

Evaluating the Effects of Botulinum Toxin Injection and Physiotherapy on Post-Stroke Patients During One Year Observation – a Pilot Study

Ocena wpływu iniekcji toksyny botulinowej oraz fizjoterapii na pacjentów po udarze mózgu w obserwacji rocznej – badanie pilotażowe

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Key words

stroke, physiotherapy, postural stability, botulinum toxin, spasticity

Abstract

Introduction: Stroke is a serious health problem in the modern population. Spasticity is one of the consequences of stroke and affects about 30% of people. Increased muscle tone affects postural control disorders. Due to the specificity of spasticity, therapy in post-stroke patients is a challenge for neurological physiotherapy. Therefore, it requires the development of appropriate management standards.

Study aim: The aim of the study was to evaluate the effectiveness of 3 combination therapy cycles based on botulinum toxin injection and physiotherapy for muscle tone, muscle strength and postural stability in post-stroke patients qualified for the spasticity treatment programme of the lower and upper limbs.

Material and methods: The pilot study involved 12 patients (6 from the lower limb and 6 from the upper limb programme). The 1-year combination therapy programmes included 3 botulinum toxin injections and 3 weeks of physiotherapy after each injection. Clinical evaluation was conducted before and after the 1-year observation cycle. The results were evaluated using: MAS (Modified Ashworth Scale), MRC (Medical Research Council Scale) and posture stability test on a balance platform (BiodexSD).

Results: A decrease was observed in muscle tone of the lower and upper limbs, as well as an increase in muscular strength of the upper limb. However, there were no noted statistical significance of the studied parameters.

Conclusions: Physiotherapy in combination with the botulinum toxin is an important element of improvement in post-stroke patients. However, further research is needed to explicitly confirm its effectiveness.

Słowa kluczowe

udar mózgu, fizjoterapia, stabilność posturalna, toksyna botulinowa, spastyczność.

Streszczenie

Wprowadzenie: Udar mózgu stanowi poważny problem zdrowotny współczesnej populacji. Spastyczność jest jedną z konsekwencji udaru mózgu i dotyka około 30% chorych. Wzmożone napięcie mięśniowe wpływa na zaburzenie kontroli posturalnej. Z powodu specyfiki spastyczności terapia pacjentów po udarze mózgu stanowi wyzwanie dla fizjoterapii neurologicznej, dlatego wymaga opracowania odpowiednich standardów postępowania.

The individual division of this paper was as follows: A – research work project; B – data collection; C – statistical analysis; D – data interpretation; E – manuscript compilation; F – publication search

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Cel pracy: Celem pracy była ocena efektywności 3 cykli terapii skojarzonej opartej na iniekcji toksyny botulinowej i fizjoterapii na napięcie mięśniowe, siłę mięśniową i stabilność posturalną pacjentów po przebytych udarze mózgu zakwalifikowanych do programu leczenia spasty czności kończyny dolnej i kończyny górnej.

Materiały i metody: W badaniu pilotażowym wzięło udział 12 osób (6 osób zakwalifikowanych do programu kończyny dolnej i 6 osób do programu kończyny górnej). Roczne programy terapii skojarzonej obejmowały trzykrotne podanie preparatu toksyny botulinowej połączone z trzytygodniową fizjoterapią. Ocena kliniczna prowadzona była przed i po zakończeniu rocznego cyklu obserwacji. Do oceny uzyskanych wyników wykorzystano: skalę MAS (*Modified Ashworth Scale*), skalę MRC (*Medical Research Council Scale*) i test stabilności posturalnej na platformie balansowej (BiodexSD).

Wyniki: Zaobserwowano zmniejszenie napięcia mięśniowego w kończynie dolnej i kończynie górnej oraz zwiększenie siły mięśniowej w kończynie górnej. Jednak nie odnotowano istotności statystycznej w badanych parametrach.

Wnioski: Fizjoterapia w połączeniu z toksyną botulinową stanowi ważny element usprawniania pacjentów po przebytych udarze mózgu. Jednak konieczne jest prowadzenie dalszych badań, których celem będzie jednoznaczne potwierdzenie jej skuteczności.

INTRODUCTION

Stroke is a serious health problem of the modern population associated with the aging process in developed countries^{1,2,3}. According to studies conducted in recent years, stroke significantly contributes to the increase in the number of deaths and percentage of people affected by disability^{1,3,4}. In Poland, 60,000 people experience stroke per year³.

Experiencing a stroke has negative impact on all spheres of human life. The physical and mental condition of those affected deteriorates, which further leads to a reduction in their functioning in social life, thus, translating into a decrease of quality of life^{5,6,7,8}.

Spasticity is one of the consequences of stroke and affects approximately 30% of people. It is defined as “*impaired sensorimotor control resulting from damage to the upper motor neuron, characterised by intermittent or sustained involuntary muscle activity*”⁹. Abnormal muscle tone can be observed in the upper limb and lower limbs, as well as the trunk¹⁰. Spasticity affects, *inter alia*, the disturbance of postural control¹¹. Postural stability is responsible for the ability to restore balance despite external and internal factors acting on the body. Thanks to this, it is possible to maintain an upright position and move¹². In patients after stroke, postural control disorders lead to imbalances and gait disturbances, which translates into an increased number of falls, and thus, reduces the independence of these people^{11,12}.

Various methods of combating spasticity are mentioned in literature on the subject. The available methods

include: pharmacotherapy, for example: botulinum toxin injection, baclofen, physiotherapy and surgery¹². However, there are still no standards of management regarding increased muscle tone.

STUDY AIM

The aim of the study was to evaluate the effectiveness of combination therapy based on botulinum toxin injection and physiotherapy on muscle tone, muscle strength and postural stability in patients following stroke, who qualified for the treatment programme for lower limb and upper limb spasticity.

The following research questions were formulated:

1. Does combination therapy change the muscle tone and strength of patients with spasticity in the lower and upper limbs?
2. Does combination therapy improve the postural stability index (general stability, antero-posterior stability and medial-lateral stability indices) in patients with lower and upper limb spasticity?
3. In which group of patients undergoing therapy was there greater improvement among the respondents?

MATERIALS AND METHODS

Lower and upper limb spasticity treatment programmes were carried out at the Kraków John Paul II Specialist Hospital in Krakow at the Department of Neurology with the Stroke Sub-Unit and the Neurological Rehabilitation Sub-Unit, and at the De-

partment of Motor Rehabilitation of the University of Physical Education in Kraków between the period from December 2017 to January 2019.

Materials

Twelve patients participated in the pilot study. Six people qualified for the lower limb programme and 6 for the upper limb programme (Table 1).

A neurologist qualified participants for the research programme. Patients were selected based on specific criteria (Table 2). All patients participating in the programme read the research protocol approved by the Bioethics Committee (99IKBLIO-LI2016) and gave their written consent to undergo the study and for its results to be published.

Test methods

Annual lower limb and upper limb combination therapy programmes consisted of triple injections of a botulinum toxin type A preparation into the spastic muscles and physiotherapy. In clinical trials, patients received a dose of 100 units. The botulinum toxin was administered by a neurologist under ultrasound control (USG). The following muscles were injected with the botulinum toxin in the lower limb: gastrocnemius (medial head, lateral head), soleus and tibialis posterior. In the upper limb, the drug was administered to the following muscles: flexor digitorum profundus, flexor digitorum superficialis, flexor carpi radialis, flexor carpi ulnaris, flexor pollicis longus and biceps brachii. The botulinum toxin was administered 3 times a year. The next injections of the botulinum toxin prepara-

Tabela 1

Characteristics of the studied groups		
Parameters	Combination therapy programme for the lower limb (n=6)	Combination therapy programme for the upper limb (n=6)
Sex (F/M)	1/5	
Age	50 ±20	54 ±5
Occupied side (right/left)	3/3	3/3
Type of stroke (ischemic/haemorrhagic)	4/2	4/2
Time since the stroke occurred (years after (number of people))	3 years (1) 4 years (3) 10 years (2)	1 year (1) 2 years (2) 3 years (2) 9 years (1)

Tabela 2

Inclusion and exclusion criteria	
Criteria for inclusion in the programme	Criteria for exclusion from the programme
<ul style="list-style-type: none"> • Age above 18 • History of haemorrhagic or ischemic stroke within at least 3 months prior to enrolment in the programme • Confirmed moderate or severe post-stroke spasticity of upper and lower limbs (modified Ashworth score - MAS equal to or greater than 2) • Capability of walking 20 meters on one's own (orthopaedic equipment in the form of AFO or DAFO brace allowed) 	<ul style="list-style-type: none"> • Severe dysphagia or respiratory distress • Pregnancy • Myasthenia gravis or myasthenic syndromes diagnosed by neurological examination • Symptoms of generalised infection • A finding of inflammation • Permanent contractures in soft tissues and joints • Paralysis of the lower limb/upper limb • Repulsion syndromes • Cognitive Impairment - MMSE (Mini-Mental State Examination <18) • Co-morbidities disrupting the gait pattern (e.g., osteoarthritis)

tion were performed after 12 weeks. After each injection, the subjects participated in a 3-week programme of physiotherapy carried out according to established guidelines. Exercises were performed 5 times a week for 60 minutes. The programme was adjusted to the individual needs, abilities and limitations of the patient.

The lower limb physiotherapy programme included:

1. Long-term elongation of spastic muscles (7 minutes);
2. Mobilisation of the trunk and exercises to stabilise the lum-

bo-pelvic-hip complex (10 min) (Figure 1);

3. Lower limb exercises: active exercises for the indirectly affected limb, active exercises for the weakened muscles of the directly affected limbs, practicing proper loading of the affected lower limb (20 min);
4. Gait exercises: forwards, backwards, sideways, varied speed, varied surfaces and stairs, and exercises to reproduce postural stability (20 min) (Figure 2 and 3);
5. Breathing exercises (3 minutes).

The physiotherapy programme for the upper limb included:

1. Long-term elongation of spastic muscles by using a pressure cuff (7 min);
2. Trunk exercises and those to restore postural stability (10 min) (Figure 4);
3. Upper limb exercises: active exercises for the indirectly affected limb, active exercises for the weakened muscles directly affected (20 min);
4. Manual dexterity exercises for the upper limb in high positions (20 min) (Figure 5);
5. Breathing exercises (3 min).

Clinical evaluation was performed by the same investigator prior to initiation and immediately after completion of the combination therapy programmes.

Patients participating in the programmes were assessed using the following scales and tests: Modified Ashworth Scale (MAS), the Medical Research Council Scale (MRC) and a postural stability test on a stabilometric platform. The MAS was used to assess the level of muscle tone¹³.

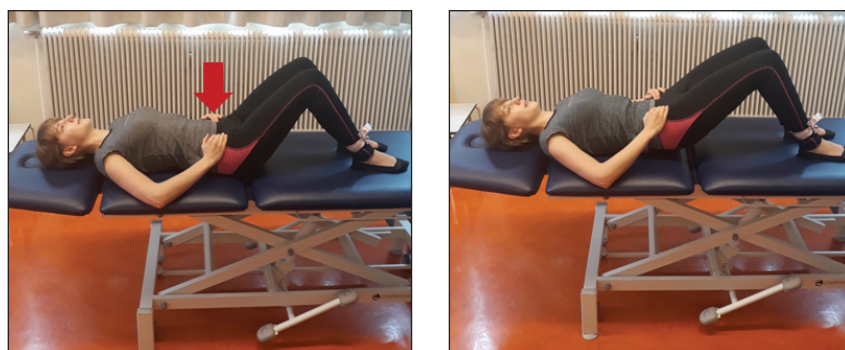


Figure 1
Exercises stabilising the lumbo-pelvic-hip complex



Figure 2
Walking with an obstacle exercise



Figure 3
Exercise to restore postural stability; learning how to transfer body weight in a standing position



Figure 4
Exercise to restore postural stability; learning how to transfer body weight in a sitting position



The MRC scale was used to assess muscle strength¹⁴. The postural stability test was used to evaluate the centre of pressure of the feet on the ground – Centre of Pressure (COP). This was performed on the specialised Biodex balancing platform. The test was carried out in the same conditions each time. Each attempt lasted 20 seconds and was performed 3 times. The following parameters were analysed in the study: general stability, anterior-posterior stability and medial-lateral stability indices¹⁵.

Methods of statistical analysis

In the study, the results are compared for the MAS, MRC scale and postural stability after combination therapy among patients qualified for the lower and upper limb programme. Analysis of the obtained results was carried out using the Statistica 13 program. In the analysis, the non-parametric Wilcoxon signed rank test was used in order to investigate the effect of the combination therapy on muscle tone, muscle strength and postural stability in patients after a stroke. In all of the tests performed, 0.05 was assumed as the level of statistical significance.



Figure 5
Upper limb exercises using a towel



RESULTS

The analysis of the obtained results showed a reduction in muscle tone in the lower limb and upper limb. In the

Table 3

Comparison of MAS results in lower limb and upper limb joints before and after combination therapy			
	Before	After	p
Lower Limb			
MAS ankle joint	2.0 ±0.6	1.5 ±0.5	0.12
MAS flexor digitorum	2.3 ±0.5	1.3 ±1.0	0.11
MAS flexor hallucis	2.0 ±0.6	1.5 ±1.0	0.27
Upper limb			
MAS elbow joint	2.2 ±1.0	1.3 ±0.8	0.11
MAS radiocarpal joint	2.7 ±0.5	1.5 ±1.0	0.05
MAS interphalangeal muscles	2.0 ±0.9	1.2 ±0.8	0.07

MAS – Modified Ashworth Scale, p – level of significance

Table 4

Comparison of MRC scale results in lower and upper limb joints before and after combination therapy			
	Before	After	p
Lower Limb			
MRC dorsal flexion of the foot	3.5 ±0.8	3.3 ±0.5	0.59
MRC plantar flexion of the foot	3.7 ±0.8	3.2 ±0.4	0.23
MRC finger flexion	3.7 ±0.8	3.0 ±0.6	0.18
MRC finger extension	3.7 ±0.8	2.8 ±0.4	0.12
Upper limb			
MRC elbow joint	3.7 ±0.5	3.8 ±0.4	1.00
MRC radiocarpal joint	3.2 ±0.8	3.5 ±0.8	0.18
MRC interphalangeal muscles	3.3 ±0.8	3.8 ±0.8	0.11

MRC – Medical Research Council Scale, p – level of significance

Table 5

Comparison of the results of postural stability parameters: general stability index, anterior-posterior stability index and medial-lateral stability index before and after lower and upper limb therapy			
	Before	After	p
Lower limb			
Overall stability index	6.5 ±3.5	7.9 ±3.3	0.46
A/P index	4.9 ±4.4	6.5 ±2.8	0.25
M/L index	2.9 ±1.8	3.6 ±3.3	0.46
Upper limb			
Overall stability index	6.2 ±3.7	5.5 ±1.7	0.75
A/P index	5.1 ±3.3	5.3 ±1.8	0.75
M/L index	2.7 ±2.4	1.0 ±0.9	0.08

A/P – Anterior/Posterior, M/L – Medial/Lateral, p – level of significance

lower limb, there was a reduction in tone by an average of 0.5 in the flexor muscles, by 1 in the flexor digitorum and by 0.5 in the flexor hallucis. In the upper limb, there was a decrease in tone by an average of 0.9 in the elbow joint, by 1.2 in the radiocarpal joint and by 0.8 in the inter-

phalangeal muscles. However, these results did not show statistical significance (Table 3).

After analysing the obtained results, it was shown that the muscle strength of the lower limb was reduced. For the dorsiflexor of the foot, this decrease was, on average, 0.2, for the

plantar flexors of the foot, an average of 0.5, for the flexor digitorum, an average of 0.7, and for the extensor digitorum, an average of 0.9. An increase in muscle strength was observed in the upper limb – for the elbow joint, an average of 0.1, for the wrist joint, an average of 0.3, and for

the interphalangeal muscles, an average of 0.5. However, these results did not show of statistical significance (Table 4).

After analysing the data obtained using the Biodex balance platform, the lower limb showed an increase in the general stability index by an average of 1.4, the anterior-posterior stability index by an average of 1.6, and the medial-lateral stability index by an average of 0.7. In the upper limb, there was an average decrease in the overall stability index by 0.7, an increase in the antero-posterior stability index by an average of 0.2, and an average decrease in the medial-lateral stability index of 1.7, however, these results did not show statistical significance (Table 5).

DISCUSSION

A history of stroke has serious health consequences that negatively affect every aspect of the lives of those affected. It has been proven in scientific works that combination therapy, i.e. the combination of pharmacotherapy with various physiotherapeutic methods, has a positive effect on the health condition of people suffering from stroke¹⁶.

In subjects qualified for the treatment of lower and upper limb spasticity, a reduction in muscle tone was observed. However, no statistical significance regarding the obtained parameters was found. Over the years, in numerous scientific studies it has been confirmed that thanks to the use of botulinum toxin injection, a reduction in excessive muscle tone can be observed. It has been proven that this form of treatment is effective and safe for both lower and upper limb spasticity^{17,18,19,20,21}.

The study by Kaja et al.¹⁷ included 120 patients with known spasticity in the lower limb, who were randomised into groups receiving botulinum toxin type A and a group that received a placebo. The researchers found that excessive muscle tone in the ankle joint was significantly reduced after 12 weeks from the use of the drug compared to the control group. The reduction in spasticity among the study

group was noted in the 4th, 6th and 8th weeks after the injection and this effect lasted up to 12 weeks¹⁷. Lim et al.¹⁸ studied 2 groups of patients after stroke (9 sub-acute people in the chronic period). After 4 weeks of botulinum toxin injection, a reduction in spasticity within the extensors of the elbow and the radiocarpal joints was observed only in sub-acute patients¹⁸. On the other hand, Ro et al.¹⁹ observed that due to botulinum toxin type A preparations, excessive muscle tone in the flexors of the radiocarpal joint, interphalangeal and ankle joints was significantly reduced after each of the 5 applied doses in the 24 patients studied. In the research by Mancini et al.²², 45 subjects with ankle spasticity were randomly assigned to 3 groups depending on dose. Four weeks after the injection of botulinum toxin type A, excessive muscle tone was reduced in all study groups. However, people who received a higher dose of the drug achieved better results²². It can be assumed that the time after stroke, as well as the dose of botulinum toxin used, affect the treatment. On the other hand, the use of combination therapy in research may extend the beneficial effects of the botulinum toxin. Takekawa et al.²³, in a study conducted among 190 patients following stroke, after using the botulinum toxin in combination with home functional exercise, observed a significant reduction in muscle tone after 1, 3 and 6 months. Furthermore, the study by Hara et al.²⁴ involved 35 people with lower limb spasticity, who participated in a 4-stage treatment programme with botulinum toxin and intensive rehabilitation. It was observed that excessive muscle tone in the dorsiflexors of the foot was significantly reduced after the first examination, and this tendency continued in the following stages of treatment²⁴.

In people enrolled in the lower limb programme, a decrease in muscle strength was observed in all studied muscle groups, and in patients enrolled in the upper limb programme, a slight increase was noted. However, no significant difference in muscle strength was found. The reduction in muscle strength may be due to the botulinum toxin's mechanism

of action^{21,25}. Botulinum toxin inhibits the release of acetylcholine from presynaptic peripheral nerve endings. By blocking neuromuscular conduction, muscle tone is reduced, but at the same time, muscle contractility is weakened, which may lead to a reduction in muscle strength. This is confirmed in the research by Caty et al.²⁵, who observed that after the use of only botulinum toxin preparations, the muscle strength of the elbow joint and flexor hallucis was significantly reduced. Therefore, it can be concluded that the process of rehabilitating patients after stroke, focusing mainly on the level of structure and function, does not lead to improvement in muscle activity, and thus, does not improve the quality of life of people affected by stroke. For this reason, appropriate physiotherapeutic methods should be introduced into pharmacotherapy, which will support the treatment of patients. This form of therapy was used in the research by Cinone et al.²⁶, who combined injections of botulinum toxin with isokinetic spastic foot training, which resulted in an increase in muscle strength after therapy. Similar results were observed by Gandolfi et al.²⁷ compared to the control group after 5 weeks of treatment.

In the authors' own research, the postural stability did not improve significantly. However, different results were observed by Jung et al.²⁸, who, thanks to a 30-minute training programme based on learning to transfer weight with the use of an unstable surface, improved trunk control in people after stroke, which also resulted in better dynamic balance. Similar results were also reported by Tsaklis et al.²⁹, who, due to a special 4-week static and dynamic balance training session and gait training, found improvement in the area of deflection and the speed of COP. In the research by de Haart et al.³⁰, there was also an increase in the control of postural stability, even in people following severe stroke. Physiotherapy improved the speed and precision of shifting the body's centre of gravity, which increased the symmetry of the load on the feet³⁰. In the study by Kerzuncuf et al.³¹, postural control was im-

proved through the use of intramuscular injection of botulinum toxin.

The lack of improvement in postural stability and muscle strength may be caused by the very structure of the exercise therapy carried out, for example, by its duration, the selection of appropriate exercises or the selection of a physiotherapeutic method. Researchers have shown that properly selected motor training, the number of repetitions and the time of performance are important components needed to reorganise motor maps and to create new synaptic connections in the motor cortex of the brain. In accordance with the study by Klein et al.³², conducted on 56 adult rats, permanent plastic changes of the brain occur only after 10 days of motor skills training. It may be assumed that in humans, the time needed for the reorganisation of the motor cortex is longer. In the study by Byun et al.³³, performed among 30 patients in the chronic phase of stroke, the authors observed an increase in the strength of the knee extensors, measured with the Manual Muscle Test, and an improvement in balance and gait after 4 weeks of therapy. While in 15 people studied by Flansbjerg et al.³⁴, the improvement of muscle strength in the knee flexors and extensors occurred after 10 weeks of exercises performed twice a day. On the other hand, in the research by Krukowska et al.³⁵, in 72 patients, the improvement of postural stability parameters was achieved after 6 weeks of intensive physiotherapy. Another important element of physiotherapy is the appropriate selection of exercises. In this study, motor tasks were performed for the limbs, focusing on conducting everyday activities. In a study by Byun et al.³³, an increase in the muscle strength of the knee extensors in patients after stroke was reported after the use of strength exercises implementing a specialised machine. Similar conclusions were drawn by Flansbjerg et al.³⁴, who, thanks to the use of progressive resistance training for the lower limb, noted an increase in muscle strength. Another important aspect of exercise therapy is the type of physical therapy performed. In numerous scientific stud-

ies, the advantage has been proved of specialised treatment methods implementing movement over classic forms of therapy. This is confirmed, among others, by the research of Kim et al.³⁶, who compared the effect of exercises using Proprioceptive Neuromuscular Facilitation (PNF) techniques with basic movement exercises. After using a specialised form of therapy, increased activity of muscles was obtained: soleus and quadriceps muscles³⁶. In the study by Sharma i Kaur³⁷, improvement in balance and trunk control was also observed in patients after stroke who underwent trunk stabilisation exercises combined with PNF techniques “on the pelvis”. However, during their research, Krukowska et al.³⁵ compared the influence of the Bobath concept and the PNF method on COP parameters. It turned out that after completing both treatments, all of the tested parameters improved. However, the Bobath concept turned out to be a more effective form of treatment for patients after stroke compared to the PNF method³⁵. In the treatment of patients after stroke, physiotherapeutic treatments are used in addition to kinesiotherapy methods. In the study by Sabut et al.³⁸, it was observed that thanks to the use of functional electrostimulation in the exercise therapy of patients after stroke, the muscle strength of the ankle flexors was significantly improved. In recent years, therapies using modern technologies have also gained popularity. In a study by Lee et al.³⁹, after applying virtual training based on a canoe game, the authors observed improvement in trunk control and balance in patients with spasticity in the upper limb. In other studies, Yang et al.⁴⁰ used the Lokomot robot for gait training, and noticed an increase in the foot load on the directly affected side, which has a positive effect on improving stability and symmetry during movement. On the other hand, in the research by Ozaki et al.⁴¹, thanks to the combination of balance exercises with a personal assisting robot, the authors noted improvement in muscle strength of the lower limb⁴. Based on the analysed articles, it can be assumed that

by combining the traditional form of therapy with specialised methods and the use of modern apparatuses and devices, post-stroke patients could benefit more in terms of postural stability and muscle strength.

Summarising, in our own research, no improvement in the indices of postural stability or muscle strength of the lower limb was achieved. However, there was slight improvement in lower and upper limb muscle tone and upper limb muscle strength. Despite individual and intensive physiotherapy, there were no statistically significant differences in the tested parameters. This may be due to a too small study group or short duration of therapy. Physiotherapy in combination with the botulinum toxin is an important element of rehabilitation of patients after stroke. However, it is very difficult to restore myofascial balance during therapy. Maintaining stable posture depends on the synchronous work of the muscles of the whole body. This balance is disturbed in people after a stroke due to abnormal muscle tone in the limbs and trunk. Therefore, during physiotherapy, it is necessary to apply a holistic approach to the patient. Due to the fact that stroke is a significant social problem, there is a need for further research.

CONCLUSIONS

Based on the obtained results, the following conclusions were formulated:

1. There were no significant differences between the study groups in the assessment of postural stability indices.
2. The clinically observed decrease in muscle tone and increase in muscle strength in the affected upper limb after the applied therapy are not statistically significant.
3. The clinically observed reduction in muscle tone and muscle strength in the affected lower limb after the applied therapy is not statistically significant.

Conflict of Interest

None declared

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