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Actuality of the use of the "OSNOVA" device in remote rehabilitation

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Abstract

The purpose of the study: is to investigate the efficiency of the developed physical rehabilitation program in the late rehabilitation period after ischemic stroke with a personalized approach with the priority use of the "OSNOVA" device for the restoration of locomotor functions.

Material & Methods: to implement a physical rehabilitation program in the late rehabilitation period after ischemic stroke with a personalized approach with the priority use of the "OSNOVA" device for the restoration of locomotor functions, 10 patients diagnosed with ischemic stroke in the late rehabilitation period after undergoing sanatorium treatment were involved. Because the patients differed in pathogenesis (flaccid and spastic paralysis, left or right-sided), a personalized physical rehabilitation program was applied to each patient, but with elements of correction depending on the patient's dynamics. All participants signed an informed consent form to participate in the study. The study used general and clinical methods of examination (medical history, patient examination), the NIHSS (National Institutes of Health Stroke Scale) scale, which allows an objective approach to the patient's condition after a stroke and assesses neurological status, and the MMSE (Mini Mental State Examination) scale, which assesses mental state and cognitive function. Also, to implement the developed program, a device for restoring locomotor functions – "Osnova" – was developed.

Results: a program of physical rehabilitation in the late rehabilitation period after ischemic stroke with a personalized approach with the priority use of the device "OSNOVA" was developed, which was conducted for three weeks and included three stages and the volume of training hours – 90. A "success diary" was introduced to motivate and monitor the workload during training. The data obtained showed that the average Barthel scale score is 77.1 against the initial value of 64. It should be noted that the scores increased by 17%. The NIHSS scale is 13.9 against the initial value of 10.1. We note that the scores have increased by 27%.

Conclusions: the results obtained showed positive dynamics, but the development of a standard rehabilitation protocol is an open question, as there is currently insufficient data to determine the optimal duration of procedures and their intensity.

Key words: remote rehabilitation, ischemic stroke, physical rehabilitation, digital technologies, "OSNOVA" device.

Актуальність використання апарату «ОСНОВА» в дистанційній реабілітації

Мета: дослідити ефективність розробленої програми фізичної реабілітації в пізньому реабілітаційному періоді після ішемічного інсульту з персоналізованим підходом при пріоритетному використані пристрою «ОСНОВА» для відновлення локомоторних функцій.

Матеріали та методи: для впровадження програма фізичної реабілітації в пізньому реабілітаційному періоді після ішемічного інсульту з персоналізованим підходом при пріоритетному використані пристрою «ОСНОВА» для відновлення локомоторних функцій були залучені 10 пацієнтів з діагнозом – ішемічний інсульт, в пізньому реабілітаційному періоді після проходження санаторно-курортного лікування. Через те що пацієнти відрізнялися патогенезом (млявий і спастичний параліч, лівобічний або правобічний), до кожного була застосована персональна програма фізичної реабілітації, але з елементами корегування в залежності від динаміки пацієнтів. Усі учасники підписали форму поінформованої згоди на участь у дослідженні. У досліджені використовували загальні та клінічні методи обстеження (збір анамнезу життя, збір анамнезу хвороби, огляд пацієнта), шкала NIHSS (National Institutes of Health Stroke Scale) – дозволить об'єктивно підходити до стану хворого після інсульту і проводити оцінку неврологічного статусу та шкала MMSE (Mini Mental State Examination) – оцінки психічного стану та оцінки когнітивних функцій. Також для реалізації розробленої програми розробили пристрій для відновлення локомоторних функцій – «Основа».

Результати: розроблена програма фізичної реабілітації в пізньому реабілітаційному періоді після ішемічного інсульту з персоналізованим підходом при пріоритетному використані пристрою «ОСНОВА», яка проводилась протягом трьох тижнів і включала в себе три етапи та об'ємом тренувальних годин – 90. Впроваджено «щоденник успіху» для мотивацій та спостереженням за навантаження під час занять. Отримані даним показали, що середній показник по шкалі Бартела становить – 77,1 проти початкового значення – 64. Відмічаємо, що показники підвищились на 17%. По шкалі NIHSS – 13,9 проти початкового значення – 10,1. Відмічаємо, що показники підвищились на 27%.

Висновки: отримані результати дали позитивну динаміку, але розробка стандартного протоколу реабілітації є відкритим питанням, оскільки наразі недостатньо даних для визначення оптимальної тривалості процедур та їх інтенсивності. Звертаємо увагу, що подальші дослідження будуть спрямовані на аналіз тривалості ефекту та реалізацію повторних тренінг-тренувань.

Ключові слова: дистанційна реабілітація, ішемічний інсульт, фізична реабілітація, цифрові технології, пристрій «ОСНОВА».

Introduction

Over the past decades, Ukraine and the other countries have seen an increase in cases of diseases associated with excessive psychoemotional stress. The effects of chronic emotional and psychosocial stress are aggravated by the negative impact of harmful environmental factors and unhealthy lifestyles such as lack of physical activity, smoking, and poor nutrition. Together, these factors contribute to accelerated aging and the development of various pathologies (Mishchenko, 2017; Mishchenko et al., 2020; Vinychuk & Fartushna, 2022; Virani et al., 2021).

Stress injuries of the heart and blood vessels that occur during prolonged and intense psychoemotional stress have a significant impact on the development of cardiovascular pathology. In this context, there is an increasing need to strengthen the body and increase its resistance to stress factors (Degan et al., 2017; Gillen, 2016; The Lancet Neurology, 2016; Zorowitz et al., 2014).

One of the most important tasks in medicine is the rehabilitation of patients who have suffered a stroke. However, the problem is the inability of patients to effectively rehabilitate, and this is often due to the lack of pathophysiologically based factors that would help predict individual rehabilitation outcomes (Harrison et al., 2016; Kashuba & Popadyuha, 2018). Such factors would determine the ability to classify patients into rehabilitation subgroups depending on their individual needs and prospects for recovery (Gandhi et al., 2017; Zorowitz et al., 2014).

In this regard, despite intensive attempts to improve functional outcomes after stroke, patients often do not recover psychomotor functions. Understanding the causes and mechanisms of "poor results" in rehabilitation will certainly allow us to act on them in a timely manner.

One of the newest areas of limb motor function restoration is robotic mechanotherapy, which is based on the use of special robotic structures to train the functions of the upper and lower extremities with biological feedback (Bird et al., 2022; Dodakian et al., 2017; Pavlova et al., 2020; Edwards et al., 2023).

Despite the use of various technical means in physical rehabilitation for stroke, the use of the latest complexes and systems with biofeedback to improve its efficiency after injuries to human limbs is an urgent scientific, medical and social problem (Degan et al., 2017; Shchetinin et al., 2020; Gillen, 2016).

To realize the existence of physical therapy programs for the restoration of locomotor functions (Popadyuxa, 2018; Hristova & Sukhanova, 2015; Yao et al., 2021), we propose a new design (Kryvyakin, 2022). The problem is to analyze the functional and constructive capabilities of the "OSNOVA" device to ensure the efficiency of physical therapy for the restoration of locomotor functions. The work was carried out in accordance with the plan of research work "Development of physical therapy technologies and technical means of its implementation" (No. of state registration – 0117U002933) of the Department of Biosafety and Human Health of NTUU "KPI" (Kryvyakin & Antonova-Rafi, 2022).

The purpose of the study – is to investigate the efficiency of the developed physical rehabilitation program in the late rehabilitation period after ischemic stroke with a personalized approach with the priority use of the "OSNOVA" device for the restoration of locomotor functions.

Material and methods of research

Participants

To implement the physical rehabilitation program in the late rehabilitation period after ischemic stroke with a personalized approach with the priority use of the device "OSNOVA" for the restoration of locomotor functions, 10 patients diagnosed with ischemic stroke in the late rehabilitation period after undergoing sanatorium treatment were involved. Because the patients differed in pathogenesis (flaccid and spastic paralysis, left or right-sided), a personalized physical rehabilitation program was applied to each patient, but with elements of correction depending on the patients' dynamics. Patients were selected of both sexes (men and women), with ages ranging from 37 to 71 years, but the most important thing was that they were in the late rehabilitation period. This is because doctors pay less attention to this period, and in vain, because physical rehabilitation in this period allows to consolidate the results obtained earlier and improve motor functions by 63-68%. All participants signed an informed consent form to participate in the study.

Methods

In our study, we used general and clinical methods of examination (taking a life history, taking a medical history, examining the patient).

The severity of neurologic symptoms in ischemic stroke should be assessed in the dynamics using specially developed scales. The NIHSS scale (National Institutes of Health Stroke Scale) is widespread and well-proven. The use of the NIHSS scale will allow an objective approach to the patient's condition after a stroke and assess the neurological status. The total score determines the severity and prognosis of the disease. With a score of less than 10 points, the probability of a successful outcome in 1 year is 60-70%, and with a score of more than 20 points – 4-16%.

The MMSE (Mini Mental State Examination) scale for assessing mental state is used worldwide to assess cognitive function. The test result depends on the sum of the scores for each item. The maximum number of points in this test is 30 points, which indicates the highest cognitive abilities. The lower the number of points is, the more severe the cognitive damage is (Kashuba & Popadyuha, 2018; Medical portal, 2022; Vakulenko & Klapchuk 2018; Zorowitz et al., 2014).

To better implement the research topic, we developed a device for restoring locomotor functions – "Osnova" (Utility Model Patent No. 151168). It contains a rectangular frame measuring 60×220×45 cm with two vertical guides inside, along which it is possible (with the help of muscle efforts of the arms or legs) to slide variable loaders, each weighing from 2.5 to 10 kg, which are connected to the cable and coils fixed on the upper and lower crossbars, connected to movable tubular rods or flexible rods (straps) for the upper and lower limbs, according to the utility model, the frame includes side stops and wall mounts, and is equipped with an exercise bike unit with pedals, which can be fixed at the required height depending on the user's height and position (standing or sitting) in the upper (for rotation of their arms) and lower positions (for rotation of their legs) on horizontal U-shaped tubular steps, which are installed and welded to the rectangular frame in front at different heights according to the "Swedish wall" type, and 110 cm long handrails are attached on the outer sides, one on each side, with the possibility of fixation in vertical and horizontal positions, and the device is equipped with a generator of electrical impulses and electrodes with the possibility of fixation on the patient's muscles and electrical stimulation (Kryvyakin, 2022).

The device (Fig. 1) with advanced functionality for performing the maximum set of exercises of therapeutic gymnastics for the upper, lower extremities and torso of persons with impaired musculoskeletal system capabilities was created, which occupies a minimum area, has a simple change of use of certain functions with one hand, keeps the simulator from falling or allows you to perform exercises while sitting, and helps to restore impaired locomotor functions using additional physiotherapeutic means.

In our opinion, the chosen research methods will qualitatively demonstrate the features of our study.

Figure 1. The device for restoring locomotor functions – "Osnova".

Procedure

To achieve the goal and objectives of the study,

we developed a program with priority use of the device for restoring locomotor functions "OSNOVA" that lasted three weeks, but taking into account the individual characteristics of each patient. When implementing the developed program, important factors that will influence the personalization of the proposed FR program will be the indicators of heart rate and blood pressure, which should not exceed heart rate – 110 beats/min, blood pressure – 100/140. For more accurate measurement of these indicators and in order not to distract the patient, he/she will wear a SAMSUNG smartwatch and the data will be automatically transmitted, which will allow adjusting the load during exercise (Bonura et al., 2022; Hu et al., 2022; Nakae et al., 2014).

The incoming informations are analysed by sophisticated software that converts analogue data from the sensors into binary signals, just as it would be in a desktop computer. The binary code is then converted into data that is displayed on the screen. They can measure heart rate and blood pressure anywhere: at work, in the gym, and at home. Measurements take from 30 seconds to 1.5 minutes. These measurements must be taken throughout the day at a set time (8.00, 10.00, 12.00, 14.00, 16.00, 18.00, 20.00). The device monitors blood pressure and heart rate around the clock, so the user just needs to press a button and the result will immediately appear, which he or she can record personally. The device is based on the coordinated work of the built-in accelerometer and heart rate monitor, which should be on the wrist. While wearing a smartwatch that measures blood pressure, you should make sure that it fits well, without pinching or hanging off your wrist. Otherwise, all the values obtained will be very different from the real ones.

Before using the device, the user will need to tell you about the following indicators: age, height, weight.

For correct blood pressure measurement results, you should watch for hours:

1. Put on the watch so that it fits your wrist.

2. Fix it where there is no tattoo. The ink blocks the IR signals, so the measurements may not be correct.

3. Stop and put your hand at chest level when measuring blood pressure with a smartwatch - this will make the readings more accurate. For the same reason, it is undesirable to talk during the measurement.

4. Do not take measurements after eating, as well as drinking coffee, strong tea and other stimulating foods, as they directly affect heart rate and pressure.

Body settings are recorded by determining the heart rate and pulse velocity inside the vessels through a photosensitive sensor. Taking into account dozens of variables, such as the color of the epidermis, the depth of the veins and the presence of plaques on the vessels, the accuracy of the results varies between 5-15%.

The patient will do the exercises independently twice a day, every day for three weeks, and under the supervision of a specialist – twice (two sessions) a week. Each session should take up to 60 minutes twice a day, 5 days a week. In general, the PT program takes 3 weeks – 30 hours.

Developed physical rehabilitation program took into account the peculiarities of the selected patients. It included four areas of training:

1. The program of upper extremities physical training in flaccid paralysis.

2. Program of physical training of lower extremities in flaccid paralysis.

3. Exercise therapy program for patients with severe hemiparesis, who are in bed, due to the loss of ability to move.

4. Exercise therapy program for patients with hemiparesis who are able to move.

The program of physical rehabilitation in the late rehabilitation period after ischemic stroke was designed for three weeks and included:

1. Gentle movement regimen, first week (5 days, 30 hours).

Tasks for the first half of the day: familiarization with the safety rules when performing exercises; familiarization with exercises; mobilization of the lower extremities; reduction of muscle atony or spasticity in the lower extremities.

Tasks for the second half of the day: familiarization with the safety rules when performing exercises; familiarization with exercises; mobilization of the upper limbs; reduction of muscle atony or spasticity in the upper limbs.

During this period of training, only one load peak was allowed in order to form the patient's correct ability to perform the exercises technically and qualitatively. This encouraged and motivated him to continue training.

2. Gentle training regimen, second week (5 days, 30 hours).

Tasks for the first half of the day: improve the range of motion in the lower extremities; improve coordination of movements during exercise; improve the functioning of the vestibular system during standing exercises.

Tasks for the afternoon: to improve the range of motion in the upper extremities; to improve coordination of movements during exercises; to improve fine motor skills of the affected arm during exercises with small objects.

During this period of exercises, two peaks of load were allowed, but each time the heart rate and blood pressure were taken into account to the maximum extent possible. Seeing a positive re-

sult, the patient could ignore these indicators in an attempt to "jump over" the body's current capabilities. This could lead to negative consequences - fatigue, which would return the patient to the first week of the program where everything started from the beginning. This aspect would negatively affect further motivation to exercise. Therefore, the second week is the most important.

3. Training regimen, third week (5 days, 30 hours).

Tasks for the first and second half of the day: improve the accuracy and speed of the movements performed; improve physical activity tolerance; consolidate the result. This week, the correct skill of performing exercises has already been formed. Therefore, 2-3 peaks of exercise are allowed. The patient will be able to closely monitor and control the exercise process based on heart rate and blood pressure.

Methods of using the "OSNOVA" device:

1) the patient takes a starting position in front of the main structure, standing with support on the side rails or sitting on the seat;

2) fixing the hands or feet to the upper cable attachment with the necessary means, perform a downward pull, press or stretch of the upper or lower extremities;

3) by fixing the hands or feet to the lower attachment of the cable with the necessary means, pull, press or stretch the upper or lower limbs up and down or pull to the side;

4) with the fixed unit of the exercise bike in the upper position, perform cyclic exercises - pedal rotations for the upper extremities forward and backward;

5) with the fixed unit of the exercise bike in the lower position, perform cyclic exercises for the lower extremities – pedal revolutions forward and backward;

6) standing, with support on the side handrails or front steps, perform coordination exercises with or without aids (rollers, hemispheres, balancers, steps, etc.) (Kryvyakin, 2022). When using electrical stimulation, it is necessary to apply electrodes to the corresponding muscles and select a comfortable force of contractions in accordance with the individual characteristics and state of the patient's neuromuscular system (Kozyavkin, 2012; Voropaiev et al.2022).

When forming individual goals for patients during the physical therapy program, the SMART methodology was taken into account to increase the efficiency of the rehabilitation program and improve the rehabilitation process from the point of view of management. The result of achieving the goal of physical rehabilitation depends on the correct formulation of the goals of the implemented program.

In the concept of "management by objectives" to achieve efficiency in rehabilitation after ischemic stroke according to SMART criteria should be as follows:

– Specific – goals should be stated in terms of specific outcomes. The main goals of rehabilitation are: return of independence and autonomy in everyday life; restoration of motor activity; safety in the process of recovery;

– measurable – the goal should determine the possibility and necessity of measuring the result in the following indicators: pain (points), range of motion (degrees), manual muscle testing (points);

– achievable – the goal should be feasible, realistic for a particular performer and predictable. At the end of rehabilitation, a person should be able to get out of bed and move around with the help of orthopedic devices.

– relevant – achievement of the goal should be provided with resources, and the goals should not conflict with each other and should not exclude each other. The physical therapist must clearly understand the significance of each goal for the rapid and complete restoration of the patient's function;

– time-bounded – limited in time. Early recovery period (up to 6 months after the onset of stroke); late recovery period (after 6 months and up to 1 year); residual stroke period (after 1 year) (Vakulenko & Klapchuk, 2018; Voropaiev et al., 2022).

Throughout the study, patients kept a "Success Diary" where each session was written in details – what the patient had to do and what the outcome of the session was. The smallest details were taken into account, because this is a late rehabilitation period after undergoing sanatorium treatment. Particular attention was paid to two aspects: firstly, to the increase in load during exercise; secondly, at the end of each week, the angles of amplitude increase in movements were measured. On the one hand, this made it possible to monitor the quality of exercise performance, and on the other hand, it motivated (Vykhliaiev et al., 2022) patients for further work.

Results of the study

The results showed interesting dynamics, given that the program was used for only three weeks (Table 1). In our opinion, this is due to the individualization of the program for each patient and constant monitoring of the results. Also, let's not forget about the motivational aspect and the support of the surrounding society.

After analyzing the data obtained, it was found that the average Barthel scale score is 77.1 against the initial value of 64. It should be noted that the scores have increased by 17%. The NIHSS scale is 13.9 against the initial value of 10.1. We note that the scores have increased by 27%. Given that the developed methodology was used for only three weeks.

This indicates the efficiency of the developed physical rehabilitation program in the late rehabilitation

Table 1. Results of the implemented FR program

No.	Age	Paresis Indicator	Result				Result
			NIHSS		Barthel		
			before	after	before	after	
			of the program				
A1	63	Left-sided flaccid	11	14	65	70	self-sufficient
Б2	46	Flaccid left-sided	8	14	75	90	returned to work
B3	52	Spastic right-sided	10	13	65	85	self-sufficient
D4	37	Spastic right-sided	8	14	75	90	returned to work
C5	43	Spastic left-sided	10	14	70	85	self-sufficient
Yu6	46	Spastic right-side	10	15	70	90	returned to work
A7	62	Spastic left-sided	11	14	65	75	self-sufficient
P8	65	Flaccid sided flaccid	11	15	60	70	self-sufficient
R9	71	Spastic right-side	10	13	62	70	self-sufficient
S10	74	Spastic left-sided	12	13	33	46	without significant changes

period after ischemic stroke with a personalized approach with the priority use of the "OSNOVA" device for the restoration of locomotor functions.

Discussion

The main cause of strokes is functional and dynamic angiodystonic disorders of the general and especially regional cerebral circulation. The main pathogenetic factors are arterial hypertension and hypertensive crises, which cause spasms or paralysis of cerebral arteries and arterioles.

Ischemic stroke is an acute cerebrovascular accident caused by acute cerebral ischemia and accompanied by structural and morphological changes in brain tissue and persistent organic neurological symptoms (Degan et al., 2017; Gillen, 2016; Horopashna & Horoshko, 2022; Hu et al., 2022).

Ischemic stroke can occur at any time of the day, but most often at night or at dawn. It can develop gradually over several days, or it can be acute.

Rehabilitation after a stroke is a set of measures (medication, psycho-physiotherapy and kinesiotherapy) aimed at mitigating its effects, preventing complications, training the cardiorespiratory system and restoring motor functions, minimizing the risk of recurrent stroke, correcting emotional and cognitive disorders, and trying to achieve full recovery of the patient's ability to work and social activity (Degan et al., 2017; Gillen, 2016; Krishnamurthi et al., 2019).

The main principles of the rehabilitation process are an individual approach (a rehabilitation program for each patient is based on the diagnosis (ischemic, hemorrhagic stroke), extent of the lesion, duration of the disease, age, comorbidities, characteristic features of the patient, systematic and duration of rehabilitation measures (Buckingham et al., 2022; Vakulenko & Klapchuk 2018; Klevaka et al., 2022; Voropaiev et al., 2022).

The developed program and device "OSNOVA" for the restoration of locomotor functions, for physical rehabilitation in the late rehabilitation period after ischemic stroke with a personalized approach is unique. This is because it is aimed at the period when all patients are already in a state of "it will not get better", but with competent, correct and careful planning, we have shown the opposite effect within three weeks. This positive feature was demonstrated by the data obtained that the average Barthel scale score is 77.1 against the initial value of 64, an increase of 17%. On the NIHSS scale – 13.9 against the initial value of 10.1, the indicators increased by 27%. The data obtained complemented existing studies in the chosen field of activity (Degan et al., 2017; Vakulenko & Klapchuk 2018; Voropaiev et al., 2022; Zorowitz et al., 2014). Also, the developed device "OSNOVA", which was used as a priority in the program, positively complemented the existing devices used in physical rehabilitation.

However, it should be noted that the clinical efficiency of this technology in different recovery periods has not yet been specifically studied, nor has the preservation of the achieved progress in motor function after the procedures, nor the effect of repeated training. The development of a standardized rehabilitation protocol remains an open question: there is still insufficient data to determine the optimal duration of procedures and their intensity.

Conclusions

Stroke rehabilitation is an important aspect of the examination and treatment of stroke patients. This process is aimed at restoring motor, speech, cognitive and other functions that may be impaired as a result of stroke, in order to improve the patient's quality of life and return him or her to active social life.

This type of rehabilitation should be individualized, focused on the needs of a particular patient and conducted under the supervision of qualified professionals, such as physiotherapists, occupational

therapists, speech therapists and psychologists, who will develop an individual rehabilitation program in accordance with the needs and capabilities of each patient.

It is important to remember that the success of rehabilitation depends on the regularity of training, support and positive progression of the results. That is why the developed program is unique and contributes to such important steps in a person's recovery and return to a harmonious life.

However, the development of a standard rehabilitation protocol is an open question, as there is currently insufficient data to determine the optimal duration of procedures and their intensity. Please note that further research will be aimed at analyzing the duration of the effect and implementing repeated training sessions.

Authors contribution

Conceptualization, OK and YuA-R; methodology, OK; software, OK and YuA-R; check, OK and Yu A-R; formal analysis, LSh; investigation, OK; resources, YuA-R; data curation, OK; writing – rough preparation, LSh; writing – review and editing, LSh; visualization, OK and LSh.; supervision, Yu A-R; project administration, YuA-R. All authors have read and agreed with the published version of the manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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