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Title:

EFFECT OF DIFFERENT THERAPEUTIC MODALITIES SUPPORTED BY VIRTUAL REALITY OR RESTRICTION-INDUCED MOVEMENT THERAPY COMPARED TO USUAL PHYSICAL AND OCCUPATIONAL THERAPY ON MOTOR RECOVERY OF PARETIC LIMBS IN PATIENTS WITH CEREBRAL VASCULAR EVENT

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ABSTRACT

EFFECT OF DIFFERENT THERAPEUTIC MODALITIES SUPPORTED BY VIRTUAL REALITY OR RESTRICTION-INDUCED MOVEMENT THERAPY COMPARED TO USUAL PHYSICAL AND OCCUPATIONAL THERAPY ON MOTOR RECOVERY OF PARETIC LIMBS IN PATIENTS WITH CEREBRAL VASCULAR EVENT

Introduction. In Mexico and the world, the Cerebral Vascular Event (CVE) o stroke is one of the leading causes of morbidity and mortality. The main repercussion is the neurological disability that it produces in those who do not die, which generates expenses in the health systems due to the need for medical consultations, the use of medications and, usually, prolonged rehabilitation. In survivors, the most frequent neurological sequelae are aphasia and hemiparesis. The motor deficit of the affected hemibody occurs between 40-70% of the subjects and the greatest condition is usually predominantly in the thoracic extremity, of these, only 5 to 20% partially recover the functionality of the hand, their prognosis is poor. poor when there is total paralysis of the thoracic limb or a lack of effective clamp 4 weeks after the event, finding that only 11% of patients with severe weakness in the thoracic limb achieve good recovery in the hand; in the rest there is an impact on independence and activities of daily living. It is important to highlight that standing and walking tends to recover more easily than function of the thoracic limb. In general, around 30-66% present a partial recovery at 6 months after the event.

The lack of movement associated with CVE contributes to a deterioration of the corticospinal tract and with the passage of time there is greater Wallerian degeneration of the affected hemisphere. Several publications support the importance of maintaining the integrity and preservation of the tract by providing timely therapy that favors motor recovery. Rehabilitation programs are aimed at recovering to the greatest possible degree the functionality of the segments of the body; The usual techniques, such as physical and occupational therapy, are widely used throughout the world and have proven their usefulness, which is why, in general, they become the management to be compared when an alternative therapy is found for disabling diseases.

One of these neurorehabilitation techniques is called movement restriction and induction therapy (TRIM), which consists of a standardized and intensive motor intervention, which has shown a substantial increase in the use and motor ability of the affected limb. The therapy consists of the restriction of the mobility of the unaffected upper extremity by means of a sling or some other attachment and then the training of the affected one is carried out with a technique called "Shaping", which focuses on the performance of fractionated functional tasks. with a gradual increase in difficulty. It has been shown to produce functional changes in brain metabolism, blood flow, and electrical excitability, with potential structural remodeling of the sensorimotor cortex, predominantly in anterior motor areas and the hippocampus. The results have shown to be positive in the rehabilitation of post-Cerebral Vascular Event patients, and the skills obtained are maintained over time.

Another relatively recent therapy is the one that is provided with the support of technology based on Virtual Reality. There are multiple publications that propose that it can significantly help brain neuroplasticity, translating greater motor learning at the cortical level, even producing a remodeling of the cortex and, therefore, greater motor recovery compared to other techniques. As a technique, it

uses electronic equipment to reveal to the individual some of the normal or abnormal physiological events, in the form of auditory or visual signals, teaching him to manipulate involuntary events through displayed signals. Several studies show that the movement of the upper and lower limbs together with a specific objective translates into greater motor learning at the cortical level and therefore greater movement recovery. Biofeedback supported by computer systems (Virtual Reality) allows the total immersion of the patient in a "real" environment where he receives sound, visual and tactile sensory information, which produces a multimodal environment. Recent research on motor recovery in paretic limbs with the use of virtual reality shows an encouraging improvement, in addition to showing greater adherence due to the associated playful factor, which allows more treatment time without costs for health systems.

According to some meta-analyses, the multiple existing publications related to these 2 types of therapies have been carried out in small populations, without considering demographic variants, affected brain territory or severity of the condition, among others, which has caused them to be considered inconsistent. and of little cost-benefit utility to be introduced in the rehabilitation units. That is why research on these "new" therapies continues to be carried out, seeking methodological support and consistent results, both clinical and cost.

Research Question.
What is the effect of different therapeutic modalities supported by Virtual Reality or Restriction and Induction of Movement compared with usual Physical and Occupational Therapy on motor recovery of paretic limbs in patients with Cerebrovascular Event?

Secondary questions

1. To determine the relationship between the therapeutic management group and motor evolution with changes in language (aphasy).
2. To measure the level of patient satisfaction with the treatment received.
3. To relate the level of patient satisfaction with adherence to treatment.

Hypothesis.
A therapeutic program supported in virtual reality will increase the motor function of the paretic thoracic extremity of patients with CVE by at least 38.6** average points measured with the Fugl Mayer scale compared with usual physical and occupational therapy.

Aim.
To measure the effect of different therapeutic modalities supported by Virtual Reality or Restriction and Induction of Movement compared with usual Physical and Occupational Therapy on the motor recovery of paretic limbs in patients with a Cerebral Vascular Event.

Material and methods.
Design: controlled, randomized, single-blind clinical trial.
Place: external consultation and therapy service of the XXI Century Physical Medicine and Rehabilitation Unit (UMFRsXXI).
Subjects: adults diagnosed with CVE and hemiparesis, with or without aphasia.
Procedures:

1. Clinical interview and random assignment to the type of therapy (evaluator 1);
2. Assessment of the motor function of the paretic limbs with scales of Motor Index, quality of fine clamp and Fugl Meyer scale (evaluator 2 -blinded-), before, during (after session 6) and at the end of the therapy (after from session 12);
3. Realization of rehabilitation programs for 1 hour, 2 times a week, 12 sessions (6 week total):
a) Virtual reality with the support of Kinect ® and software: "tennis"® and "ski"® for shoulder, arm and hand, the "cover the cracks"® for thoracic member and foot, and "Star Wars- battles in the galaxy" ® for fine clamp of the hand.
b) Movement restriction and induction therapy with a standardized program, but without the healthy arm immobilized.
c) Regular physical and occupational therapy with the same standardized program, with the healthy arm immobilized.
4. Evaluation of the quality of language with the Boston Aphasia Intensity Scale and evaluation of the Satisfaction or Pleasure perceived by the patient when performing the different types of therapy measured with the Intrinsic Motivation Inventory, both applied by the neuropsychologist, who will also be blinded to the treatment received by the patient.

Statistics. According to the distribution of the quantitative variables, the analysis will be carried out using the ANOVA for repeated measures or Kuskal-Wallis test for the comparison between groups and ANOVA 1-factor or Friedman for the intragroup comparison ($p<0.05$).

Infrastructure and group experience: financing was not obtained to acquire virtual reality equipment and additional materials for physical and occupational therapy, so we worked with 2 teams owned by the participants. The occupational therapy materials were those of the Medical Unit where the patient was treated. The participating personnel are experts in the area and contributed to the acquisition of materials and equipment, mainly the doctoral student.

Keywords: aphasy, hemiparesis, modified constraint-induced movement therapy, occupational therapy, physical therapy, satisfaction, stroke, virtual reality.

BACKGROUND

VASCULAR CEREBRAL EVENT

Definition

The term Cerebral Vascular Event is used to designate a brain disease that results from a pathological process in which one or more of the blood vessels that supply the brain are affected[1, 2]. It is characterized by its sudden onset, with symptoms that they can last more than 24 hours, and can cause sequelae or death [3, 4]. The rapid development of signs and symptoms usually correspond to a focal and sometimes global neurological condition, which persist for more than 24 hours or lead to death, without other apparent cause than a vascular origin [5, 6].

The term cerebrovascular disease (CVE) refers to any alteration, temporary or permanent, of one or several areas of the brain as a consequence of a cerebral circulation disorder; while the term stroke or cerebral vascular event (CVE -stroke-) refers to acute cerebrovascular disease, and generically encompasses a group of disorders that include: cerebral ischemia, intracerebral hemorrhage (ICH) and subarachnoid hemorrhage (HS). The most widely used classification of CVE is the one that refers to its nature, dividing it into two groups: ischemic and hemorrhagic. Ischemia occurs as a consequence of the lack of blood supply to the brain, while hemorrhagic is due to extravasation of blood due to the rupture of an intracranial blood vessel [6, 7].

Epidemiological aspects

CVE is among the first 3 causes of mortality worldwide 3 and its incidence is 1.5-4 cases per 1,000 inhabitants, and its prevalence is 8-20 cases per 1,000 inhabitants. This disease implies large monetary expenses. It is estimated that approximately 20% of survivors require special care during the three months following the event and almost 30% are left with permanent severe disability [3, 4]. CVE is the second global cause of death with 9.7% of of which 4.95 million occur in low- and middle-income countries, according to data from the World Health Organization [8]. The average age at which the first stroke occurs in men is 69.8 years, while in women it is 74.8 years [9]. Its 2-year recurrence rate ranges from 10 to 22%, but it can increase up to 80% with the modification of risk factors [10, 11]. If there are no adequate prevention interventions, it is estimated that by the year 2030 its incidence will increase up to 44% [12-14].

In Mexico, it has been published that so far this century CVE is among the first 8 causes of death and, specifically, in Mexico City, it is among the first 5; being the sixth cause of death in men and the fourth in women. In the period from March to April 2008, the epidemiology of CVE was reported in some hospitals in the Federal District, and the prevalence was 11.15% [3]. It has been considered that of the subjects who suffer an acute event, between 15 and 30 % die within thirty days [15].

Data from the Mexican Ministry of Health show that the CVD mortality rate has increased since the year 2000, particularly in those under 65 years of age [13, 14]. During 2007, 1% of all discharges from public hospitals were attributed to to CVD, while in 2008, the mortality rate was 28.3/100,000 inhabitants [3, 12, 13].

CVE, along with heart disease and diabetes, cause losses of billions of Wristars in annual income in most countries in the world, causing a 0.5% decrease in annual economic growth [8]; In addition, it is the cause of frequent falls, with the clinical and economic implications that this entails [16]. This condition represents the first cause of disability worldwide in the adult population and the second cause of dementia [17-19].

Clinical manifestations

Because the central nervous system has a somatotopic distribution, ischemia in the MCA territory will affect the contralateral side for motor activity and the ipsilateral side for sensory activity. After a CVE, the presentation of neurological impairment depends on the location and size of the lesion. The territory most frequently affected is that of the left middle cerebral artery (LMCA) and the most common motor deficit is hemiplegia or hemiparesis, with or without aphasia, affecting the extremities and muscles of the lower contralateral hemiface [2]. The loss of voluntary movement can be accompanied by alterations in sensation throughout the length of one of the sides of the body, although there can be variations in the clinical presentation related to perilesional disorders [20]. When the acute phase is over, almost always the limb The lower one has a greater tendency to recover than the upper one. At 3 months, a large percentage of hemiplegics already begins to walk, while the upper limb is more difficult to recover and, of these, approximately 40-45% experience major hand problems. In the condition of the upper extremity, 44% of patients recover motor activity and 40% present minimal or no recovery. The sensory pathways play an important role in motor control, since severe sensory alterations produce disability similar to paresis and a poor recovery of motor function, worsening the functional prognosis [21].

After a stroke, people who survive have a high risk of developing a wide range of secondary conditions such as pain, depression, pressure ulcers and falls, among others, during the acute or post-acute recovery period; there may also be balance disorders and functional dependence, which is why basic daily life activities oriented towards caring for one's own body are compromised, such as dressing, eating, etc., which causes incapacity for work and limitations in quality of life [16].

NEURO-REHABILITATION

Rehabilitation techniques aimed at improving hemiparesis vary their objectives, depending on the evaluations and the therapeutic approach, since a way is sought to explore the patient's capacities that can improve their autonomy. Neuromuscular rehabilitation is based on teaching-learning techniques such as performing and reproducing movements [22].

The techniques called conventional can vary in programs and exercises, but in general they consider 3 essential aspects: 1. They provide a progressive management respecting the levels in which the motor patterns were acquired, with this they integrate the previous neurosensory-motor schemes, considering a strategy proper posture. 2. Motor stimulation through various sensory and sensitive information: vestibular, kinesthetic and visual for support activities; of postural strategy and locomotion in a proximal distal progression; and tactile and visual for fine and differentiated voluntary movements

in a disto-proximal progression. 3. Inhibition of pathological motor reactions and facilitation of motor skills altered by tonic and synkinetic disorders [22].

For example, Bóbath and Brunnstrom proposed that the lack of inhibition of a damaged postural reflex mechanism caused increased muscle tone and allowed primary reflex activity to emerge; observed that if the position and posture of the proximal joints of the body were modified then muscle tone could be influenced, these stimuli helped to initiate the movement that the patient was unable to produce voluntarily and then try to control the volition of the joints synergies obtained by mixing the different movement patterns and causing changes in the patient's motor responses helped the hemiplegic side to avoid forgetting it, restore asymmetry and integrate it into functional movements [23]. Kabath, Knott and Voss proposed the facilitation technique proprioceptive neuromuscular on the hypothesis that all voluntary effort is the response to a stimulation of the central nervous system from some sensitive receptors; Proprioceptive neuromuscular facilitation proposes improving awareness of movement by provoking a motor response through proprioceptive stimulation, such as skin pressure, joint traction and mobilization, rapid stretching, strengthening weak movements through synergistic movements, and the use of verbal guidelines [21, 23].

Neurorehabilitation, then, is an attempt to manipulate the plasticity of the central nervous system in order to recover its functionality. Functional magnetic resonance imaging, among other studies, has made it possible to observe the neuroplastic changes that occur in association with rehabilitation therapies, as well as the continuous remodeling of neural connections and cortical maps. The only prerequisite is that the patient's brain has the potential capacity to compensate for the injuries [24].

The recovery of a function after brain injury is based on two mechanisms: the compensatory process and the restitution process (both occur simultaneously in some cases). The compensatory process is functional reorganization or adaptation and is achieved by structuring the surviving neural circuits in a different way, allowing them to handle themselves in different ways and connections with other areas; therapy or training leads to redistribution of tasks to undamaged areas and reorganization of the cerebral cortex. In the neurophysiological process of restitution, which depends on brain plasticity, plastic reorganization occurs, first, from an alteration in synaptic sensitivity related to an unmasking of existing connections through changes in inhibitory dynamics, which occurs in seconds or minutes, in contrast to structural changes that can take days or weeks. And second, due to the reduction in the level of activity in the area of the lesion, the synaptic connections between the healthy and damaged site are weakened, which depresses the function in the undamaged structures, so that the stimulation and manipulation of the processes inhibitory become a stimulus for recovery [25].

Modified Constraint-Induced Movement Therapy

In conventional therapies, the healthy side is stimulated to replace the functions of the affected one, this was called "learning not to use" the paretic upper extremity. In contrast, Taub et al., demonstrated that if the movement of the healthy limb is restricted and the affected limb is trained, motor control is favored by means of the technique called "Shaping" and which consisted of the restriction of the mobility of the upper extremity not affected by putting a sling for a time that corresponded to 90% that the patient remained awake for a period of 12 days, and training the affected upper extremity for about seven hours a day, during the same days; this involved intense training but produced large changes in

cortical reorganization and was correlated with improvement in motor function [26-30]. A similar result was also observed in a group of patients with subacute or chronic CVD who received a non-intensive form of Movement Restriction Therapy (MRT), noting an increase in the activation of the injured hemisphere by magnetic resonance imaging after therapy and that persisted for at least 4 months after treatment [26, 28].

The current neurorehabilitation proposal to promote the function of the upper extremity of the person with hemiplegia must start from motor learning approaches, through training strategies in specific tasks and performing specific functions with practice and constant repetition, the basic principle of this intervention modality seeks to work directly on the underlying modification of neural mechanisms. Therefore, it is necessary to describe the main applications of the healthy side restriction therapy for the improvement of spastic hand function in adults with hemiplegia. CIMT has repeatedly been associated with brain plastic changes (both functional and structural), demonstrating that with the use of the paretic limb, activation of the somatosensory cortex ($p=<0.03$) and other structures related to ipsilesional or contralesional brain motor outputs increases, along with an induction of middle cerebral artery blood flow. In addition, it is capable of producing changes in the organization of brain functions, through neuroplastic processes. In this sense, mention is made of neuroplasticity, conceptualizing it as the anatomo-functional adjustments that are made in order to return to functional recovery using other sectors that have not had a previously established function or that have remained silent. These changes occur days after a brain injury, modulated in turn by various strategies or therapies. Although it is agreed that a higher level of evidence is still lacking in the studies [25-27].

Biofeedback and virtual reality.

Virtual reality is defined as the approach between the user and the computer, involving a simulated environment in real time, scenario or activity that allows the user a pathway of interaction through multiple sensory channels [31]. Virtual reality technology and its applications have expanded rapidly into many disciplines. The virtual environment that it uses can be enriched with complex and multimodal sensitive information for the user and can create a substantial sensation of reality [32].

Biofeedback is the technique that uses electronic equipment to reveal to the individual some of the normal or abnormal physiological events, in the form of auditory or visual signals, teaching him to manipulate involuntary events through displayed signals. The term feedback was coined to designate a method of controlling the system aimed at restoring the results of its past function, but later the term was given a physiological context, referring to any technique that uses instruments that attempt to give an individual continuous signals and immediate changes in a bodily function of which one is usually unaware [31], such as electromyographic biofeedback, which showed greater motor activity compared to physical therapy in hemiplegic patients due to CVE [33].

Biofeedback aims, mainly, to get a person to notice their own physiological state and can develop it by themselves or in a pathological situation, to modify it; Its objectives are the re-education of the motor order, of cognitive disorders and the fight against spasticity, but in order to take advantage of it the patient must have a minimum of understanding and motivation [34].

In their first works, Taub et al., mentioned that the literature suggested that these therapies have a neutral, negative or variable effect on motor learning through mechanical tasks; however, they maintained that rehabilitation procedures that engage the mind in the recovery process could promote cortical reorganization [35]. The specific task in training must be repetitive in patients with CVE to favor the neuroplasticity process, both in the brain injured as well as healthy, although it is currently considered that there is no specific program for the recovery of motor disability. It has been found that a rehabilitation program with virtual reality simulating activities of daily living compared to a conventional Occupational Therapy program applied to patients with CVE sequelae showed similar results in general motor recovery [34]. Various results suggest that virtual reality is a complementary tool for existing programs that favors adherence to treatment by the patient due to the playful aspect. Therefore, it is urged to continue exploring the effects of the use of technology in the rehabilitation of neurological patients [34, 36].

A challenge in neuromotor rehabilitation is to design effective methods to provide repetitive and specific therapy, the processes must be multimodal to facilitate recovery of function, they must involve cognitive functions, as well as being attractive (to maintain the patient's attention) and easy to understand. Biofeedback supported by computer systems allows compliance with these characteristics, achieving total immersion of the patient in a virtual environment of computerized graphics where he receives sound, visual and tactile sensory information, which produces a multimodal environment. Saposnik et al., conducted a randomized clinical study, in which they compared motor recovery of the upper extremity, in patients with CVE, using the Nintendo-Wii® video game console in the case group and occupational therapy activities in the control group; obtaining encouraging results in VR group, such as a similar recovery achieved in less time (which is reflected in a decrease of up to 7 seconds in the speed of movement execution) [36, 37].

The inclusion of technology in rehabilitation not only allows innovative treatments, but also causes the patient to be motivated to meet the objectives set, favoring adherence to treatment [34, 36, 38]. It has been observed that currently, there is a greater acceptance for the use of personalized gaming technologies used to support the rehabilitation of CVE survivors with moderate-severe disability, as a high level of pleasure or enjoyment was detected (qualified with scores between 6.8 - 8.1 of 10 -Likert-type scale -) and moderate perception of effort (scores between 11.6 - 12.9 of 20 -BORG scale-) when working with virtual reality computer systems during rehabilitation. Noting an improvement in the limitations due to the EVC and an increase in the spontaneous performance of activities at home when compared with the initial state of the patient ($p < 0.05$) [3]8.

Virtual reality collaborates in an important way with neuroplasticity, especially at the level of the cerebral cortex. Numerous studies mention that the benefit in the recovery of the paretic limb is due to greater activation of cortical maps, better attachment and more motivation [34], even in the presence of pathological synergies, which are very difficult to correct with traditional rehabilitation [38]. In Mexico there is a virtual reality program that has been used in some research, called the Gesture Therapy System, and although this treatment has shown good results for many patients, it is only useful for the upper limb and includes the stimulation of practically the entire movement of the limb [39, 40], which would make it difficult to quantify the handling of the segments, including the hand and fine forceps. However, it is a fact that virtual reality supported by video game equipment has increased its application in physical rehabilitation, especially commercial consoles, which have been implemented

in some medical units [37], so it is considered relevant to carry out more research in this area. environment, but using accessible software [34,37, 38] that stimulates adherence on the part of the patient.

Nevertheless, a meta-analysis (analysis of 40 reviews -19 Cochrane and 21 non-Cochrane-) mentions a moderate improvement with some techniques, including virtual reality; a "relative effectiveness" is described in relation to a small number of participants, as well as errors in the methodology (demographic variants, affected brain territory or severity of the condition, among others), inconsistency of results and little cost-benefit utility, suggesting the need to continue conducting studies [41]. Another Cochrane review that included 37 trials and 1019 patients concluded that the evidence was low or very low, relating it to failures in the design of the interventions, the risk of bias could not be established because the studies were not clear, most of the participants were young and with more than one year since the EVC, in addition to the fact that some focus only on the upper limb (12 studies with 397 participants), finding that the differences were not significant for gait and global movement, but they were for the activities of daily living, so it is concluded that although the evidence suggests that virtual reality can be beneficial for the function of the upper limb and activities of daily life, there is still insufficient evidence on its effect on gait quality and global motor function. Nor can it be established yet which are the most important characteristics of virtual reality and what are its effects over time [42].

Clinical evaluation of patients with CVE

In patients with CVE and paresis of the extremities, different clinical scales are used to measure the changes that occur, spontaneously or related to rehabilitative management. There are multiple publications that support the relationship between the results of the Fugl-Meyer scale and the possible functionality of brain structures associated with movement. Cunningham described a good relationship ($rs= -0.768$; $p=0.016$; Spearman) between high scores with said scale and the functionality of the corticospinal tracts, preferably the contralateral [43].

Similarly, studies carried out in our country have shown the advantages of virtual reality as support in the rehabilitative management of patients with CVE. Although the improvement has been insignificant in different measurements, a positive emotional component and better adherence to treatment are frequently described. In a study carried out at the National Institute of Neurology and Neurosurgery (INNN) an increase in the score measured with the Fugl-Meyer scale was found in patients managed with virtual reality (-initial- 13.41 to 31.91 -final-) compared to the group who received habitual occupational therapy (18 to 26.3); when measuring motor changes with the Motor Index, the findings were similar (virtual reality from 32.33 to 52.91 -initial/final- compared to the control group from 42.1 to 52.6 -initial/final-). Changes in patient satisfaction were measured with the intrinsic motivation inventory, and those who underwent virtual reality therapy were more satisfied than the group with only therapy [34].

As described in some reviews and meta-analyses, many studies focus only on the upper limb and/or the hand, perhaps because they are the most frequently difficult to recover or show sequelae even over time. In another study conducted in Korea, only the upper limb was managed and evaluated; in it, functionality was evaluated with the Fugl-Meyer scale and the modified Barthel index. However, as

can be seen in the following table, the differences between the groups were only significant in hand scores, while the intragroup changes were significant in all evaluations [44].

Variations between groups pre and post intervention.

	FMA (score)								K-MBI (score)	
	Arm		Wrist		Hand		CS		Total	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
MCAG (n=6)	17.8 ± 9.7	22.8 ± 6.8[a]	5.3 ± 3.4	5.5 ± 3.6	8.2 ± 4.7	9.0 ± 5.1[a]	3.3 ± 0.8	3.8 ± 0.8	81.5 ± 5.4	83.3 ± 5.4[a]
BGG (n=8)	21.0 ± 4.5[b]	27.5 ± 4.7[a]	5.6 ± 1.6	6.9 ± 1.6[a]	7.9 ± 2.6[b]	11.9 ± 2.5[ab]	3.8 ± 0.9	4.6 ± 0.7[a]	79.6 ± 8.2	82.0 ± 8.1[a]

A lowercase “a” indicates a significant intragroup difference and “b” indicates a significant difference between groups. FMA = Fugl-Meyer scale. K-MBI = Korea Modified Barthel Index. CS = coordination and speed. MCAG = middle cerebral artery group. BGG = basal ganglia group.

Few studies focused on the management and evaluation of the lower limb were identified, considering balance, mobility and gait, highlighting that the improvement was greater in the group managed with virtual reality, although only in some aspects such as balance and march duration. However, it is noteworthy in this work that the therapy was provided for short periods (20 minutes a day for 10 to 12 sessions in a period of 3 weeks), identifying positive changes as shown in the following table [45].

	TMWT, ft	CMSA-Leg	TUG, s
MCID	62	N/A	−4.8
Control			
Pre	279.1 (86.4)	5.9 (0.3)	22.5 (8.9)
Post	349.6 (103.5)	6.0 (0.3)	16.8 (5.2)
Post−pre	70.5*	0.1	−5.7*
Treatment			
Pre	327.3 (146.2)	5.9 (0.5)	21.4 (9.6)
Post	438.5 (153.6)	6.3 (0.5)	13.6 (6.0)
Post−pre	111.2*	0.4	−7.8*

TMWT = 2 minute walk test. CMSA-leg = Chedoke McMaster CVD assessment in the leg domain. TUG = get up and go test. MCID = minimal clinically important difference.

Regarding the evaluation and management of the lower limb related to stroke, a systematic review with meta-analysis of 15 randomized trials (341 patients) showed that when conventional therapy program was replaced with virtual reality technology (part or all) showed significant benefits in gait speed (0.15 m/s, 95% CI 0.10 to 0.19), balance (2.1 points -Berg Balance Scale-, 95% CI 1.8 to 2.5) and mobility (2.3 seconds on the time of completion of the Up and Go test, 95% CI 1.2 to 3.4). Although the benefits were small and there was insufficient evidence about gait speed and balance (due to high heterogeneity), the extra costs related to the use of virtual reality were also small and it is proposed that it can be applied to many patients in the same medical unit [45]. Videogame consoles with virtual reality attachments represent a safe, potentially effective, easy-to-use, and attractive tool to favor rehabilitation and promote recovery after CVE [46].

EXPERIENCE IN A REHABILITATION UNIT

In the Physical Medicine and Rehabilitation Unit "XXI Century" (PMRUXXIc) of the Mexican Social Security Institute (IMSS, by its acronym in spanish), the CVE is second in demand for consultation and cause of neurological disability. Traditional rehabilitative treatment of hemiparesis can be lengthy and sometimes incomplete, predominantly in the upper extremity and especially the hand. These motor alterations affect the quality of life and consume resources in the institution. The usual treatments have shown relative benefits since they are based on facilitation/inhibition principles, with which the affected limb is "learned not to use". Recent studies confirm that arm movement coupled with a specific objective translates into greater motor learning at the cortical level and therefore greater motor recovery compared to the aforementioned facilitation/inhibition techniques [33, 36].

Research directed at this type of treatment in the PMRUXXIc, showed results consistent with what was described by other authors. In the studies, rehabilitation programs supported by virtual reality or movement restriction and induction were compared separately, and they were compared with groups of only physical and occupational therapy [47, 48]. The Table 1 summarizes the results of the clinical evaluation using the applied scales and their comparison with therapy alone.

In the study, the intragroup differences were always significant ($p<0.05$; Friedman), but the comparison between groups in the virtual reality study was only significant in the hand motor index ($p<0.05$; Kruskal-Wallis) and close to the significance with the Fugl-Meyer scale ($p>0.05$; Kruskal-Wallis). The lowest scores were found in the group of physical and occupational therapy alone. These works present some of the deficiencies mentioned, such as the low number of patients, but they can be considered as pilot studies in order to establish the size of the sample, considering the values found in a population similar to the one that will be included in the present investigation.

Table 1. Comparison of results measured in points of different scales in groups of patients with hemiparesis due to a cerebrovascular event managed with a rehabilitation program supported with virtual reality or Therapy with restriction and induction of movement modified or occupational therapy alone.

Applied scales		Therapy whit virtual reality (n=13)	Therapy with restriction and induction of movement (n=23)	Occupational therapy alone (n=10)
Hand motor index	I.V.	20.77		20.20
	F.V.	24.92		22.80
	Diff.	**4.15**		**2.6**
Shoulder-elbow motor index	I.V.	41.15		37.20
	F.V.	47.85		44.0
	Diff.	**6.7**		**6.8**
Total motor index	I.V.	61.92		56.40
	F.V.	72.69		66.90
	Diff.	**10.77**		**10.5**
Fine Forceps Test	I.V.	4.30 ± 1.03	12 ± 4.99	3.90 ± 0.99
	F.V.	7.38 ± 1.19	17.34 ± 4.27	6.60 ± 0.96
	Diff.	**3.007**	5.34	**2.8**
Fugl-Meyer Scale	I.V.	28.31 ± 12.02	9.34±3.7	27.70 ± 12.23
	F.V.	41.07 ± 9.28	11.27±2.67	38.60 ± 11.8
	Diff.	**12.77**	1.93	**10.9**

V.I.: Initial Valoration V.F.: Final valoration Diff.: Difference.

JUSTIFICATION

Actually, the CVE continues to be one of the main causes of morbidity and mortality in Mexico and in the world; the neurological disability that it produces requires prolonged rehabilitation and the motor sequelae affect the quality of life of patients, due to gait problems, but above all hand problems. The lesions of the cortex in the affected territory during the CVE contribute to a deterioration of the corticospinal tract, and its Wallerian degeneration can spread over time if it is not stimulated, for this reason it is important to maintain the integrity and conservation of the corticospinal pathway. corticospinal tract, favoring motor recovery through therapy as soon as possible after the event was installed.

Despite the existence of multiple rehabilitation treatments for the motor disability of patients with CVE, the sequelae continue to maintain their proportion. Therapy supported by Virtual Reality and Modified Constraint-Induced Movement (TMIRm, by its acronym in spanish) are relatively recent, but have not yet been incorporated into the usual clinical application in our country. Various publications highlight that in the investigations there are methodological deficiencies, variations in the characteristics of the subjects, such as the territory affected or the time of evolution, for which reason the evidence is usually insufficient, especially its effect on the quality of gait and overall motor function. This work aims to solve the deficiencies of other publications and measure the influence of treatments early in patients after a CVE, which, in the future, could influence a better recovery, both in brain functionality and in its clinical representation, with minor sequelae.

RESEARCH QUESTION

What is the effect of different therapeutic modalities supported by Virtual Reality or Restriction and Induction of Movement compared with usual Physical and Occupational Therapy on motor recovery of paretic limbs in patients with Cerebrovascular Event?

Secondary questions

1. To determine the relationship between the therapeutic management group and motor evolution with changes in language (aphasy).
2. To measure the level of patient satisfaction with the treatment received.
3. To relate the level of patient satisfaction with adherence to treatment.

WORK HYPOTHESIS

A therapeutic program supported in virtual reality will increase the motor function of the paretic thoracic extremity of patients with CVE by at least 38.6** average points measured with the Fugl-Meyer scale compared with usual physical and occupational therapy.

**The smallest difference in the improvement of the hemiparesis function calculated in points with the Fugl Meyer scale, found in patients with characteristics similar to those of the patients in this protocol, was taken. As well as the lowest standard deviation to cover all values [46, 47].

AIM

To measure the effect of different therapeutic modalities supported by Virtual Reality or Restriction and Induction of Movement compared with usual Physical and Occupational Therapy on the motor recovery of paretic limbs in patients with a Cerebral Vascular Event.

VARIABLES

Independent Variable

Cerebral vascular event

Conceptual definition. It is defined as a clinical syndrome characterized by the rapid development of signs and/or symptoms usually corresponding to a focal or global neurological condition (applicable to patients with loss of consciousness or acute headache), which persist for more than 24 hours or which lead to death, with no other apparent cause than a vascular origin" [1, 2].

Operational definition. In this work, the patient who comes to request care at the outpatient clinic of the UMFR sXXI will be considered, with the interconsultation format 4-30/8 where it is indicated that the patient suffered a cerebral vascular event and who presents neurological data consistent with the diagnosis, mainly hemiparesis, with or without aphasia. The verification of the diagnosis will be made later in the office, with the support of the computed tomography and verified during the physical examination; It will also be verified that it covers the rest of the selection criteria.

Indicators. What was described in the interconsultation format 4-30/8 and verified by clinic and skull tomography.

Measurement scale. Qualitative, nominal.

Virtual reality supported rehabilitation program.

Conceptual definition. It is a concept based on biofeedback supported by computer systems that allows the total immersion of the patient in a "real" environment where he receives sound, visual and tactile sensory information, which produces a multimodal environment, through which the individual is revealed, some of the normal or abnormal physiological events, in the form of auditory or visual signals, teaching him to manipulate involuntary events through displayed signals. The set of rehabilitation techniques is carried out with the support of the team, hoping that the movements of the paretic limbs together with a specific objective translate into greater motor learning at the cortical level and therefore greater motor recovery [33, 36].

Operational definition. For this investigation, a virtual reality equipment, commercial, Xbox One Kinect ®, will be used with the software "tennis"® and "ski" ® for shoulder, arm and hand, "cap the cracks" ® for thoracic limb and foot and "Star Wars-battles in the galaxy" for fine hand forceps. The equipment will be connected to reference points on the body of the individual sitting or standing in front of the device, with which it will establish the displacement of the images on a normal television-type screen or with Googles and a manual device for the fine clamp. In front of the patient, visual images accompanied by chord sounds will be displayed, where a character represents himself, in such a way that when moving the limbs or the body, he will also observe a similar movement in front of him, with which he will realize if his movements are appropriate or not, having then the possibility of "forcing" to correct or "appreciate the changes" as you progress in training. The movement directed in this way will be carried out for 1 hour, 2 times a week, for 6 weeks (12 sessions).

Indicators. The same equipment will always be used for each patient, with the same software, directed by the same therapist at pre-established times and days and which will be different days from those of the subjects who will receive the other therapies.

Measurement scale. Qualitative, nominal.

Rehabilitation program supported by the movement restriction and induction therapy.

Conceptual definition. Movement restriction-induction therapy modified (Constraint-Induced Movement Therapy –mCIMT-) is a rehabilitation technique developed by Edward Taub et al., in which the recovery of a limb affected by a brain injury, mainly a CVE, can be induced by immobilizing the intact arm and training the injured arm [26-28].

Operational definition. For the purposes of this investigation, a sling will be placed on the healthy thoracic limb so that it can carry out the therapeutic activities indicated in Annex 1 with the sick limb, without any help, not even from the therapist.

Indicators. The therapy will be directed by the same therapist at pre-established times and days and that will be different days than those of the subjects who will receive the other therapies, it will be carried out for 1 hour, 2 times a week, for 6 weeks. The therapy program is shown in Annex 1 with the specific activities that will be standardized for all patients.

Measurement scale. Qualitative, nominal.

Rehabilitation program with regular physical and occupational therapy

Conceptual definition. Physiotherapy (from the Greek φυσις physis, 'nature', and θεραπεία therapéia, 'treatment') is a health discipline that offers a non-pharmacological therapeutic alternative, to alleviate symptoms of multiple ailments, both acute and chronic, through exercise therapeutic, heat, cold, light, water, manual techniques including massage and electricity; and the occupational is the set of techniques, methods and actions that, through activities applied for therapeutic purposes, prevents disease and maintains health, favors the restoration of function, makes up for disabling deficiencies and assesses the assumptions of behavior and its deep significance to achieve the greatest possible independence and reintegration of the individual in all its aspects: work, mental, physical and social.

Operational definition. In the present investigation, a "usual" program has been developed in the rehabilitation unit where the work will be carried out. They are a series of standardized and individualized activities according to the state of the subject. For study purposes, the programs are presented in Annex 1, and will be provided without the support of virtual reality or the restriction-induction technique of movement.

Indicators. The therapists who will provide the neurorehabilitation programs will always be the same and will handle the same assigned patients, in the same workplace, with common materials, 1-hour sessions, 2 times a week for 6 weeks (12 sessions).

Measurement scale. Qualitative, nominal.

Dependent Variable

Hemiplegia-Hemiparesis secondary to a Cerebral Vascular Event

Conceptual definition. It is the loss of voluntary movement with alteration of muscle tone and sometimes sensation in the entire extension of one side of the body, it can be secondary to injuries, such as the cerebral vascular event that occurs in one hemisphere and affects the extremities and contralateral facial muscles. It behaves like an upper motor neuron syndrome with hypertonia, spasticity or rigidity [2].

Operational definition. In this work, the motor or sensorimotor disorder of the hemibody secondary to a cerebral vascular event will be verified clinically and by imaging. The usual way of evaluating the hemibody is through internationally accepted functional scales, widely validated in Spanish. For muscle tone, strength, and movement, the Ashworth and Brunnstrom scales will be used. The modified Ashworth scale allows an assessment that, although subjective, is accepted as allowing a quantitative approach. It assesses resistance to passive movement, is easy to apply, works for any joint, and has a high inter-observer reliability rate; grades muscle tone in relation to the range of motion of a joint. The Brunnstrom scale is a facilitation method that uses certain synergistic patterns of the hemiplegic patient to create movements. In this way, it seeks the immediate achievement of more coordinated and normal voluntary primitive movements, enhancing fine motor skills.

Indicators.

Modified Ashworth scale for the measurement of limb muscle tone.

Degree	
0	No increase in muscle tone
1-	Slight increase in tone manifested by minimal resistance at the end of the range of motion during a flexion or extension movement
1+	Slight increase in tone manifested by resistance in less than half the arc of movement
2	Increased pitch by more than half the range of motion, but the joint moves easily
3	Considerable increase in muscle tone with significant difficulty in joint movement
4	Stiffness in flexion or extension

Brunnstrom scale

Degree	
I	Hypotonia. There are no movements.
II	Beginning of recovery. Beginning of basic synergies, mainly through associated reactions. The hypertonia begins.

III	Voluntary control of basic synergies. Hypertonia rises to the maximum.
IV	Beginning of movement combinations. The hypertonia begins to decrease.
V	More complex combinations. Decreased synergistic influence. The hypertonia continues to decrease.
VI	The hypertonia disappears. You can make isolated movements (very analytical). Coordination is almost identical to normal.
VII	There is no difference with the opposite side.

Measurement scale. Qualitative, ordinal.

Motor function of the thoracic limb and pelvic limb

Conceptual definition. For the upper limb, it is the ability of a person to use the shoulder, arm, forearm and hand, through which multiple movements and voluntary actions necessary for survival and relationship with the environment are carried out, using the nervous and musculoskeletal system. , in response to the media. For the lower limb, they are the characteristics of the hip, thigh, knee, leg, ankle and foot joints to carry out activities that allow standing and displacement in a useful way; voluntary actions necessary for survival and relationship with the environment, as well as activities of daily human life [49].

Operational definition. In the present investigation, instruments that translate the clinical evaluation and allow the results to be expressed in an objective and quantifiable way will be used. They are internationally accepted scales, translated and validated in Spanish, widely used in clinical research. They measure disability based on the patient's performance and allow classifying dependence/independence on it according to the severity of the sequelae or limitations. The scales will be:

The **Fugl Meyer scale**.
The **Motor Index**.

The score for each of the dimensions is calculated by adding the partial score of each item and, finally, the sum of each dimension provides the total score. The following tables show the grades that are awarded according to the response presented by the patient during the evaluation. The scales are shown below and in Annex 2.

Fugl-Meyer scale

Domain	Dimension	Number of items	Minimum-maximum score	Total score
Motor function and balance	Motor function in the upper limb	33	0 – 66	114
	Motor function in the lower limb	17	0 – 34	
	Balance	7	0 – 14	

Sensitivity	Aesthetic sensitivity	4	0 – 8	24
	Proprioceptive sensitivity	8	0 – 16	
Passive range of motion and joint pain	Passive joint range of motion	22	0 – 44	88
	Joint passive mobility pain	22	0 – 44	
Total		113		226

Motor index

Score	Action/ Movement	Initial valoration	Intermedia valoration	Final valoration
Sitting patient 0: no movement 9: palpable contraction 14: perform movement but not full range vs gravity 19: full range of motion vs gravity but not vs resistance 25: movement vs resistance but less than contralateral 33: normal strength	1. Shoulder abduction			
	2. Elbow flexion Voluntary movement of 90º			
0: no movement 11: prehension starts 19: takes the cube but is not able to hold it vs gravity 22: he takes the cube and is able to hold it vs gravity but not vs resistance 26: take the cube overcomes gravity and resistance but is less than the contralateral 33: regular clamp	3. Grasp Hand: 2.5 cm cube between thumb and other fingers.			
0: no movement 9: palpable contraction 14: perform movement but not full range vs gravity 19: full range of motion vs gravity but not vs resistance 25: movement vs resistance but less than contralateral 33: normal strength	4. Hip flexion			
	5. Knee extension			
	6. Ankle dorsiflexion			
Upper limb Index:1+2+3+(1)/100				
Lower limb index: 4+5+6+(1)/100				
Total motor index: (Motor Index of UL + Motor Index of LL/2)/100				

Indicators. The application process is described in the procedures section. They will always be performed by the same doctor, who will ignore which therapy group the patient corresponds to, at the beginning, at 6 and 12 treatment sessions.

The equivalence of the results for the Motor Index is considered based on 100 total points (sum of upper limb + lower limb divided by 2).

Qualification	Equivalence
- 100 a 90 points.	Independent patients with rehabilitation for work adjustment and activities of daily living.
- 89 a 80 points.	Independent patients with limitations, who need integral rehabilitation treatment.
- 79 a 70 points.	Semi-dependent patient who needs external help and orthotics.
- 69 a 60 points.	Patients with help-dependent limitation.
- Less 60 points.	Dependent patient needs prolonged rehabilitation.

The equivalence of the results for the Fugl-Meyer scale is considered based on 100 total points, taking into account only the motor aspect of the lower and upper limb (maximum of 66 points for the upper limb + 34 points for the lower limb). The original equivalence established by the author in 1980 and the most recent one proposed by other authors are shown.

Fugl-Meyer (1980)	Duncan, Goldstein, Horner, Landsman, Samsa y Matchar (1994)
<50 = Severo	0-35 = Muy severo
50-84 = Marcado	36-55 = Severo
85-94 = Moderado	56-79 = Moderado
95-99 = Leve	>79 = Leve

Measurement scale. Qualitative, Ordinal.

Manual function

Conceptual definition. It is the ability of a person to carry out, through the distal effector segment of the thoracic extremity and the grasp, multiple movements as well as the voluntary actions necessary for survival and the relationship with the environment [48].

Operational definition. In the present work, the evaluation of the manual function will be measured through motor acts by means of the quality test of the fine forceps.

Indicators. The scales are shown below and in Annex 2; the application process is described in the procedures section. They will always be performed by the same physician, who will ignore which therapy group the patient corresponds to, at the beginning, at 6 and 12 treatment sessions.

Fine forceps test

Score	Action/ Movement	Initial valoration	Intermedia valoration	Final valoration
0: inability to take the cube 1: Grab with your whole hand 2: Radial or tridigital clamp 3: Forefinger thumb clamp	1.4 cm 2			
	2.5 cm 2			
	3.1 cm 2			

A higher score corresponds to a better quality of the fine forceps, the changes in the scores in the different measurements are related to the evolution of the functionality of the hand, especially in relation to the performance of activities and the level of disability.

Measurement scale. Quantitative, ordinal.

Aphasia secondary to the Cerebral Vascular Event

Conceptual definition. It is described as the loss or deterioration in the production or comprehension of oral or written language or both, caused by a brain lesion, frequently a Cerebral Vascular Event, although it may be secondary to other causes [1].

Operational definition. In the present work, the evaluation of language will be carried out with the Boston Aphasia Intensity scale, which is a validated form for a simple test [49].

Indicators. The scale is shown below and in annex 2; the application process is described in the procedures section. It will always be performed by the same doctor, who will ignore which therapy group the patient corresponds to, at the beginning, at 6 and 12 treatment sessions.

Boston Aphasia Intensity Scale

Description of language features	Score
Absence of speech or listening comprehension	0
Communication is made entirely from incomplete expressions. It requires inference, questions and guessing by the listener. The flow of information can be exchanged, it is limited and the weight of the conversation falls on the listener.	1
The patient can, with the help of the examiner, have a conversation on familiar topics. There is frequent failure to express an idea, but the patient shares the weight of the conversation with the examiner.	2
The patient can deal with virtually all problems of daily living, with little or no help. However, reduced speech and/or comprehension make conversation on certain types of topics extremely difficult or impossible.	3
There is some obvious loss of speech fluency or ease of understanding with no significant limitation of the ideas delivered to their mode of expression.	4
Minimal observable impairments in speech. The patient may present subjective difficulties that are not evident to the listener.	5

Measurement scale. Quantitative, ordinal.

Patient satisfaction when performing rehabilitation therapy

Conceptual definition. Feeling of well-being or pleasure that one has when a desire has been fulfilled or a need covered. In relation to therapy, this feeling is linked to the development of different therapeutic activities [50].

Operational definition. For this research, the Intrinsic Motivation Inventory will be used, which is a multidimensional measurement device designed to evaluate the subjective experience of the participants related to an objective activity in experiments; It consists of a varied number of subscale items, all of which have been shown to be factor analytically consistent and stable across a variety of tasks, conditions, and settings. The general criteria for the inclusion of items in the subscales have been a factor loading of at least 0.6 in the appropriate subscale. The multiple investigations in which they are used suggest that the order effects of item presentation appear to be negligible, and the inclusion or exclusion of specific subscales appears to have no impact on the others. Therefore, it is used as the equivalent of satisfaction, pleasure in carrying out the activity, and potential adherence to treatment. The Task Assessment version will be used, the subscales it includes are:

- Interest and satisfaction with the treatment
- Perception of competence (of the patient versus the treatment)
- Effort and importance of treatment
- Stress or tension (caused by the treatment)

In each one, different questions are answered (Annex 2), and the answer is qualified from 1 to 7 points, where one is "not everything is true" and 7 is "very true".

Indicators. The sum of the scores obtained by the patient indicates that higher scores correspond to better states in the subject and are comparable between groups of participants or the same subject on different occasions.

Measurement scale. Qualitative, ordinal.

Demographic variables

Age

Conceptual definition. It is the time that a person has lived, counting from birth, measured in years [51].

Operational definition. For this study, the age reported by the patient measured in years or that found in the clinical record or any other legal document will be considered.

Indicators. The age reported by the patient or obtained from the clinical record or legal documents.

Measurement scale. Quantitative, ratio.

Sex

Conceptual definition. Set of anatomo-physiological characters that distinguish the male from the female among individuals of the same species [51].

Operational definition. What is referred by the patient or written in the clinical file or legal documents will be considered in this study.

Indicators. Referred by the patient or in the clinical record or legal documents.

- Women
- Man

Measurement scale. Qualitative, nominal, dichotomous.

SELECTION CRITERIA

Inclusion criteria

1. Adult patients between the ages of 35 and 70 with a clinically and tomographically proven diagnosis of a cerebral vascular event in the territory of the middle cerebral artery.
2. Patients with hemiparesis secondary to the cerebrovascular event
3. Patients with a maximum Ashworth of 2 and Brunnstrom of minimum 4
3. Patients with or without aphasia
4. Patients with a maximum evolution of 1 month from the start of the cerebrovascular event
5. Patients with a cerebrovascular event of either sex
6. Patients with a vascular event without cognitive deficit
7. Patients who agree to participate by signing an informed consent, by them or their family member or person in charge (Annex 3).

Exclusion Criteria.

1. Patients with uncontrolled comorbidities, such as arterial hypertension or diabetes mellitus, etc.
2. Patients with a known prior diagnosis of mental neurological disorder, such as dementia, psychiatric disorders, etc.
3. Patients with previous hemiparesis not fully recovered from any etiology.

Elimination criteria

1. Patients who develop dementia or neurological-psychomotor complications during the study.
2. Patients who present a new cerebrovascular event during the investigation
3. Patients who do not complete at least 90% of the program
4. Patients in whom a lack of family support or secondary gain is detected.

STUDY TYPE AND DESIGN

Type study

Clinic

Design Study

Controlled clinical trial, randomized, single-blind.

MATERIAL AND METHODS

Population

Adult patients with a clinically and tomography-confirmed diagnosis of a Cerebral Vascular Event, with body hemiparesis, with or without aphasia.

Geographic scope

Outpatient services and physical/occupational therapy of the Physical Medicine and Rehabilitation Unit XXI Century (PMRUcXXI). Southern Delegation of the Federal District, IMSS.

Limits in time

March 2020 to June 2024.

Study General description

Patients with a diagnosis of cerebrovascular event (CVE) will be recruited upon arrival at the PMRUcXXI in the first-time appointment area. The diagnosis will be verified and an appointment will be made to the office of one of the researchers (evaluator 1). During the appointment the purpose of the study will be explained and doubts will be clarified. Whether they accept or not, the patient will receive the consultation that is normally provided to this type of patient and the information will be recorded in the clinical record. If patient do not accept, after the consultation, the appropriate management for your condition will be prescribed and a subsequent appointment will be made with the corresponding doctor to continue the control. In case of agreeing to participate, a summary will be made in Annex 4, which includes demographic data, whether or not is a worker, the need for temporary disability for work and clinical data for the research file. The signature of the informed consent letter will be also requested (Annex 3). This physician 1 will assign the therapeutic modality by using a table of random numbers to: Group 1. Therapy supported by virtual reality; Group 2. Therapy supported by constraint-induced movement; o Group 3. Usual physical and occupational therapy. An appointment will then be made to be assessed by the second doctor (evaluator 2), who will remain blind to the treatment, and will measure the functionality of the thoracic and pelvic limbs with the different scales, described in the procedures section, including muscle tone, trophism, ranges of mobility, functionality of the limbs, as well as of the hand, coordination, balance, sensory aspects and language (Annex 2). The limb functionality scales will be applied before (initial assessment -V.I.), during (intermediate assessment -V.Int.- week 3, session 6) and after (final assessment -V.F.- week 6, session 12) of the performance of the different rehabilitation programs. At the same times, the Boston Aphasia Intensity Scale and the Intrinsic Motivational Inventory will be applied by a neuropsychologist blinded to the treatment.

Procedures.

1. Clinical assessment and randomization. Once the patient, family member or person responsible has expressed their willingness to participate by signing the informed consent letter, they will be sent to office 16 of the outpatient rehabilitation clinic where they will be received by doctor 1 (treating) who will perform a clinical summary that will include age, sex, occupation, somatometry and the need for temporary incapacity for work, will carry out their own clinical evaluation in the way that is usually practiced in the office and will record it in the clinical file. He will be the one who monitors the patient as the treating physician and who answers all the questions that the patient, family member or person in charge may have throughout the investigation or in relation to his own condition, for which reason he will insist that he not give any information to the patient, doctor who will evaluate you later (evaluator 2) and who does not comment on aspects related to the therapy you are receiving, who reserves any doubt until the consultation. In addition, he will not know the results of the assessment using all the scales that the doctor will perform 2.

Finally, the invetigator will write the corresponding information on the information capture sheet (Annex 4. Information collection sheet) and will randomly assign to the different therapeutic modalities by using a table of random numbers, which will be placed in the corresponding place of annex:

Group 1: Virtual reality
Group 2: Constraint-induced motion.
Group 3: Usual physical and occupational therapy.

When finished, the sheet will be sent to the responsible investigator, who will take the patient to physician 2 for the evaluation of the affected hemibody and date for language, then he will take him to the corresponding therapists to carry out the assigned treatment. An appointment will be made with the neuropsychologist for the evaluation of language and satisfaction.

2. *Extremity motor assessment*. The patient will be admitted to consulting room 22, by appointment, where he will be received by physician 2 (blinded evaluator), who will have the indication to address the patient specifically in relation to obtaining data during the physical examination (actions to obtain the evaluation with scales). He will introduce himself and establish a rapport with the subject, but remind him that this assessment is related to an investigation and insist that he not give more information than what he requests. The evaluating physician will not know the therapeutic modality that the patient will receive. Afterwards, he will ask you to sit on the examination table and the clinical review related to the functionality of the hemibody will begin. The evaluation will begin with the motor index scale, then the quality of the fine forceps will be measured, and finally the Fugl Meyer scale. The assessment will be made before starting therapy, half the number of sessions (3 weeks) and at the end of treatment (6 weeks).

a) **Evaluation with Fugl Meyer scale.** This scale is specific to the Cerebral Vascular Event, designed with the objective of measuring the motor deficit, balance, sensitivity and state/pain of the joints of patients who present hemiplegia/hemiparesis as a consequence of the event. In clinical practice it helps to assess the severity of the deficit, describe motor recovery, plan rehabilitation treatment and monitor the clinical evolution of patients after a stroke.

The result of this scale is measured in a numerical score, the higher numerical score corresponds to a better state of the patient's functioning. The scale is built to give ratings separately (both members, balance and sensitivity), but it can also be used globally, with a maximum of 226 points. The questionnaire must be administered by the evaluating physician, it contains 113 items encompassed in 5 domains that in turn cover three dimensions of the state of functioning and functionality in the EVC. For each item, the examiner must grant the corresponding qualifications indicated in each section.

Fugl-Meyer scale (spanish versión).

Dimension: Assessment of motor function in the upper limb.

Dominio	Item	Ini. Val.	Interm. Val	Fin. Val.
I. Osteotendinous reflexes 0: no reflexes 2: reflexes are obtained	1. Biceps			
	2. Triceps			
II. Flexor synergy 0: does not perform the action 1: does it partially 2: it does it perfectly	3. Scapular elevation			
	4. Shoulder retraction			
	5. Shoulder abduction			
	6. External rotation of the shoulder			
	7. Elbow flexion			
	8. Supination of the forearm			
III. Extensor synergy 0: does not perform the action 1: does it partially 2: it does it perfectly	9. Adduction/internal rotation of the shoulder			
	10. Elbow extension			
	11. Forearm pronation			
IV. Movements combining synergies 0: cannot perform the action 1: carry out the action partially (the hand must pass thorn anterior superior iliac) 2: it does it perfectly	12. Hand towards lumbar spine			
0: arm is abducted immediately, or elbow is flexed at start of movement 1: abduction or flexion of the elbow occurs at a later stage of the movement 2: perform the action perfectly	13. Shoulder flexed at 90º, elbow at 0º			
0: correct shoulder position and neither elbow flexion nor pronation/supination can be achieved. 1: active pronation or supination can be performed partially (shoulder and elbow are correctly positioned). 2: perform the action perfectly	14. Forearm pronation/supination, elbow at 90º, shoulder at 0º			
V. Movements that do not combine synergies 0: initial flexion occurs at the elbow, or some tendency to pronate the forearm. 1: the movement can be carried out partially, or, if during the movement, the elbow is flexed, or the forearm cannot be maintained in pronation. 2: it performs perfectly	15. Shoulder abduction up to 90º, elbow at 0º, forearm pronated			
0: elbow flexion is initiated, or the shoulder is abducted 1: elbow flexion or shoulder abduction occurs during shoulder flexion (later in the movement).	16. Shoulder flexion between 90-180º, elbow at 0º and forearm in intermediate position			

2: it performs perfectly				
0: supination and pronation cannot be performed. 1: properly positioned elbow and shoulder are properly positioned but supination is in range limited 2: it performs perfectly	17. Pronation/supination of the forearm, elbow at 0º and shoulder at 30-90º of flexion			
VI. Reflexes 0: at least 2 of the 3 reflexes are markedly hyperactive 1: one reflex is markedly hyperactive or at least 2 reflexes are present 2: no more than one reflex is present and none is hyperactive	18. Exploring Reflexes			
VII. Wrist 0: patient is unable to dorsiflex to the required 15 degrees 1: dorsiflexion is performed but no resistance is applied 2: position can be held with resistance	19. Dorsiflexion of the wrist (elbow at 90º and shoulder at 0º)			
0: there are no voluntary palmar flexion movements 1: the patient is unable to actively complete the full range of motion of the wrist 2: impeccable, repetitively completing the full range of joint movement.	20. Dorsiflexion and palmar wrist (flexion/extension, elbow at 90º and shoulder at 0º)			
0: patient is unable to dorsiflex to the required 15 degrees 1: dorsiflexion is performed but no resistance is applied 2: position can be held with resistance	21. Dorsiflexion of the wrist (elbow at 0º and shoulder flexed at 30º)			
0: there are no voluntary palmar flexion movements 1: patient cannot actively complete full range wrist movement 2: full movement.	22. Dorsiflexion and palmar wrist (flexion/extension, elbow at 0º and shoulder in 30º)			
0: cannot perform 1: erratic movement or incomplete circumduction 2: fullmovement.	23. Circular movements			
VIII. Hand 0: no bending 1: some flexion but does not redo the full movement 2: full (active) flexion (compared to unaffected hand)	24. Finger flexion			
0: no extension 1: patient can perform active flexor grip but not full movement 2: full (active) extension (compared to unaffected hand)	25. Finger extension			
0: the required position cannot be achieved 1: grip is weak 2: Grip can be maintained with relatively large relative resistance	26. MCF extension Grip			
0: the required position cannot be achieved 1: grip is weak 2: grip can be maintained with relatively large relative resistance	27. Grab paper			
0: the function cannot be performed 1: the pencil between the pads of the index finger and thumb can be held in place but not by light tugging 2: the pencil grips firmly by holding the pull	28. Pencil grip			

0: the function cannot be performed 1: a can can be held between the index finger and thumb but not after a pull 2: the can is held firmly after the pull.	29. Can grip			
0: the function cannot be performed 1: can hold tennis ball in place with ball grip but not after chuck 2: the tennis ball can be held firmly after the pull	30. Grab ball			
COORDINATION 0: marked tremor 1: light tremor 2: no tremor	31. Tremor			
0: pronounced or unsystematic dysmetria 1: slight or systematic dysmetria 2: no dysmetria	32. Dysmetria			
0: activity is more than 6 seconds slower that with the unaffected hand 1: between 2 and 5.9 seconds slower than with the unaffected hand 2: less than 2 seconds apart	33. Speed			
	Sum of points obtained			
		Partial score	#	/66 points

Dimension: Assessment of motor function in the lower limb

Dominio	Item	Ini. Val.	Interm. Val	Fin. Val.
REFLEXES 0: not obtained 2: are obtained	34. Achilles reflexes			
	35. Patellar reflexes			
FLEXOR SYNERGY (recumbent position supine) 0: cannot perform it at all. 1: perform the movement partially. 2: perform the movement completely	36. Hip flexion			
	37. Knee flexion			
	38. Ankle dorsiflexion			
EXTENSIONAL SYNERGY **(recumbent position side)** 0: cannot perform it at all. 1: perform the move partially. 2: perform the move completely	39. Hip extension			
	40. Hip adduction			
	41. Knee extension			
	42. Ankle plantar flexion			
MOTION COMBINING SYNERGIES (position sitting) 0: no movement active 1: from the slightly extended position, the knee can be flexed but not more than 90º. 2: knee flexion more than 90º	43. Knee flexion (bring the ankle back and under the chair)			
0: no movement active 1: incomplete active flexion (the heel should stay on the ground with the medial and lateral edges of the forefoot clear of the ground during dorsiflexion) 2: normal dorsiflexion (active full range of motion with heel on the ground)	44. Ankle dorsiflexion (raise the tip of the foot with the heel on the ground)			
MOVEMENTS WITHOUT SYNERGIES (in standing) 0: the knee cannot be flexed without hip flexion. 1: knee flexion begins without hip flexion but does not reach 90º or the hip begins to flex later in the movement. 2: the knee is flexed more than 90º	45. Knee flexion (heel back kick)			

0: no active movement. 1: partial movement or with knee without extensión complete 2: full motion (full joint range in dorsiflexion with knee extended and heel on the ground)	46. Ankle dorsiflexion (raise the toe with the heel on the ground)			
REFLEXES (in position sitting) 0: at least 2 of the 3 reflexes are markedly hyperactive 1: a reflex is markedly overactive or at least 2 reflections are present 2: no more than one reflection is alive, and none is hyperactive	47. Reflexes in the lower limbs (score only if 4 points are obtained in the previous section)			
COORDINATION 0: marked tremor 1: light tremor 2: no tremor	48. Tremor			
0: pronounced or unsystematic dysmetria 1: slight or systematic dysmetria 2: no dysmetria	49. Dysmetria			
0: the activity is performed in more than 6 seconds slower than by hand does not affect 1: between 2 and 5.9 seconds slower than with the unaffected hand 2: less than 2 seconds apart	50. Speed			
	Sum of points obtained			
		Partial score	#	/34 points

Dimension: Assessment of balance

Dominio	Item	Ini. Val.	Interm. Val	Fin. Val.
0: do not sit without support 1: sits without support for a short time 2: sit without support for 5 minutes and adjust self posture	51. Sitting without support with feet suspended			
0: does not maintain the posture to avoid falling 1: partially holds the pose 2: maintains posture properly	52. Parachute reaction on the unaffected side			
0: does not maintain the posture to avoid falling 1: partially holds the pose 2: maintains posture properly	53. Parachute reaction on the affected side			
0: does not stand up 1: does not want important help from other person(s) 2: can be maintained for at least one minute with minimal or token assistance from another person	54. Standing with support			
0: does not stand up 1: standing 1 minute without oscillations 2: good balance (+1 minute safely)	55. Standing without support			
0: holds the position for 1-2 sec 1: balance 4-9 sec 2: balance -10 sec	56. Mono-standing on the leg does not affect			
0: holds the position for 1-2 sec 1: balance 4-9 sec 2: balance -10 sec	57. Mono-standing on the affected leg			
	Sum of points obtained			
		Partial score	#	/14 points

Dimension: Sensitivity

Dominio	Item	Ini. Val.	Interm. Val	Fin. Val.
Exteroceptive 0) Anesthesia 1) Hypoesthesia 2) Normal	58. Arm			
	59. Palm of the hand			
	60. Leg			
	61. Sole of foot			
Proprioceptive 0) No answer is correct 1) Diminished: ¾ of answers are correct 2) All the answers are correct	62. Shoulder			
	63. Elbow			
	64. Wrist			
	65. Fingers			
	66. Hip			
	67. Knee			
	68. Ankle			
	69. Toes			
	Sum of points obtained			
	Partial score		#	/24 points

Dimension: Joint range and joint pain

	Joint range 0: Just a few degrees of movement 1: Decreased passive mobility 2: Normal passive mobility				**Joint pain** 0: Pain in all ranges of motion and severe pain at the end of range of motion. 1: Mild pain 2: No pain			
Dimension	**Dominio**	**Val. Ini.**	**Val Int.**	**Val. Fin.**	**Dominio**	**Val. Ini.**	**Val Int.**	**Val. Fin.**
Shoulder	70. Abduction				71. Abduction			
	72. Flexion				73. Flexion			
	74. External rotation				75. External rotation			
	76. Internal rotation				77. Internal rotation			
Elbow	78. Flexion				79. Flexion			
	80. Extension				81. Extension			
Forearm	82. Pronation				83. Pronation			
	84. Supination				85. Supination			
Wrist	86. Flexion				87. Flexion			
	88. Extension				89. Extension			
Fingers	90. Flexion				91. Flexion			
	92. Extension				93. Extension			
Hip	94. Flexion				95. Flexion			
	96. Abduction				97. Abduction			
	98. External rotation				99. External rotation			
	100. Internal rotation				101. Internal rotation			
Knee	102. Flexion				103. Flexion			
	104. Extension				105. Extension			
Ankle	106. Dorsiflexion				107. Dorsiflexion			
	108. Plantar flexion				109. Plantar flexion			
Foot	110. Eversion				111. Eversion			
	112. Inversion				113. Inversion			
					Sum of points			
					Partial score		#	/ 44 points
					TOTAL score		#	/226

Ini. Val.: initial valoration; Interm. Val.: intermediate valoration; Fin. Val.: final valoration.

The assessments will be made before starting the therapy (Initial value), at 6 sessions and at the end of therapy (12 sessions).

b) **Motor index scale.** It is a method of scoring muscle strength on the hemiplegic side by assessing the action of six key muscles, in a sitting or lying position. It is examined: shoulder abduction and elbow flexion (upper limb), grasp (hand), hip flexion, dorsiflexion and ankle knee extension. The maximum score in the upper limb is 100 and in the lower limb 100. The global motor index score is obtained by adding the position obtained in the upper limb with the lower limb and dividing by two (Annex 2. Motor evaluation of plegic limbs /paretic).

Score	Action/ Movement	Initial valoration	Intermedia valoration	Final valoration
Sitting patient 0: no movement 9: palpable contraction 14: perform movement but not full range vs gravity 19: full range of motion vs gravity but not vs resistance 25: movement vs resistance but less than contralateral 33: normal strength	1. Shoulder abduction			
	2. Elbow flexion Voluntary movement of 90º			
0: no movement 11: prehension starts 19: takes the cube but is not able to hold it vs gravity 22: he takes the cube and is able to hold it vs gravity but not vs resistance 26: take the cube overcomes gravity and resistance but is less than the contralateral 33: regular clamp	3. Grasp Hand: 2.5 cm cube between thumb and other fingers.			
0: no movement 9: palpable contraction 14: perform movement but not full range vs gravity 19: full range of motion vs gravity but not vs resistance 25: movement vs resistance but less than contralateral 33: normal strength	4. Hip flexion			
	5. Knee extension			
	6. Ankle dorsiflexion			
Upper limb Index:1+2+3+(1)/100				
Lower limb index: 4+5+6+(1)/100				
Total motor index: (Motor Index of UL + Motor Index of LL/2)/100				

c) **Fine clamp quality test.** The test evaluates the grip capacity between the thumb and forefinger achieved by the patient to take cubes of 1.4, 2.5 and 3.1 cm3; the rating is awarded from the inability to take the cube, support with the whole hand or another finger and only with the 2 fingers, as shown in the table (the higher the score, the better the grip quality):

Score	Action/ Movement	Initial valoration	Intermedia valoration	Final valoration
0: inability to take the cube 1: Grab with your whole hand 2: Radial or tridigital clamp 3: Forefinger thumb clamp	1.4 cm 2			
	2.5 cm 2			
	3.1 cm 2			

d) **Language assessment (aphasia).** The patient will be summoned to the psychology service, in which the neuropsychologist will carry out a structured conversation and questions not related to the treatment, for example, family or work situations, through which she will interpret the level of language, based on the description written in the Boston Aphasia Intensity Scale and will assign the corresponding rating in Annex 2.

Boston Aphasia Intensity Scale

Description of language features	Score
Absence of speech or listening comprehension	0
Communication is made entirely from incomplete expressions. It requires inference, questions and guessing by the listener. The flow of information can be exchanged, it is limited and the weight of the conversation falls on the listener.	1
The patient can, with the help of the examiner, have a conversation on familiar topics. There is frequent failure to express an idea, but the patient shares the weight of the conversation with the examiner.	2
The patient can deal with virtually all problems of daily living, with little or no help. However, reduced speech and/or comprehension make conversation on certain types of topics extremely difficult or impossible.	3
There is some obvious loss of speech fluency or ease of understanding with no significant limitation of the ideas delivered to their mode of expression.	4
Minimal observable impairments in speech. The patient may present subjective difficulties that are not evident to the listener.	5

e) **Evaluation of satisfaction when performing rehabilitation therapy.** The characterization of the patient's perception of satisfaction will be evaluated by the same neuropsychologist, who will be blinded to the treatment the patient is receiving, using the Intrinsic Motivation Inventory (IMI). The IMI is a multidimensional measurement device intended to assess the subjective experience of participants related to an objective activity in experiments; it has been used in various experiments related to intrinsic motivation and self-regulation. The instrument assesses participants' interest/enjoyment, perceived competence, effort, value/utility, felt pressure and strain, and perceived choice while performing a given activity, yielding six subscale scores. The concepts of perceived choice and perceived competence are theorized to be positive predictors of both self-report and behavioral measures of intrinsic motivation, and pressure/strain is theorized to be a negative predictor of intrinsic motivation. Effort is a separate variable that is relevant to some motivation questions, so it is used as relevant. The value/utility subscale is used in internalization studies, with the idea that people internalize and self-regulate with regard to activities that they experience as useful or valuable to themselves.

The subscales and items are:

Intrinsic Motivation Inventory (Assessment of satisfaction when performing rehabilitation therapy) (Spanish versión)

	Reality Virtual			Restriction and Induction of Movement			TF and TO habitual		
Patient perception	**Ini. Val.**	**Interm. Val.**	**Fin. Val.**	**Ini. Val.**	**Interm. Val.**	**Fin. Val.**	**Ini. Val.**	**Interm. Val.**	**Fin. Val.**
Interest and satisfaction with treatment									
As he worked on the task he thought how much he enjoyed it.									
I found the task very interesting.									
Doing homework was fun.									
I really enjoyed doing homework.									
I thought the homework was very boring (R).									
I seemed the task very interesting.									
I would describe the task as very pleasant.									
Perception of competence (of the patient versus the treatment)									
I think I'm very good at this task.									
I think I did very well in this activity, compared whit other									
I am satisfied with my performance in this task.									
I felt quite skilled at this task.									
After working on this task for a while, I felt quite competent.									
Effort and importance of treatment									
I felt it was my choice to do the task.									
I didn't really have the option to do task (R).									
I felt like I was doing what I wanted to do while working on the assignment.									
I felt that I had obligation to do task (R)									
I did the homework because I had no other option (R).									
Stress or strain (caused by treatment)									
I didn't feel nervous about doing task (R).									
I felt tense while doing task.									
I felt relaxed while doing task (R).									
I was anxious while doing task.									
I felt stressed while doing task.									

Ini. Val.: initial valoration; Interm. Val.: intermediate valoration; Fin. Val.: final valoration.

Subscale scores can be used as dependent variables, predictors, or mediators, depending on the research questions being addressed. The higher the score, the higher the satisfaction.

3. *Therapy programs.*

a. Virtual reality program. The activities indicated in the tennis and ski software for the upper limb, covering cracks for both limbs and Star Wars-battles in the galaxy for the hand and fine pincer,

which will be carried out with the interface of the virtual reality equipment "connected" to the patient through movement sensors, with the multiperceptual feedback of the Kinect equipment or with googles.

b. *Movement restriction and induction therapy*. The patient will be placed a sling on the "healthy" thoracic limb, attached to the thorax, through a bra, gently but firmly, in such a way that it does not alter circulation or compress peripheral nerves. It will be explained to you that you should do all your activities with the “sick” member, to the extent possible. The restriction of the healthy side forces the patient to put all his effort into carrying out the activities of daily life, simulated during the therapy. This restriction will be carried out for 1 hour in therapy in the medical unit. And the patient will be told to repeat it at home at least once a day for one to five hours, without receiving support from family members while wearing the sling.

c. *Regular physical and occupational therapy.* The specific activities are shown in Annex 1. They include:

- **Motor management:** tasks to promote mobility of the shoulder, elbow, pentadigital clamp, fine clamp, transfers; volitional movements, eye-motor coordination, hip, knee, ankle and gait mobility.
- **Sensory training:** deep sensitivity, stereognosis, sensory discrimination, graphesthesia, topognosis and proprioception.

4. *Concentration and analysis of information.* The results of the different evaluations will be noted on the information capture sheet (Annex 2 and 4); Subsequently, they will be entered into an Excel spreadsheet and finally exported for analysis to the SPSS V-19 program.

STATISTICAL ASPECTS

Sampling

Non-probabilistic, of consecutive cases.

Sample size

The sample size calculation was performed to test the working hypothesis* (average difference of 38.6 points and a SD 12.23), with a standardized effect size greater than 1 in a prefabricated table to establish mean differences (Appendix 1. 13 -A) [52], considering a unilateral hypothesis, in a finite population and without replacement, with a value $\alpha = 0.05$ and $\beta = 0.10$.:

For 17 patients plus 20% of possible losses, for a total of 19 patients per group.

* The score of the motor evolution evaluated with the Fugl-Meyer scale was considered, with therapy supported by virtual reality, found in the study of the unit, considered as a pilot [47, 48].

Statistic analysis

Descriptive statistics will be carried out for the qualitative variables through tables, graphs and percentages; for the quantitative ones, measures of central tendency and its corresponding dispersion will be used, depending on the distribution of the data. The distribution of the numerical data will be compared with the distribution curve using the Shapiro-Wilk test, depending on the result, the ANOVA or Friedman test will be used for intragroup comparison; for compassion between groups, ANOVA of repeated measures or the Kruskal-Wallis test will be used. In case of detecting variables that could be potentially related to the result, correlation tests such as Pearson or Spearman will be applied. An α value of 0.05 will be considered.

ETHICAL ASPECTS

This research respects the institutional, national and international standards that govern research on human beings in our country. Including the General Health Law, TITLE FIVE Research for Health, sole chapter [53]; the regulation of the General Law of Health in Matters of Research for Health [54]; and the Official Mexican Standard NOM-012-SSA3-2012, which establishes the criteria for the execution of research projects for health in human beings [55].

Considering what is specified in the regulation of the General Health Law, second title of the Ethical Aspects of Research in Human Beings chapter I, the present work was considered as research with greater than minimum risk, since the techniques to be contrasted, although they are considered as moderate therapeutic exercise, they are based on activities included in classic physical and occupational therapy -common in patients with a cerebrovascular event in the rehabilitation unit-, but they will be supported and carried out with unusual or computerized devices and changes are expected to occur in brain architecture, evident by clinical changes, since imaging studies will not be performed.

> **Article 17. III. Research with greater than minimal risk:** are those in which the probabilities of affecting the subject are significant, among which are considered: radiological and microwave studies, drug trials and modalities defined in article 65 of this Regulation, trials with new devices, studies that include surgical procedures, blood extraction of 2% of the circulating volume in neonates, amniocentesis and other invasive techniques or major procedures, those that use random methods of assignment to therapeutic schemes and those that are controlled with placebos, among others .

The signature of the informed consent letter will be requested, by the patient or relatives. A detailed explanation of participation will be provided and anonymity will be ensured at all times. Likewise, it will be guaranteed that in case of not accepting or suspending the participation, this will not affect the management received by the institute. In this case, the patient will go to the regular consultation of the doctor in office 16.

This research project was submitted for consideration by the local research and research ethics committee, where it was verified that it met the necessary requirements to be carried out and was authorized with the registration number **R -2016–3702-44**.

RESOURCES

Human Resources

1. A PhD student and person in charge of the project
2. A consultant with a doctorate in Medical Sciences and a specialist in rehabilitation medicine
3. Two advisors with doctorates in medical sciences and specialists in Internal Medicine
4. A physician specializing in rehabilitation medicine for blinded assessment of patients
5. A doctor specializing in rehabilitation medicine for regular consultation and monitoring of patients
6. A psychologist with a master's degree in neuropsychology for mental evaluation
7. A physical therapist
8. An occupational therapist

Material resources

1. Physical and occupational therapy materials: buckets, jars, wood, etc.
2. A virtual reality equipment and accessories (googles, sensors).
3. A 50 or 60-inch screen compatible with the Xbox One Kinect.
4. Office supplies

Economic resources

The infrastructure of the rehabilitation unit will be used, which has spaces for the management of patients with cerebral vascular event, as well as most of the necessary supplies for the production of stationery and physical and occupational therapy materials.

FINANCING

Funding was not obtained to purchase virtual reality equipment and supplementary materials for physical and occupational therapy, so we worked with 2 equipment owned by the participants. The occupational therapy materials were those of the Medical Unit where the patient was treated. The participating personnel are experts in the area and contributed to the acquisition of materials and equipment, mainly the doctoral student.

FEASIBILITY

Approximately 32 patients per month with a diagnosis of cerebrovascular event and with the necessary characteristics to enter this study attend the rehabilitation unit. There is broad support from the authorities to carry out the research and permissions would be granted to the participants to carry out the activities in a timely manner. Therefore, it is considered that the study is feasible to be completed within the scheduled time.

DIFFUSION

At the conclusion of this work, the results will be disseminated in the different research forums of the IMSS, as well as within the rehabilitation units for their knowledge. It is also intended to be published in a journal with impact, as well as to take it to national or international congresses of the specialty.

TRANSCENDENCE

With the proposed methodology, it is expected that the results are considered generalizable to the population. It is intended that they be seriously considered as a therapeutic tool in the different rehabilitation units or medical units that have physical or occupational therapy personnel (first and second level), which could impact the care of these patients. It can even affect the cost of the same patient who would not have to go to a medical unit for check-ups or reinforcements, due to the fact that virtual reality equipment can currently be found in private homes, on the one hand; on the other, adherence to the treatment described (if verified) would allow a continuous evolution towards improvement with the need for sporadic medical review.

BIOSECURITY ASPECTS

Does not apply.

SCHEDULE OF ACTIVITIES

Gantt chart

Start month: Mz = March 2017 (an important delay in the scheduled activities is accepted, related to the earthquake of 2017 and the pandemic in 2020)

		2018-19*			**2020-21* ***				**2022**				**2023**				**2024**				**2025**	
Month	T*		En-Dc	En-Dc	En-Dc	En	…	Dc	En	…	Dc	…	En	…	Dc	En	…	Dc	En	…	Dc
Modifications of research in doctoral seminars	P*	X	X	X																		
	R*	X	X	X																		
Standardization of procedures	P*		X	X																		
	R*		X	X																		
Recruitment, evaluation and patient monitoring	P*				X	X	X	X	X	X	X	X	X	X	X	X						
	R*						X	X	X	X	X	X	X	X								
Analysis and writing of Results partial/final	P*								X	X	X	X	X	X	X	X	X					
	R*								X	X	X	X	X									
Preparation of final report partial/final	P*								X	X	X	X	X	X	X	X	X	X				
	R*									X	X	X	X	X								
manuscript writing for publication	P*									X	X	X	X	X	X	X	X	X	X			
	R*									X	X	X	X	X								
Send to publication	P*										X	X	X	X	X	X	X	X	X	X	X	X
	R*										X	X	X	X								

* México city, earthquake of 2017: structural damage and partial suspension of the therapy service of the physical medicine and rehabilitation unit

** COVID19 pandemic: suspension of the therapy service for patients with stroke sequelae in the physical medicine and rehabilitation unit.

T* = Tiempo P* = Programado R* = Realizado

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ANNEX 1. REHABILITATION PROGRAM SENSORY-MOTOR (Spanish)

Training Type	Activity	Material	Objectives
1. Motor Seated patient, with hip and knee flexion of approximately mind 90º, with support on the floor of both feet with placement of a sling on the healthy arm	Place each of the objects in front of the patient at a distance of 10cm, ask him to take them with the affected hand for 5 seconds and release them, making sure that he does not replace the movement.	-4 plastic buckets 10 x 10cm 8x 8 cm 6x6 cm 4x4 cm - Styrofoam spheres with the following diameters 5 cm 4cm 3cm 2cm - Cones with base diameter 7.5cm 6.5cm 5cm 3.5cm	- Encourage the patient to perform the pentadigital clamp, promote relaxation of the hand flexor muscles - Promote volitional control
	Place a cube, a sphere and a cone in front of the patient at a distance of approximately 30 cm. The therapist will stand behind the patient asking him to try to pass the object behind his own shoulder.		-Promote elbow and shoulder flexion movements. -Favor volitional control.
	Place in front of the patient and on the table 6 dominoes (horizontal) and a plastic container on one side of the extremity, ask the patient that with the shoulder in a functional position and elbow flexion at 90º, take the dominoes and place them in the bowl. Place 3 uncapped vials in an upright position in front of the patient and instruct them to change them upside down.	Wooden dominoes 4 x 10 cm Plastic jar with 20cm length	-Favor prono-supination movements
	Place 10 cones on the table, on the opposite side to the affected one at a distance of 30cm, instruct the patient to take them to the opposite side forming towers (the length of the tower will vary according to the patient's progress and their ability to release it) Place jars (filled with sand) in an upright position in front of the patient at a distance of 20 cm and instruct him to open and close them.	- Cones of the size mentioned in Item 1.1 - Bottle with lids with a diameter of: 7cm 5cm 3cm 2cm	Favor the movements of ulnar and radial deviation, flexion and abduction of the shoulder

Training Type	Activity	Material	Objectives
2. Seated motor patient with hip and knee flexion of approximately 90º, with both feet supported on the floor with sling placement on the healthy side.	Give the patient a pencil and ask him to draw a straight line, and once the patient does it curve ask him to write his name.	Pencil will initially be taken with adaptations that will be withdrawn according to the evolution of the patient.	- Promote digital-digital clamp, eye-motor coordination.
	Take objects and try to cut and bring the food to the mouth.	Fork Knife Soup spoon Coffee spoon Food Adjuncts	- Favor tridigital clamp, pronosupination and movements of flexion, elbow extension, flexion and abduction of the shoulder. -Promote visual motor coordination
	Take the objects in front of the patient at a distance of 5cm between them, ask him to take the objects and take them to the side of the affected limb, placing it in a container achieving maximum abduction of the patient.	plastic buckets Spheres Cones(sizes mentioned above)	-Favor pentadigital clamp, increase shoulder mobility arcs: Flexion and abduction, elbow extension and wrist flexion, MCF
	Place 5 spheres at one end of the table distal to the patient at a distance where it is possible to take them, ask him to collect them with each finger in a container which is located next to the affected finger, said container will be on a bench at a distance that the range of movement of the patient allows it, perform them with the eyes open, and then close them.	-Spheres with a diameter of:4cm 3cm 2cm 1cm - Container of 40 x 40cm	-Favor end-to-end clamp, transfers, shoulder abduction movements, visual-motor coordination.
	Assemble a puzzle which will change the number of pieces and half according to the evolution of the patient, the pieces will be placed at a distance of 3cm between them, 10cm from where it was assembled.	- Foami 10-12 piece -Cardboard paper: 24-30 pieces	-Favor eye-hand coordination, tweezers, flexo elbow extension movements, bottom figure.
	Place the table of nuts in front of the patient and instruct him to try to put or remove as many of them as possible, taking them from the healthy side to the affected side from distal to proximal.	- Table of nuts -Table with a diameter of 6cm	-Promote voluntary control, tweezers, eye-motor coordination. - Facilitate relaxation of the shoulder girdle
	Place the cylinders and the wooden base on the affected side on the opposite side of the affected limb and instruct the patient to take the cylinders and place them on their bases	- Wooden cylinders of different diameters: 4cm 3cm 2cm 1cm	- Favor pincers, shoulder abduction and adduction, eye-motor coordination

Training Type	Activity	Material	Objectives
3. Patient seated with hip and knee flexion of approximately 90º, with both feet resting on the floor, with sling placement on the healthy side.	Place shoulder, elbow and hand in functional position or as close as possible to said position, place the left end of the table the jars and ask him to take them to the opposite end of where	-Jars with height of: 20cm 10cm 8cm 4cm	-Favor transfers, abduction and adduction of the shoulder.
	Place a ball in the palm of the hand and ask the patient to wrap his fingers around it with the minimum force required to perform the activity and release it.	- Gel ball -Plastic flexible ball -Compact ball of 6cm diameter	-Promote deep sensitivity and stereognosis.
	Play dominoes, chopsticks. The objects will be placed on the table at the end of the affected side of the patient.	-Wooden domino of 5x2.5cm and 3.5 x 7xm. -Plastic Chinese chopsticks (the activities will alternate according to the evolution of the patient).	-Promote fine motor activity
	Ask the patient to take the marble with each of the fingers and place them in the container in the manner of a digital-digital clamp.	-Marbles of diameters: 4cm 3cm 2cm 1cm	-Favor digital digit clamp
	Place the material on the work table and fix it, ask the patient to slide the roll of cloth over the lines, favoring abd movements and shoulder rotation.	-Tablecloth 90 x60cm with curved lines in the form of 8 -Roll of cloth	-Favor the movements of abd, flexion and rotation of the shoulder

Training Type	Activity	Material	Objectives
4. Sensory Training:	4.1 Place different objects in the palm of the patient's hand and ask him to identify the shapes of the objects themselves (done with eyes closed)	-Plastic geometric figures -Square 5.5cm -Rectangle 3x5cm -Spheres 5 cm	-Promote deep sensitivity, stereognosis
	4.2 Place a box full of rice, beans and some objects, introduce the patient's hand and ask him to retrieve them, which will be changed according to the evolution of the patient, starting with those of common use and later with geometric figures and the needles.	-36 x 30cm container filled with sand, beans and wheat. - Soup spoon and coffee pot - Fork -Toothbrush, comb, plastic and metal keys, geometric figures, clicks, 5cm long needles with blunt tip.	
	4.3 Pass different textures over the upper extremity and ask the patient to try to identify them.	Fabrics of different textures: -Gentle -Smooth -Padded -Rough	-Favor sensory discrimination

	4.4 Replicate the letters x, o, s, l, z and the numbers from 1 to 5 on the patient's skin in different places on the limb and at different stages, asking the patient to identify the replicated letter or number.	-Wooden pencil	-Graphesthesia
	4.5 Patient with eyes closed, touch a part of the extremity very superficially and ask the patient to identify if he feels it, as well as to identify the stimulated site.	-Cotton	-Topognosia
	4.6 The therapist using the index or middle finger as a reference to move the patient's upper extremity and place it in a new place, ask the patient to bring it to the starting position by alternating periods with the patient standing and sitting.		-Proprioception

Anexo 2.

GUIDE SHEETS (Spanish version)

MOTOR ASSESSMENT SCALES Date: _____ Patient number: ____ Group: ___

Fugl-Meyer scale (spanish versión).

Dimension: Assessment of motor function in the upper limb.

Dominio	Item	Ini. Val.	Interm. Val	Fin. Val.
I. Osteotendinous reflexes 0: no reflexes 2: reflexes are obtained	1. Biceps			
	2. Triceps			
II. Flexor synergy 0: does not perform the action 1: does it partially 2: it does it perfectly	3. Scapular elevation			
	4. Shoulder retraction			
	5. Shoulder abduction			
	6. External rotation of the shoulder			
	7. Elbow flexion			
	8. Supination of the forearm			
III. Extensor synergy 0: does not perform the action 1: does it partially 2: it does it perfectly	9. Adduction/internal rotation of the shoulder			
	10. Elbow extension			
	11. Forearm pronation			
IV. Movements combining synergies 0: cannot perform the action 1: carry out the action partially (the hand must pass thorn anterior superior iliac) 2: it does it perfectly	12. Hand towards lumbar spine			
0: arm is abducted immediately, or elbow is flexed at start of movement 1: abduction or flexion of the elbow occurs at a later stage of the movement 2: perform the action perfectly	13. Shoulder flexed at 90º, elbow at 0º			
0: correct shoulder position and neither elbow flexion nor pronation/supination can be achieved. 1: active pronation or supination can be performed partially (shoulder and elbow are correctly positioned). 2: perform the action perfectly	14. Forearm pronation/supination, elbow at 90º, shoulder at 0º			
V. Movements that do not combine synergies 0: initial flexion occurs at the elbow, or some tendency to pronate the forearm. 1: the movement can be carried out partially, or, if during the movement, the elbow is flexed, or the forearm cannot be maintained in pronation. 2: it performs perfectly	15. Shoulder abduction up to 90º, elbow at 0º, forearm pronated			
0: elbow flexion is initiated, or the shoulder is abducted 1: elbow flexion or shoulder abduction occurs during shoulder flexion (later in the movement). 2: it performs perfectly	16. Shoulder flexion between 90-180º, elbow at 0º and forearm in intermediate position			
0: supination and pronation cannot be	17. Pronation/supination of the			

performed. 1: properly positioned elbow and shoulder are properly positioned but supination is in range limited 2: it performs perfectly	forearm, elbow at 0º and shoulder at 30-90º of flexion			
VI. Reflexes 0: at least 2 of the 3 reflexes are markedly hyperactive 1: one reflex is markedly hyperactive or at least 2 reflexes are present 2: no more than one reflex is present and none is hyperactive	18. Exploring Reflexes			
VII. Wrist 0: patient is unable to dorsiflex to the required 15 degrees 1: dorsiflexion is performed but no resistance is applied 2: position can be held with resistance	19. Dorsiflexion of the wrist (elbow at 90º and shoulder at 0º)			
0: there are no voluntary palmar flexion movements 1: the patient is unable to actively complete the full range of motion of the wrist 2: impeccable, repetitively completing the full range of joint movement.	20. Dorsiflexion and palmar wrist (flexion/extension, elbow at 90º and shoulder at 0º)			
0: patient is unable to dorsiflex to the required 15 degrees 1: dorsiflexion is performed but no resistance is applied 2: position can be held with resistance	21. Dorsiflexion of the wrist (elbow at 0º and shoulder flexed at 30º)			
0: there are no voluntary palmar flexion movements 1: patient cannot actively complete full range wrist movement 2: full movement.	22. Dorsiflexion and palmar wrist (flexion/extension, elbow at 0º and shoulder in 30º)			
0: cannot perform 1: erratic movement or incomplete circumduction 2: fullmovement.	23. Circular movements			
VIII. Hand 0: no bending 1: some flexion but does not redo the full movement 2: full (active) flexion (compared to unaffected hand)	24. Finger flexion			
0: no extension 1: patient can perform active flexor grip but not full movement 2: full (active) extension (compared to unaffected hand)	25. Finger extension			
0: the required position cannot be achieved 1: grip is weak 2: Grip can be maintained with relatively large relative resistance	26. MCF extension Grip			
0: the required position cannot be achieved 1: grip is weak 2: grip can be maintained with relatively large relative resistance	27. Grab paper			
0: the function cannot be performed 1: the pencil between the pads of the index finger and thumb can be held in place but not by light tugging 2: the pencil grips firmly by holding the pull	28. Pencil grip			

0: the function cannot be performed 1: a can can be held between the index finger and thumb but not after a pull 2: the can is held firmly after the pull.	29. Can grip			
0: the function cannot be performed 1: can hold tennis ball in place with ball grip but not after chuck 2: the tennis ball can be held firmly after the pull	30. Grab ball			
COORDINATION 0: marked tremor 1: light tremor 2: no tremor	31. Tremor			
0: pronounced or unsystematic dysmetria 1: slight or systematic dysmetria 2: no dysmetria	32. Dysmetria			
0: activity is more than 6 seconds slower that with the unaffected hand 1: between 2 and 5.9 seconds slower than with the unaffected hand 2: less than 2 seconds apart	33. Speed			
	Sum of points obtained			
		Partial score	#	/66 points

Dimension: Assessment of motor function in the lower limb

Dominio	Item	Ini. Val.	Interm. Val	Fin. Val.
REFLEXES 0: not obtained 2: are obtained	34. Achilles reflexes			
	35. Patellar reflexes			
FLEXOR SYNERGY (recumbent position supine) 0: cannot perform it at all. 1: perform the movement partially. 2: perform the movement completely	36. Hip flexion			
	37. Knee flexion			
	38. Ankle dorsiflexion			
EXTENSIONAL SYNERGY **(recumbent position side)** 0: cannot perform it at all. 1: perform the move partially. 2: perform the move completely	39. Hip extension			
	40. Hip adduction			
	41. Knee extension			
	42. Ankle plantar flexion			
MOTION COMBINING SYNERGIES (position sitting) 0: no movement active 1: from the slightly extended position, the knee can be flexed but not more than 90º. 2: knee flexion more than 90º	43. Knee flexion (bring the ankle back and under the chair)			
0: no movement active 1: incomplete active flexion (the heel should stay on the ground with the medial and lateral edges of the forefoot clear of the ground during dorsiflexion) 2: normal dorsiflexion (active full range of motion with heel on the ground)	44. Ankle dorsiflexion (raise the tip of the foot with the heel on the ground)			
MOVEMENTS WITHOUT SYNERGIES (in standing) 0: the knee cannot be flexed without hip flexion. 1: knee flexion begins without hip flexion but does not reach 90º or the hip begins to flex later in the movement.	45. Knee flexion (heel back kick)			

2: the knee is flexed more than 90º				
0: no active movement. 1: partial movement or with knee without extensión complete 2: full motion (full joint range in dorsiflexion with knee extended and heel on the ground)	46. Ankle dorsiflexion (raise the toe with the heel on the ground)			
REFLEXES (in position sitting) 0: at least 2 of the 3 reflexes are markedly hyperactive 1: a reflex is markedly overactive or at least 2 reflections are present 2: no more than one reflection is alive, and none is hyperactive	47. Reflexes in the lower limbs (score only if 4 points are obtained in the previous section)			
COORDINATION 0: marked tremor 1: light tremor 2: no tremor	48. Tremor			
0: pronounced or unsystematic dysmetria 1: slight or systematic dysmetria 2: no dysmetria	49. Dysmetria			
0: the activity is performed in more than 6 seconds slower than by hand does not affect 1: between 2 and 5.9 seconds slower than with the unaffected hand 2: less than 2 seconds apart	50. Speed			
	Sum of points obtained			
		Partial score	#	/34 points

Dimension: Assessment of balance

Dominio	Item	Ini. Val.	Interm. Val	Fin. Val.
0: do not sit without support 1: sits without support for a short time 2: sit without support for 5 minutes and adjust self posture	51. Sitting without support with feet suspended			
0: does not maintain the posture to avoid falling 1: partially holds the pose 2: maintains posture properly	52. Parachute reaction on the unaffected side			
0: does not maintain the posture to avoid falling 1: partially holds the pose 2: maintains posture properly	53. Parachute reaction on the affected side			
0: does not stand up 1: does not want important help from other person(s) 2: can be maintained for at least one minute with minimal or token assistance from another person	54. Standing with support			
0: does not stand up 1: standing 1 minute without oscillations 2: good balance (+1 minute safely)	55. Standing without support			
0: holds the position for 1-2 sec 1: balance 4-9 sec 2: balance -10 sec	56. Mono-standing on the leg does not affect			
0: holds the position for 1-2 sec 1: balance 4-9 sec 2: balance -10 sec	57. Mono-standing on the affected leg			
	Sum of points obtained			
		Partial score	#	/14 points

Dimension: Sensitivity

Dominio	Item	Ini. Val.	Interm. Val	Fin. Val.
Exteroceptive 0) Anesthesia 1) Hypoesthesia 2) Normal	58. Arm			
	59. Palm of the hand			
	60. Leg			
	61. Sole of foot			
Proprioceptive 0) No answer is correct 1) Diminished: ¾ of answers are correct 2) All the answers are correct	62. Shoulder			
	63. Elbow			
	64. Wrist			
	65. Fingers			
	66. Hip			
	67. Knee			
	68. Ankle			
	69. Toes			
	Sum of points obtained			
	Partial score		#	/24 points

Dimension: Joint range and joint pain

	Joint range 0: Just a few degrees of movement 1: Decreased passive mobility 2: Normal passive mobility				**Joint pain** 0: Pain in all ranges of motion and severe pain at the end of range of motion. 1: Mild pain 2: No pain			
Dimension	**Dominio**	**Val. Ini.**	**Val Int.**	**Val. Fin.**	**Dominio**	**Val. Ini.**	**Val Int.**	**Val. Fin.**
Shoulder	70. Abduction				71. Abduction			
	72. Flexion				73. Flexion			
	74. External rotation				75. External rotation			
	76. Internal rotation				77. Internal rotation			
Elbow	78. Flexion				79. Flexion			
	80. Extension				81. Extension			
Forearm	82. Pronation				83. Pronation			
	84. Supination				85. Supination			
Wrist	86. Flexion				87. Flexion			
	88. Extension				89. Extension			
Fingers	90. Flexion				91. Flexion			
	92. Extension				93. Extension			
Hip	94. Flexion				95. Flexion			
	96. Abduction				97. Abduction			
	98. External rotation				99. External rotation			
	100. Internal rotation				101. Internal rotation			
Knee	102. Flexion				103. Flexion			
	104. Extension				105. Extension			
Ankle	106. Dorsiflexion				107. Dorsiflexion			
	108. Plantar flexion				109. Plantar flexion			
Foot	110. Eversion				111. Eversion			
	112. Inversion				113. Inversion			
					Sum of points			
					Partial score		#	/ 44 points
					TOTAL score		#	/226

Ini. Val.: initial valoration; Interm. Val.: intermediate valoration; Fin. Val.: final valoration.

Motor Index

Score	Action/ Movement	Reality Virtual			Restriction and Induction of Movement			TF and TO habitual		
		Ini. Val.	Interm. Val.	Fin. Val.	Ini. Val.	Interm. Val.	Fin. Val.	Ini. Val.	Interm. Val.	Fin. Val.
Sitting patient 0: no movement 9: palpable contraction 14: perform movement but not full range vs gravity 19: full range of motion vs gravity but not vs resistance 25: movement vs resistance but less than contralateral 33: normal strength	Shoulder abduction									
	Elbow flexion Voluntary movement of 90º									
0: no movement 11: prehension starts 19: takes the cube but is not able to hold it vs gravity 22: he takes the cube and is able to hold it vs gravity but not vs resistance 26: take the cube overcomes gravity and resistance but is less than the contralateral 33: regular clamp	Grasp Hand: 2.5 cm cube between thumb and other fingers									
0: no movement 9: palpable contraction 14: perform movement but not full range vs gravity 19: full range of motion vs gravity but not vs resistance 25: movement vs resistance but less than contralateral 33: normal strength	Hip flexion									
	Knee extension									
	Ankle dorsiflexion									
Upper limb Index:1+2+3+(1)/100										
Lower limb index: 4+5+6+(1)/100										
Total motor index: (Motor Index of UL + Motor Index of LL/2)/100										

Ini. Val.: initial valoration; Interm. Val.: intermediate valoration; Fin. Val.: final valoration

Fine clamp quality test (Spanish version)

Score	Action/ Movement	Reality Virtual			Restriction and Induction of Movement			TF and TO habitual		
		Ini. Val.	Interm. Val.	Fin. Val.	Ini. Val.	Interm. Val.	Fin. Val.	Ini. Val.	Interm. Val.	Fin. Val.
0: inability to take the cube 1: Grab with your whole hand 2: Radial or tridigital clamp 3: Forefinger thumb clamp	1.4 cm 2									
	2.5 cm 2									
	3.1 cm 2									

Ini. Val.: initial valoration; Interm. Val.: intermediate valoration; Fin. Val.: final valoration.

LANGUAGE EVALUATION

Boston aphasia intensity scale (Spanish version)

		Reality Virtual			Restriction and Induction of Movement			TF and TO habitual		
Description of language features	**Score**	**Ini. Val.**	**Interm. Val.**	**Fin. Val.**	**Ini. Val.**	**Interm. Val.**	**Fin. Val.**	**Ini. Val.**	**Interm. Val.**	**Fin. Val.**
Absence of speech or listening comprehension	0									
Communication is made entirely from incomplete expressions. It requires inference, questions and guessing by the listener. The flow of information can be exchanged, it is limited and the weight of the conversation falls on the listener.	1									
The patient can, with the help of the examiner, have a conversation on familiar topics. There is frequent failure to express an idea, but the patient shares the weight of the conversation with the examiner.	2									
The patient can deal with virtually all problems of daily living, with little or no help. However, reduced speech and/or comprehension make conversation on certain types of topics extremely difficult or impossible.	3									
There is some obvious loss of speech fluency or ease of understanding with no significant limitation of the ideas delivered to their mode of expression.	4									
Minimal observable impairments in speech. The patient may present subjective difficulties that are not evident to the listener.	5									

Ini. Val.: initial valoration; Interm. Val.: intermediate valoration; Fin. Val.: final valoration.

EVALUATION OF SATISFACTION WHEN PERFORMING REHABILITATION THERAPY

Intrinsic Motivation Inventory (Spanish version)

Cuestionario de Evaluación de Tareas

	Reality Virtual			Restriction and Induction of Movement			TF and TO habitual		
Patient perception	**Ini. Val.**	**Interm. Val.**	**Fin. Val.**	**Ini. Val.**	**Interm. Val.**	**Fin. Val.**	**Ini. Val.**	**Interm. Val.**	**Fin. Val.**
Interest and satisfaction with treatment									
As he worked on the task he thought how much he enjoyed it.									
I found the task very interesting.									
Doing homework was fun.									
I really enjoyed doing homework.									
I thought the homework was very boring (R).									
I seemed the task very interesting.									
I would describe the task as very pleasant.									
Perception of competence (of the patient versus the treatment)									
I think I'm very good at this task.									
I think I did very well in this activity, compared whit other									
I am satisfied with my performance in this task.									
I felt quite skilled at this task.									
After working on this task for a while, I felt quite competent.									
Effort and importance of treatment									
I felt it was my choice to do the task.									
I didn't really have the option to do task (R).									
I felt like I was doing what I wanted to do while working on the assignment.									
I felt that I had obligation to do task (R)									
I did the homework because I had no other option (R).									
Stress or strain (caused by treatment)									
I didn't feel nervous about doing task (R).									
I felt tense while doing task.									
I felt relaxed while doing task (R).									
I was anxious while doing task.									
I felt stressed while doing task.									

Ini. Val.: initial valoration; Interm. Val.: intermediate valoration; Fin. Val.: final valoration.

ANNEX 3. Informed consent letter

MEXICAN SOCIAL SECURITY INSTITUTE
EDUCATION AND RESEARCH UNIT AND HEALTH POLICIES
HEALTH RESEARCH COORDINATION
INFORMED CONSENT LETTER
(ADULTS)

LETTER OF INFORMED CONSENT FOR PARTICIPATION IN RESEARCH PROTOCOLS

Study name:	EFFECT OF DIFFERENT THERAPEUTIC MODALITIES SUPPORTED BY VIRTUAL REALITY OR MOVEMENT RESTRICTION AND INDUCTION COMPARED TO USUAL PHYSICAL AND OCCUPATIONAL THERAPY ON MOTOR RECOVERY OF PARETIC LIMBS IN PATIENTS WITH CEREBRAL VASCULAR EVENT.
External sponsor (if applicable):	Does not apply
Place and date:	Mexico City, march 2017
Número de registro:	**R -2016 – 3702 - 44**
Justification and objective of the study:	The investigator has informed me that the present study is necessary because the cerebrovascular event in Mexico causes neurological disability, such as the person who suffers from it being unable to speak well or not walk. I understand that these problems have repercussions on the economic aspect of hospitals due to the rehabilitation that is usually long and also to the patient, due to transfers and problems with his autonomy. The therapies that will be applied in this study have proven their usefulness in patients with a vascular event and it has been explained to me that the objective of this study is to verify that it can also be performed routinely in this rehabilitation unit with good results and to know how much is that the IMSS could be saved in the management of the sequelae of the vascular event and also patients like me, in my routine activities, medical consultations and transportation.
Procedures:	I understand that if I participate, by chance I will be assigned to and perform one of the two neurorehabilitation therapies or the usual therapy (physical and occupational) in this unit. If it is in the movement restriction and induction therapy, they will immobilize my healthy arm for about 5 hours a day, so that I can carry out activities with my diseased arm and with this it is possible that there is improvement in my brain with damage. If it is in virtual reality therapy, I will be fitted with an electronic device that will allow me to carry out activities with the arm that I am not moving and see myself on a screen and that could also help me regain mobility with an effect on my injured brain. It has been explained to me that the physical and occupational therapy that is normally carried out in this unit also allows improvement of motor problems related to the brain event like mine, because in fact it is the therapy that has been carried out for a long time and has good results. . So I understand that any of the 3 procedures can help me in recovery, but you want to know which one is better.
Potential risks and discomfort:	The doctor has explained to me that there is no real risk from performing therapy. Although I can feel some discomfort from having my healthy arm immobilized and feeling somewhat clumsier; Virtual reality is like a video game and in it you will most likely not feel discomfort, as well as in the usual therapies. Other discomforts or risks are not related to the therapy, but to my underlying problem or illnesses that I have suffered from before, such as high blood pressure or diabetes. I know that due to my age or my embolism I could have accidents or fall, and that this would not necessarily be related to this study, so I must be accompanied and I must carry out the activities at home with a person who supports me to avoid accidents, but that does not help me in the exercises.
Possible benefits you will receive from participating in the study:	I understand that the 3 types of therapy have been shown to improve the movement sequelae secondary to my vascular event, but it is possible that one of them is better than another, but ultimately the rehabilitation that I receive will help me in the recovery of my motor skills if the I do as they tell me and reinforce them at home. I have been told that, in addition to the improvement from the therapy, at the moment there is no greater benefit, since the differences are hardly being evaluated. In the future I will be contacted by phone and it is possible that I will be offered a new reinforcement with the therapy that has shown the greatest benefits.
Information about results and treatment alternatives:	It has been explained to me that if I so wish, in the end they will inform me of the results of the investigation, but that I myself will see my evolution with the therapies. In addition to rehabilitation, other

	treatments with drugs or different alternatives have not shown better results, which is why they are not used in rehabilitation units.
Participation or withdrawal:	I know that my participation is voluntary, so I can withdraw from the study at any time I want, without affecting the care I receive from the institute and I will continue to receive care with my treating physician.
Privacy and confidentiality:	I have been assured that my name will not be mentioned, nor will I be identified in any other way, in this work or any derivative of it, in publications or presentations in places where the results of different scientific investigations are disseminated.

In case of collection of biological material (if applicable):

☐	Does not authorize the sample to be taken.
☐	Yes, I authorize the sample to be taken only for this study.
☐	Yes, I authorize the sample to be taken for this study and future studies.

Availability of medical treatment in beneficiaries (if applicable):	Does not apply
Benefits at the end of the study:	Due to the type of therapy that I will receive, my recovery may be different from that of other patients, but I will continue my care by the IMSS until my maximum benefit.

In case of doubts or clarifications related to the study, you can contact:

Responsible Investigator:	María del Carmen Rojas Sosa; registration tag: 7267339; Southern Delegation, CDMX.; Phone: 55 2109 0980
Collaborators:	Juan Garduño Espinosa; Research Directorate; Children's Hospital of Mexico; juan.gardunoe@gmail.com Jose Antonio Zarate; registration tag: 5570263; UMFR siglo XXI; Phone: 1373 1675 Norma de la Rosa Peña; registration tag: 99381087; UMFR siglo XXI; Phone: 2915 1185 Cindy Cueva Sierra; registration tag: 99388872; UMFR siglo XXI; Phone: 6073 1827 Alma Patricia Ortiz Islas; registration tag:; UMFR siglo XXI; Phone: 7048 2677. Evaristo Hinojosa Medina; registration tag: 5552648; Southern Delegation, CDMX, IMSS.; Phone: 5634 5259 José Luis Olvera Gómez; registration tag: 8379491; Southern Delegation, CDMX, IMSS; Phone: 1849 6027

In case of doubts or clarifications about your rights as a participant, you can contact: IMSS CNIC Research Ethics Commission; in Avenida Cuauhtémoc 330 4th floor Block “B” of the Congress Unit, Colonia Doctores. México, D.F., PC 06720. Phone (55) 56 27 69 00 extension 21230, E-mail: comision.etica@imss.gob.mx

Name and signature of the subject	Name and signature of the person obtaining the consent
Testigo 1	Testigo 2
Name, address, relationship and signature	Name, address, relationship and signature

This format constitutes a guide that must be completed according to the characteristics of each research protocol, without omitting relevant information from the study.

Clave: 2810-009-013

ANNEX 4.

INFORMATION COLLECTION SHEET

Folio No.: _____

Phone: _____ Address: _____

Name: _____ Affiliation: _____

Age: _____ Sex: _____ Treatment: _____ Date: _____

Diagnosis: _____

Type of CVE: Ischemic: ( ) Hemorrhagic: ( )

Affected side: Right: ( ) Left: ( )

Clinical summary:

nPPA:

Alcoholism: Yes ( ) No ( ) Smoking: Yes ( ) No ( )

Schooling: Yes ( ) No ( ) Works: Yes ( ) No ( )

Specify:_____.

Requires Disability: Yes ( ) No ( ) Specify:_____.

PPA: DM ( ) HTA ( ) Other: ( ) Specify:_____.

Neurological diseases: Yes ( ) No ( ) Specify: _____.

Psychiatric illnesses: Yes ( ) No ( ) Specify:_____.

AP:_____

_____.

Physical exploration:

_____

_____.

Treatment group: _____

Modified Ashworth scale

Segment	Ini. Val.	Interm. Val	Fin. Val.
Superior limb			
Lower limb			

Ini.Val.= Initial valoration;
Interm.Val.= Intermedia valoration;
Fin.Val.= Final valoration

Brunnstrom scale

Segment	Ini. Val.	Interm. Val	Fin. Val.
Superior limb			
Lower limb			

Ini.Val.= Initial valoration;
Interm.Val.= Intermedia valoration;
Fin.Val.= Final valoration

Appendix 1

TABLA 13.A. **Tamaño de la muestra por grupo para comparar dos medias**

α unilateral = / *α bilateral =*	*0,005* / *0,01*			*0,025* / *0,05*			*0,05* / *0,10*		
β = / *E/S**	*0,05*	*0,10*	*0,20*	*0,05*	*0,10*	*0,20*	*0,05*	*0,10*	*0,20*
0,10	3.563	2.977	2.337	2.599	2.102	1.570	2.165	1.713	1.237
0,15	1.584	1.323	1.038	1.155	934	698	962	762	550
0,20	891	744	584	650	526	393	541	428	309
0,25	570	476	374	416	336	251	346	274	198
0,30	396	331	260	289	234	174	241	190	137
0,40	223	186	146	162	131	98	135	107	77
0,50	143	119	93	104	84	63	87	69	49
0,60	99	83	65	72	58	44	60	48	34
0,70	73	61	48	53	43	32	44	35	25
0,80	56	47	36	41	33	25	34	27	19
0,90	44	37	29	32	26	19	27	21	15
1,00	36	30	23	26	21	16	22	17	12

* E/S es el tamaño estandarizado del efecto, calculado como E (tamaño esperado del efecto) dividido por S (desviación estándar de la variable de desenlace). Para estimar el tamaño de la muestra, se busca el *tamaño estandarizado del efecto* y se cruza el valor encontrado con los correspondientes a los valores especificados de α y β para hallar el tamaño requerido de la muestra en cada grupo.