetition and difficulty during physiotherapy sessions. And, the fact of taking at the same time, sometimes 3 to 6 patients to be controlled during the time of rehabilitation. Thus, reducing the chances of having sharp control over the activities and motor performance of each patient.

Stroke takes sufficient time for motor recovery in general and spastic deforming paresis in particular. Hence clinicians should think about training and informing the patient in self-rehabilitation in order to achieve maximum recovery and restoration of bodily deformities which most often pose a major problem of aesthetics, function, social exclusion and disability [15].

At the level of physiological mechanisms, training in rapid alternative efforts of maximum amplitude without unassistance reduce co-contraction around a joint by restoring reciprocal inhibition. The difficulty, the speed of contraction are exciting and creative elements of cortical maps and also increase the excitement of the synaptic connection forces [28,29,3,7]. At the level of biochemical mechanisms, spontaneous movements also create flow at the extracellular level (glucose, amino acids, neuroactive (ASP, taurine), etc.). Underuse, on the contrary, lowers extracellular glucose levels and even the quality of oxygen and circulatory flow leading to neuronal death [3,7]. Training in rapid alternative efforts of maximum amplitude and prolonged chronic "aggressive" stretching at home are physical therapies that induce brain plasticity. These rapid reciprocating movements should be of maximum amplitude for those who can create movement. Because, this induces an eccentric stretching of the antagonist which is added to the active effort in the fight against co-contraction, active unassisted movements and repeated at maximum speed so that the stress imposed on the CNS is maximum [3,7]. This training should be offered in the same way to patients who initially present a movement opposite to that sought (co-contraction of the antagonist greater than the agonist during the execution of a movement) in short series. Because both mental and neuronal exhaustion appears quickly. After a while of training, we will be able to see the movement neutralize and then become positive [3,7].

One of the notions of functional rehabilitation in spastic paresis is that the simple use of a function maintains it, hence the famous concept ("use it or loose it"). In some cases it improves ("use it and improve it") [30]. With this in mind, the intensity and repetition parameters, associated with the duration of training are essential [20,31-33]. For a motor learning program to be effective, the exercises proposed must be close to normal movements, which corresponds to rehabilitation by approaches to functional tasks [34, 28]. Movements must be oriented and targeted on specific tasks [7, 3]. In view of our experiences in neurorehabilitation, corroborated by medical imagery, we now know that the imagination of a movement (related effect: mirror therapy, virtual motor imagination, etc.) is less effective than muscular activation (efferent: execution of the movement in reality, even if it is not possible). This is perhaps again what has shown the inferiority of conventional physiotherapy compared to supervised self- rehabilitation, which instead targeted the antagonistic muscles and did not remain holistic like conventional physiotherapy. It would be better to actually activate the muscle in question, and the attention focused on the task at hand (which was the case with patients in the intervention group). Classen and al., in 1998, insisted on the value of numerous repetitions in making a difference in the recovery of these paretic patients [20]. During our protocol, we insisted on the intensive program, either in terms of the difficulty of the movement worked, or by the number of repetitions performed, associated with a fairly long duration (1 h to 2 h per day, for at least 5 days / week, apart from the meeting sessions that we had with these subjects once every two weeks to take stock and re-write other muscles to stretch and to perform eccentric movements). This may justify the linear results obtained at six months, then at 9 months and subsequently at 12 months after stopping the monitoring of the two groups.

Ethic We followed the ethical protocols for this type of study. The study was registered with ANSM: National Agency for Safety and Medicines and Health Products France, ID-RCB number: 2019-A02495-34_0_2019-09. In addition to this administrative registration, medical consultations were made upstream to reassure us about our criteria in order to be reassured that our patients were complying with our inclusion rules. Also, at any time during the study, each patient was free either to leave the study or to change to return to conventional physiotherapy if the latter so wished. During the entire study, these patients received special attention from the physicians included in this study. One consultation per month was organized to be reassured if there were no other pathologies in the meantime that did not emerge to interfere with the smooth running of our protocol.

Limitations

The major limitations of this study are first of all quantitative. The small number of subjects involved does not allow us to draw a clear conclusion. Then the second limitation is methodological: the study supposed to last 12 months, has been extended by another four months, due to the international health crisis, COVID-19. Since 18% of our recruited cohort could not continue until the end of the study. Some patients have abandoned their initial groups to return to conventional physiotherapy. Another limitation is that we may have become too involved in the intervention group than in the control group. COVID 19 has also prevented some patients in the conventional physiotherapy group from going to their care at their city physiotherapists. This is because of restrictions that were made by states at the time to focus only on the care of COVID-19 patients. Some patients, themselves for fear of contagion, have spent for some two weeks without going to their conventional physiotherapy session.

Conclusion

Training (conventional physiotherapy or supervised self-rehabilitation) is a springboard for functional acquisition associated with an increase in cortical maps for long-term memorization. It is important to understand that if we refrain from (voluntarily) forcing patients to work difficult, active, repetitive tasks. And, prolonged, if we fall into a permanent lucidity of passive work (fun and just occupying), then we also remove the cortical excitability and therefore the efficient results. Rehabilitation should not be

"fun" in general. However, this is what is generally observed in city physiotherapy practices, patients are bored, they are at times abandoned on a bicycle, or on a machine, and the physiotherapist, between two or three patients does not have enough time, to still be serious for hemiparetics who need special attention in rehabilitation. This is also what may justify this slow recovery in the control group (conventional physiotherapy). It has to be difficult and onerous, either by increasing the number of repetitions or by increasing the rehabilitation time, but both would be ideal. It is therefore necessary to ask patients for rapid alternative efforts which sometimes result in movements when the patient has a good level at the start. These rapid reciprocating movements must be of maximum amplitude, on the principle of all or nothing. Because, it induces an eccentric stretching of the antagonist which adds to the active effort in the struggle of the co-contractions.

The supervised self-rehabilitation register must be well maintained by the patient and checked at each appointment by the therapist who can, after an evaluation, change the muscles to be stretched at home. We advise the therapist not to give the patient more than four muscles to stretch at home, instead to insist on a small number of muscles and to increase the rehabilitation time at home and of course also continue the physiotherapy in town. It is possible to evolve well beyond the so-called "plateau" period. The intensive work induces a modification of the cortical maps well beyond 3 years or 10 years after a stroke. Our study is also proof of this: because all the people recruited in this study were mostly more than seven months from their stroke, and some more than two years. Disregarding this, they increased their function in both groups, but still significantly in the intervention group, to the point where a persistent effect was observed, lasting for three months after stopping the protocol.

NB: Authors say they have no internet conflicts in this study

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