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Effectiveness and Safety of Robotic Mechanotherapy with FES and VR in Restoring Gait and Balance in the Acute and Early Rehabilitation Period of Ischemic Stroke: Prospective Randomized Comparative Study

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ABSTRACT

INTRODUCTION. Impaired gait and balance after a stroke significantly affect patients' daily activities and quality of life. Robotic mechanotherapy and virtual reality technologies are actively studied and used to restore lower limb muscle strength, balance and gait pattern.

AIM. To assess the effectiveness and safety of rehabilitation using robotic mechanotherapy (exoskeleton) with functional electrical stimulation (FES) and virtual reality (VR) technology with plantar stimulation in the restoration of gait and balance disorders in patients in acute and early recovery periods of ischemic stroke.

MATERIAL AND METHODS. Men and women aged 39 to 75 with ischemic stroke in acute and early recovery periods with gait impairment and lower limb paresis from 0 to 4 MRC scores. The patients were randomized using the envelope method into 4 groups: Group 1 (33 people) — exoskeleton with FES, Group 2 (32 people) — combined application of robotic mechanotherapy with FES and VR with plantar stimulation, Group 3 (35 people) — VR with plantar stimulation, Control group (30 people) — conventional training.

RESULTS. Group 2 and 3 had significantly greater increases in muscle strength in the hip extensors, tibia flexors and flexors of the foot compared to the control group. Patients in the main groups also had a significant improvement in Tinetti Walking and balance Scale at follow-up. The analysis of the stabilometry results on the first and last day of the study revealed a decrease in the area of the statokinesiogram in the main groups both in the intragroup comparison and in the comparison with the control group.

DISCUSSION AND CONCLUSION. Exoskeleton gait training with FES and exercises on a VR with plantar stimulation, as well as combined use of these techniques allowed to achieve better recovery of lower limb muscle strength, walking functions and balance in patients in acute and early rehabilitation periods of stroke. This is probably due to the large number of steps or their imitation performed by the patient during rehabilitation sessions, which leads to activation of neuroplasticity and better recovery. The study demonstrated the safety and efficacy of an exoskeleton interval training system that prevents the development of orthostatic hypotension in patients in the acute period of ischemic stroke.

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KEYWORDS: robotic mechanotherapy, functional electrical stimulation, virtual reality, medical rehabilitation, neurorehabilitation, stroke, gait rehabilitation, balance rehabilitation.

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Опыт применения технологий роботизированной механотерапии с функциональной электростимуляцией и виртуальной реальности в восстановлении ходьбы и равновесия в остром и раннем реабилитационном периоде ишемического инсульта

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РЕЗЮМЕ

ВВЕДЕНИЕ. Нарушение ходьбы и равновесия после перенесенного инсульта в значительной степени влияют на повседневную активность и качество жизни больных. Роботизированная механотерапия и технологии виртуальной реальности активно изучаются и используются для восстановления силы мышц нижних конечностей, баланса и паттерна ходьбы.

ЦЕЛЬ. Исследование эффективности и безопасности реабилитационных программ с применением технологии роботизированной механотерапии (экзоскелет) с функциональной электростимуляцией (ФЭС) и технологии виртуальной реальности (ВР) с подошвенной стимуляцией в восстановлении нарушений ходьбы и у пациентов в остром и раннем восстановительном периодах ишемического инсульта.

МАТЕРИАЛЫ И МЕТОДЫ. В исследование были включены мужчины и женщины в возрасте от 35 до 75 лет с впервые возникшим ишемическим инсультом в остром и раннем восстановительном периоде. Выраженность пареза нижних конечностей составляла от 0 до 4 баллов по MRC. Пациенты были распределены случайным порядком в 4 группы: группа 1 (33 пациента) — применение экзоскелета с ФЭС, группа 2 (32 пациента) — комбинированное применение экзоскелета с ФЭС и ВР с подошвенной стимуляцией, группа 3 (35 пациентов) — применение ВР с подошвенной стимуляцией, контрольная группа (30 больных).

ОБСУЖДЕНИЕ И ЗАКЛЮЧЕНИЕ. Восстановление ходьбы в экзоскелете с ФЭС и занятия на тренажере ВР с подошвенной стимуляцией, а также комбинированное применение этих методик позволили добиться лучшего восстановления силы мышц нижних конечностей, функций ходьбы и равновесия у пациентов в остром и раннем восстановительном периодах ишемического инсульта.

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INTRODUCTION

According to WHO, stroke is recognized as the second leading cause of death among cardiovascular diseases after myocardial infarction [1,2]. In adults, stroke is the main factor causing long-term disability. The result of the population aging and an increase in the efficiency of medical care was an annual increase in the number of patients with the consequences of a stroke, especially hemiplegia [3]. Gait disorder is considered the most common in the strength decrease in lower extremities. Up to 80 % of patients with ischemic stroke have an altered walking pattern and 70 % have episodes of falling during the first year after disease onset [4]. The main statolocomotor disorders are gait asymmetry, increased muscle tone of the lower extremities and balance disorders [3]. In the acute stroke, spasticity and imbalance contribute most to the restriction of daily activity [1]. It is known that there are processes of self-recovery of muscle strength, which can be completed in 2–3 months. However, the pathological walking pattern (impairment of the neural mechanism of movement control, occurrence of pathological synergies, leading to improper muscle activation in movement and at rest, incomplete hip extension, circumferential leg movement, improper transfer of the center of gravity) [5] can become anchored, therefore, early rehabilitation with the formation of correct movement stereotypes is crucial for optimizing human functioning after a stroke [6]. Correction of the resulting neurological deficit occurs in the first months after a stroke, but some functions can be actively restored during the first year [7,8].

In the last 15 years, robotic mechanotherapy (RM), in particular exoskeletons, has become actively studied and introduced into clinical practice, presenting an alternative to classical conventional rehabilitation [9,10]. There is evidence that the use of an exoskeleton allows not only muscle strength recovery, but also contributes to the improvement of cognitive functions in stroke patients [11,12]. This phenomenon is explained by the active production of myokines during walking, which, penetrating through the blood-brain barrier, activate the processes of neuroplasticity and neurogenesis. One of the latest trends is the combination of functional electrostimulation (FES) with robotic orthoses, which allows achieving greater efficiency in the reconstruction of walking pattern [13,14].

The use of virtual reality (VR) technology is another recognized method for restoring muscle strength after a stroke [7,15]. However, most of the data in the clinical guidelines focus on upper limb paresis. According to one systematic review on the role of virtual reality in post-stroke rehabilitation, this technique slightly improves walking speed (by 0.09 m/s) [16]. There are also sporadic data on the combined and combined application of these techniques, but this direction needs further study.

AIM

The main purpose of this clinical trial was to study the effect of RM with FES and VR with plantar stimulation on gait and balance recovery in patients in the acute and early rehabilitation period of ischemic stroke. The main objectives were to prove the safety and effectiveness of the use of innovative technologies, as well as to create a program of motor rehabilitation using these methods.

MATERIALS AND METHODS

The clinical protocol of the study was approved by the local ethical committee of Moscow Centre for Research and Practice in Medical Rehabilitation, Restorative and Sports Medicine of Moscow Healthcare Department, protocol 1 date 17.03.2022 and registered at ClinicalTrails.gov ID: NCT05423626. Before starting the study, all patients received detailed information about the rehabilitation technologies applied and signed informed agreement. The inclusion criteria were as follows: men and women aged 18 to 75 years with established diagnosis of ischemic stroke in acute (up to 3 weeks) and early recovery (up to 6 months) periods with walking impairment, lower limb paresis from 0 to 4 MRC scores. An important criterion was the preservation of cognitive functions (at least 27 points on the MoCA) and a Rankin scale score of 3 to 4, the weight of the patients was no more than 100 kg, and the height varied from 160 to 190 cm, this was due to the technical characteristics of the exoskeleton. The exclusion criteria were as follows: significant muscle spasticity (more than 3 score MAS), bone and joint diseases or serious diseases affecting organ function, expressed vegetative dysreflexia, uncontrolled arterial hypertension visual or hearing disorders, unable to cooperate with the study. All patients underwent physical and neurological examination on admission and discharge. The degree of lower limb paresis was assessed according to the five-point MRC scale, National Institutes of Health Scale (NIHSS). Spasticity was determined using the modified Ashworth scale (MAS). Functional independence was examined using the modified Rankin Scale (mRS) and the Rivermead Mobility Index. Gait and balance impairment were assessed using the Tinetti Scale. Diagnostic stabilometry was also performed on admission and at discharge. The patients were randomized using the envelope method into 4 groups:

- Group 1 (robotic mechanotherapy with FES) — in addition to basic therapy, patients received 10 procedures of walking in ExoAtlet I exoskeleton with FES, 5 times a week, the duration of medical rehabilitation course — 12–14 days. The duration of the procedure was 30 minutes.
- Group 2 (combined application of robotic mechanotherapy with FES and VR with plantar stimulation) — besides basic therapy, the patients received 10 procedures on Virtual reality simulator with sole stimulation (ReviVR), the duration of one procedure was 30 minutes, 5 times a week, followed by training in ExoAtlet I exoskeleton with FES after 90 minutes. Duration of motor activity during one session was 30 minutes, 5 times a week, duration of medical rehabilitation course was 12–14 days.
- Group 3 (VR technologies with plantar stimulation) — besides basic therapy patients received 10 procedures on ReviVR simulator, 5 times a week, the duration of medical rehabilitation course was 12–14 days. The duration of one procedure was 30 minutes.
- Control group — restoration of walking and balance was carried out with the help of conventional training (individual or group therapeutic exercise classes), 5 times a week, the duration of the medical rehabilitation course — 12–14 days.

Exoskeleton training duration, according to the patient's condition, up to 1 hour (taking into account the time for exoskeleton readjustment and patient positioning). Measurement of pulse, pressure and saturation in the preparatory, main and final parts. The length of time in the upright position depends on the patient's condition. In patients in the acute period of stroke, a pause for rest in a sitting position is made every 10 minutes of training. Transition to the formation of subsequent skills is recommended after mastering the skills of the previous procedure. Starting from the 4th session, patients are switched to continuous walking. The total duration of the VR procedure is 30 minutes. Before the procedure, BP and HR are measured and the size of pneumatic cuffs on the feet is selected. After briefing the patient and selecting the virtual environment and optimal speed of movement in VR, VR glasses are fitted. Next, rehabilitation exercises are performed for 15 minutes. The patient moves in the virtual environment, receiving visual, auditory and tactile cues that form the correct walking pattern. At the end of the exercise, the VR goggles are disassembled. Then BP and HR are measured and information about the feeling and sensations during

Table 1. Characteristics of groups on admission

Feature	Group 1, *n* = 33	Group 2, *n* = 32	Group 3, *n* = 35	Control group, *n* = 30	*p*
Age (years)	62.5 ± 7.7	57.4 ± 8.2	60.6 ± 7	62 ± 6.5	> 0.05
Stroke onset time (days)	15 [12; 2 4]	21 [13; 91]	15 [12; 67]	17.5 [12; 67.5]	> 0.05
BMI	26 [23.9; 29.9]	28 [25.7; 29.4]	27.7 [24; 30.4]	27.5 [25; 29.3]	> 0.05
Systolic BP	130 [120; 132.5]	130 [122; 139]	130 [120; 140]	130 [120; 130]	> 0.05
MRC int.	3.66 [2.5; 4]	3.44 [2.38; 4]	3 [2.66; 4]	3.5 [2.9; 4]	> 0.05
MAS int.	0 [0; 1]	0.33 [0; 1]	0 [0; 1]	0 [0; 1]	> 0.05
mRS	3 [3; 4]	3 [3; 3]	3 [3; 4]	3 [3; 4]	> 0.05
Rivermead Mobility Index	7 [5; 8]	7 [7; 9.75]	7 [7; 9]	7 [7; 7]	> 0.05
Tinetti Scale balance	6 [4; 9]	8 [5.25; 9]	7 [4; 9]	6 [3.75; 9]	> 0.05
Tinetti Scale walking	4 [2; 5.5]	5 [4; 6]	4 [3; 6]	5 [2; 7]	> 0.05
MoCA	28 [27; 28]	28 [28; 28]	28 [27; 28]	27.7 [27; 28]	> 0.05

Note: *MRC int. — integral index of strength in all studied muscles; MAS int. — integral index of muscle tone in all studied muscles.*

the procedure is recorded. Basic therapy included laser therapy, magnetic therapy, and therapeutic massage of the lower extremities. The control group additionally used electrical stimulation of the affected limb. All basic therapy was performed according to protocols from the National Physical Therapy Manual [17]. A system of interval training was developed for groups using RM with FES, which consisted in dividing the exercise into 10-minute intervals with mandatory 5-minute breaks, which the patient spent in a sitting position. This approach allowed the patients to adapt faster to physical activity and achieve a distance of 1500–1800 steps per exercise, as well as to avoid orthostatic reactions during the exercise.

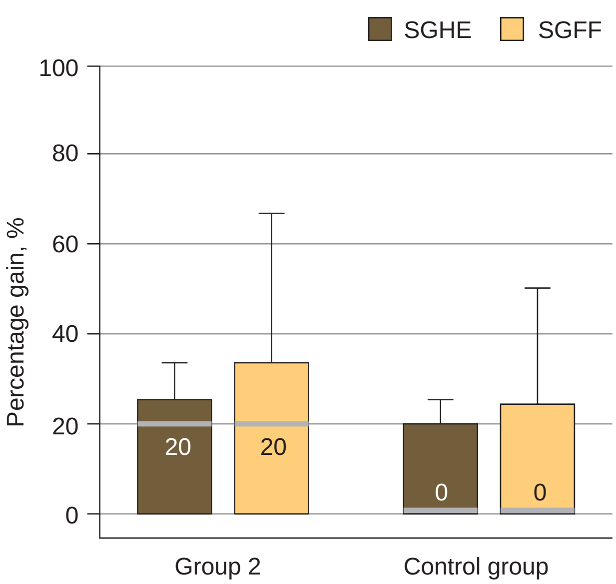

Fig. 1. Comparison of strength gains in the hip extensors and foot flexors in groups 2 and 4

Note: *SGHE — strength gain in hip extensors; SGFF — strength gain in the foot flexors.*

Statistical analysis

Statistical analysis to assess the effectiveness of rehabilitation in different groups was performed by comparing initial and final data, as well as changes in the main and additional neurological scales before and after the rehabilitation course. Nonparametric tests (Wilcoxon test, Mann-Whitney test, Kruskal-Wallis test) were used to reveal statistically significant changes. The data were checked for normality using the Kolmogorov-Smirnov test. Spearman correlation analysis was used to determine the mutual influence of the variables. Results are presented as mean values with standard deviation, medians with the 25th and 75th percentiles.

RESULTS

The study included 130 patients (38 women and 92 men), mean age was 60.6 ± 7.6 years. Patients were divided into a main (group 1 — 33 patients, group 2 — 32 patients, group 3 — 35 patients) and a control group (30 patients). The comparative characteristics of the groups are shown in Table 1.

On admission, the groups were comparable for all parameters. On examination after the course of treatment, patients in all groups had comparable values of absolute strength indices for all muscle groups. Group 2 had significantly greater increases in muscle strength in the hip extensors and flexors of the foot compared to the control group (Figure 1).

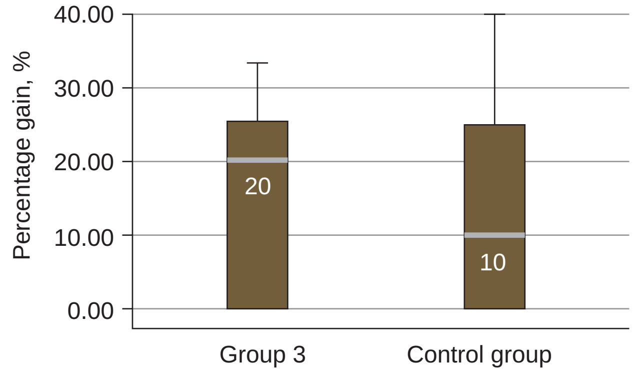

Fig. 2. Comparison of hip extensor strength gains in groups 3 and 4

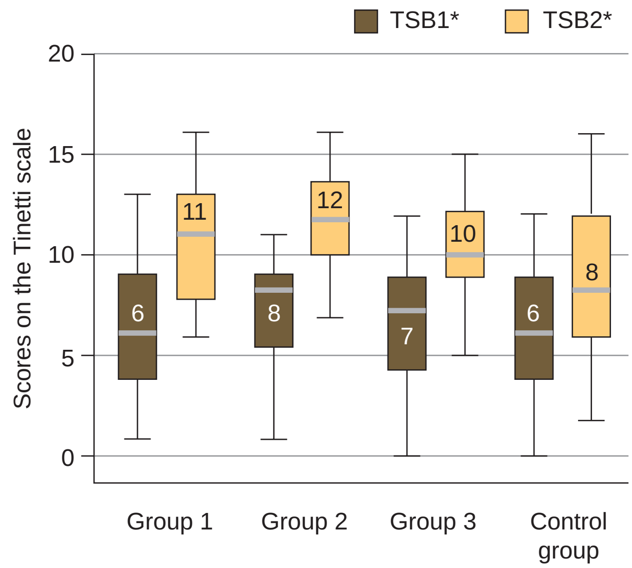

Fig. 3. Comparison of balance values on the Tinetti scale at admission and discharge in the main and control groups
***Note:** TSB1* — Tinetti scale balance value at admission; TSB2* — Tinetti Scale balance value at discharge.*

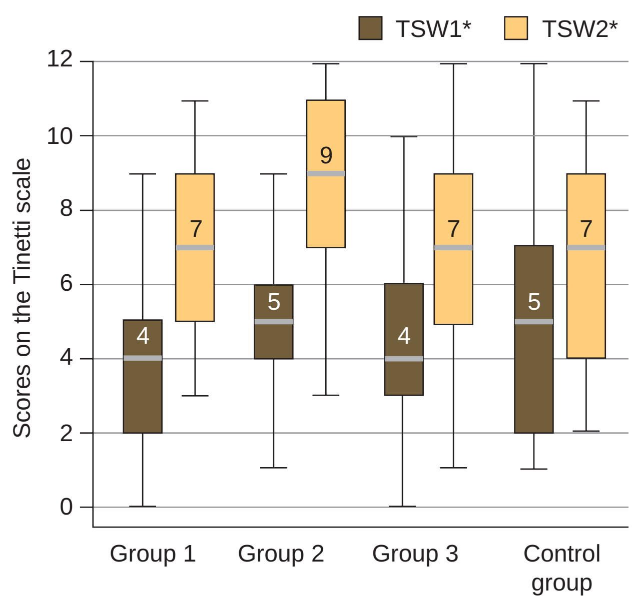

Fig. 4. Comparison of Tinetti Walking Scale values on admission and discharge in the main and control groups
***Note:** TSW1 — Tinetti Walking Scale value at admission; TSW2 — Tinetti Walking Scale value at discharge.*

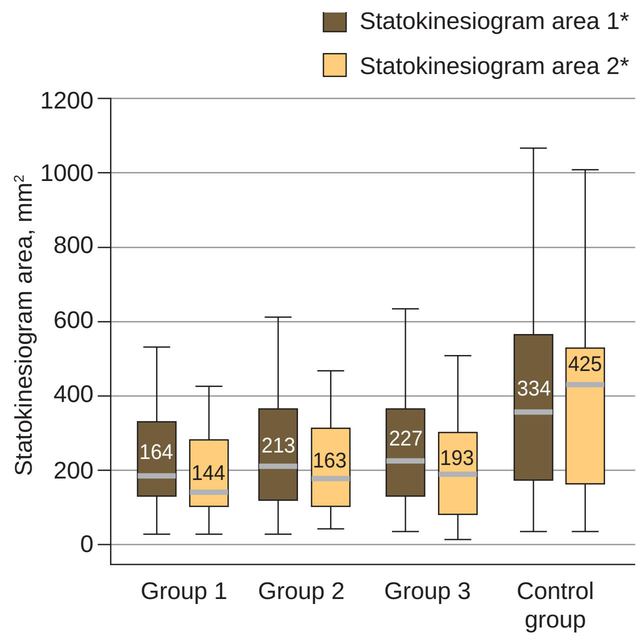

Fig. 5. Comparison of the dynamics of statokinesiogram area in the main groups and the control group on the first and the last day of the study
***Note:** Statokinesiogram area 1* is the area of the statokinesiogram on admission; statokinesiogram area 2* — statokinesiogram area at discharge.*

There was significantly more growth in the tibia flexors in the VR technology group compared to the control group (Figure 2).

Patients in the main groups also had a significant improvement in balance on the Tinetti Scale (Kruskal-Wallis test, p = 0.606 vs 0.007) at follow-up (Figure 3). However, no difference was found when comparing between the main groups.

In the Tinetti Walking Scale assessment, patients in the combined VR and RM with FES group achieved better results both when compared to the control group (Kruskal-Wallis test, p = 0.314 vs 0.023) (Figure 4), and to the main groups (Mann-Whitney test, group 2 vs group 1 p = 0,028, group 2 vs group 3 p = 0,048, group 2 vs control group p = 0,001).

The analysis of the stabilometry results on the first and last day of the study revealed a decrease in the area of the statokinesiogram in the main groups both in the intragroup comparison and in the comparison with the control group. In the control group, there was an increase in the values of this index (Figure 5).

DISCUSSION AND CONCLUSION

VR technologies and robotic mechanotherapy have been used in motor rehabilitation after stroke for the past 15 years. National guidelines around the world mention these approaches to the restoration of walking and balance in one way or another, but there are no clear criteria for the severity of neurological symptoms and the timing of the application of these technologies [18]. At present, there is a lack of sufficient data proving the superiority of RM or VR over conventional (traditional) methods of gait and balance restoration [18]. The main advantage of training in an exoskeleton is considered to be the possibility of achieving a large number of correct walking cycles. On the one hand, these trainings help to restore the physiological gait pattern — the correct weight distribution and hip extension of the affected limb. On the other hand, the patient performs about 1500–1800 steps per workout, it contributes to myokine production and increases afferent innervation from the lower extremities, which leads to activation of neuroplasticity [19]. When using the ReviVR, walking is induced by plantar stimulation combined with the projection of movement in a virtual reality helmet. During these trainings proprioceptive stimulation is significantly increased in combination with simulation of movement in the virtual environment without the risk of falling.

According to the results of the study, the use of VR technology and RM with FES demonstrated its effectiveness and safety in restoring muscle strength of the lower extremities. The VR group and the combined technology group showed a significantly better increase in lower limb muscle strength compared to the control group. Moreover, Group 2 achieved statistically significant strength gains in the hip extensors and foot flexors, the main muscles involved in the step cycle. Patients in all main groups achieved a significant improvement in balance according to stabilometry data. Improvement of support function was directly related to recovery of gait and general stability, which was confirmed by the results of the motor performance evaluation scale (Tinetti Scale). After the course of rehabilitation, the patients in Group 2 were able to walk at a faster pace and walk a greater distance compared to the other groups.

An important achievement was the creation and testing of a system of interval training in an exoskeleton with FES, which demonstrated its safety and effectiveness in reducing the risks of orthostatic reactions, as there were no adverse events during the entire study. Also, patients reached the required distance of 1500–1800 steps in 3–4 training sessions. When comparing with the results of other studies on the effect of robotic mechanotherapy on gait recovery after a stroke [20–26], the small number of patients both in the main groups and the practical absence of control groups is immediately noted. Masafumi M. [20] — 10 patients in the main group, no control group; Tan C.K. [21] — 8 patients in the main group, absent of control group; Molteni F. [22] — 12 patients in acute stroke group and 8 patients with consequences of cerebral circulation disorder, no control group; in Murray S.A. [23] and Lifang Li [24] 3 patients each without control groups, in the study of Hassan M. [25] included 5 patients. Only in the study of Jayaraman A. [26] study, 27 patients were included in the main and control groups. Also, the vast majority of studies included patients with both ischemic and hemorrhagic stroke [20–26]. Practically all researchers note high efficiency of RM use in gait recovery, except Hassan M., in whose study patients had increased asymmetry and desynchrony of step after HAL use. This can be explained by the presence of a robotic orthosis only on the affected side and the absence of FES, which has proven to be an effective method to restore synchronous contraction of the lower limb muscles. In the Jayaraman A. study, patients in the main group showed an increase in muscle strength in the lower extremities, and the authors attribute this to the greater number of steps walked during the day, including per exoskeleton training, compared with the control group (4,100 vs 3,000 steps per day). It is worth noting that heterogeneity in the etiology and localization of stroke, can greatly affect the rehabilitation process. For example, a patient with a subarachnoid hemorrhage differs from a patient with a hemispheric ischemic stroke, including the amount and intensity of physical activity they are able to perform. Similarly, stem stroke differs from hemispheric in the presence of more pronounced coordinator and ataxic abnormalities. Homogeneity and sample size is a significant strength of our study. Also, there are practically no studies comparing effectiveness of RM and VR technologies with traditional methods of walking and balance restoration in patients with ischemic stroke, as well as their cross-sectional comparison and comparison with the group of combined application.

Thus, combining robotic mechanotherapy with FES and VR technology with plantar stimulation during rehabilitation allows to achieve a significant improvement in gait and balance, as well as restoration of lower limb muscle strength. Further studies are required to investigate the long-term results of these technologies. It is likely that an increase in the number of procedures, as well as repeated rehabilitation cycles will contribute to the improvement of motor functions. It is possible that the results achieved will trigger the activation of neuroplasticity and contribute to a fuller recovery of patients in the future.

ADDITIONAL INFORMATION

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Ethics Approval. The authors declare that all procedures used in this article are in accordance with the ethical standards of the institutions that conducted the study and are consistent with the 2013 Declaration of Helsinki. The study was approved by the Local Ethics Committee of the Moscow Centre for Research and Practice in Medical Rehabilitation, Restorative and Sports Medicine of Moscow Healthcare Department, Protocol No. 1 dated 17.03.2022.

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