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A retrospective analysis of the results of treatment with Intensive Neurophysiological Rehabilitation System

Summary.

The Intensive Neurophysiological Rehabilitation System (INRS), also known by the name of its founder as the Kozyavkin method, is a relatively new approach to rehabilitation of children with cerebral palsy (CP). Diverse treatment components of this method that complement and potentiate each other are aimed at achieving the major goal of rehabilitation – to improve the quality of life of the patients.

This study assessed changes of the key developmental parameters in children with CP during the INRS treatment course by retrospectively analyzing medical records.

Methods. 4309 patients that had received rehabilitation in the International Clinic of Rehabilitation during 2014-2016 were included in the analysis. The analyzed group underwent a total of 12.785 rehabilitation courses. Medical records before and after a two-week course were compared. This was possible due to the dedicated software, developed specifically for informational support in INRS. The muscle tone, active and passive range of motion, gross motor function, fine motor skills, and several other parameters were evaluated.

Results. Muscle tone decreased in 93% of patients with spastic forms of CP. Passive range of motion increased in 92% and active range of motion – in 84%. Changes in the gross motor function were measured with regard to the severity of motor impairment according to the Gross Motor Function Classification Scale (GMFCS). Head control improved in 27% of patients with GMFCS IV-V, crawling – in 16% with GMFCS III, sitting – in 49% with GMFCS II-III, standing – in 68% with GMFCS I-II. Fine motor function improved in 32% of patients, psycho-emotional state – in 7,938 patients (83%), functions of the autonomic nervous system – in 2,163 patients (23%), and language skills – in 969 patients (10%).

Conclusions. The study describes the changes of the motor and mental functions in children with CP after a two-week INRS course. The results provide the basis for further investigation of the INRS, particularly, in randomized controlled trials.

Keywords: cerebral palsy, treatment, retrospective study

Introduction

Cerebral palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to nonprogressive disturbances that occurred in the developing fetal or infant brain [1]. CP is the most common movement disorder in children, affecting 2.5 in 1,000. One in five children with CP have severe mental retardation and cannot move without assistance [2].

There are many approaches to the treatment of this disease [3]. The Bobath neurodevelopmental treatment [4], Vojta reflex locomotion [5], Peto method of

conductive education [6], and Semenova's dynamic proprioceptive correction [7] are some quite well-known methods. However, the efficacy of none of them has been proved according to the principles of evidence-based medicine.

Recently, many publications about the new methods have been emerging. Constraint induced treatment attracts much attention. Numerous publications have demonstrated the effectiveness of this method [8], which stimulates compensatory reorganization of the nervous system. No consensus exists on whether strength training in cerebral palsy patients improves motor function [9].

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There are plenty of studies on the application of botulinum toxin, many of which have been sponsored by pharmaceutical companies. The research suggests that botulinum toxin effectively decreases the muscle tone in the upper and lower extremities, although the evidence that it improves motor functions is conflicting. The researchers also admit that the long-term effects of botulinum toxin therapy in CP patients are yet to be studied [10].

Children with cerebral palsy widely differ by their motor, psychical and social characteristics [11]. This is not surprising, as CP can be caused by many factors. Nowadays, dozens and hundreds of etiological factors and risk factors are known to be associated with CP, which explains the clinical polymorphism of the disease [12-14]. Every patient is unique and no uniform rehabilitation approach will suit everyone. Unfortunately, relying exclusively on the conventional treatment methods does not always bring the desired outcomes. Only using a combination of multifaceted treatments can lead to the anticipated results.

One of such methods offering a multicomponent approach is the Intensive Neurophysiologic Rehabilitation System (INRS), also known by the name of its author as the Kozyavkin Method. INRS stimulates compensatory mechanisms of the child's body, creating a new functional state, boosting brain plasticity, and enabling faster motor and mental development. A combination of various treatment techniques, complementing and potentiating each other, are aimed at achieving the main goal of rehabilitation – improvement of the quality of the patient's life.

The method is patented as “A method of multicomponent treatment of patients with cerebral palsy according to Kozyavkin V.I.” (patent number – 119048) [15] and “A method of intensive neurorehabilitation of patients with cerebral palsy according to Kozyavkin V.I.” (patent number – 66711) [16].

The INRS is implemented in numerous medical centers in Ukraine and abroad. First of all, these are the International Clinic of Rehabilitation (Truskavets, Ukraine), “Elita” Rehabilitation center (Lviv, Ukraine), International Clinic of Medical Rehabilitation (Limassol, Cyprus), and Cambridge Medical and Rehabilitation Center (Al Ain, UAE).

This rehabilitation method has been the focus of many clinical studies, analyzing its application in patients with various neurological disorders, evaluating its efficacy, and looking for what could be improved.

In this study, we retrospectively analyzed changes of developmental parameters in children with cerebral palsy after treatment according to the INRS.

Materials and methods

The analyzed group included patients treated in the International Clinic of Rehabilitation during 2014-2016.

Upon admission and at discharge from the Clinic, all patients undergo medical examination, the results of which are stored in the electronic medical record of the

patient. The examination is carried out according to the diagnostic algorithm, outlined in the “Handbook of the manual therapist” [17], and consists of a neurological, neuroorthopedic, and somatic examinations.

In the study, the electronic records before and after the rehabilitation course were compared; the main parameters that were analyzed included the muscle tone, active and passive range of motion, and gross motor and fine motor function.

The analysis was possible due to the availability of the original software, designed with a specific purpose of informational support of the INRS [18]. The software is incorporated in the Clinic's medical informational system. It allows fast and seamless saving of the results of medical examinations, manage the discharge documents, optimize the operation of the institution, and perform an in-depth analysis of the accumulated data.

The study was designed as retrospective case series, aimed to describe changes rather than make statements about the causal relationships. For that reason, we did not calculate the statistical significance of the before-after difference of the studied parameters and only descriptive statistics were used.

Patients

Medical records of patients who underwent rehabilitation over the course of three years – from January 1, 2014, to December 31, 2016 – were analyzed. A total of 4,309 patients treated in the Clinic underwent 12,785 courses.

No personal information was used in the study; all data was retrieved and processed anonymously. Many patients underwent more than one rehabilitation course during the period of study, so we analyzed the number of courses, not the number of patients.

Different forms of cerebral palsy comprised 75% of all cases, while other disorder, such as vertebral pathology and organic diseases of the nervous system (stroke, trauma) accounted for 25% of cases. In this study, only the data of CP patients was analyzed. Another 127 courses were excluded because of incomplete data in the medical records. A total number of courses included in the study was 9,622. Demographic characteristics of the patients are presented in the table 1 and graph 1

Among the patients who received treatment 47% had spastic diplegia, 33% - spastic tetraparesis, 9% - hemiparesis, 5% dyskinetic form, 2% - ataxic form, and 4% - mixed form.

Of those treated, the patients aged 2-7 years comprised the largest group – 53%, 30% were patients aged 8-14 years, 8% - < 2 years, 5% - 15-18 years, and 4% - >18 years.

Distribution of the patients by Gross Motor Function Classification System (GMFCS) level [19] was as follows: GMFCS I – 12% (1,161 patient), GMFCS II – 22% (2,114), GMFCS III – 22% (2,077), GMFCS IV – 33% (3,168), GMFCS V – 11% (1,102).

Table 1. Distribution of patients by age, form of cerebral palsy, and GMFCS level

By Age (years)	N	%	By Diagnosis	N	%	By GMFCS level	N	%
Below 2 years	749	8	Spastic diplegia	4547	47	GMFCS I	1,161	12
2-7 years	5076	53	Spastic tetraparesis	3154	33	GMFCS II	2,114	22
8-14 years	2931	30	Spastic hemiparesis	854	9	GMFCS III	2,097	22
15-18 years	482	5	Dyskinetic form	487	5	GMFCS IV	3,168	33
Over 18 years	384	4	Atactic form	189	2	GMFCS V	1,082	11
			Mixed form	391	4			

The patient return rate was one of the important parameters of the analysis. Only 21% of patients had never been treated in the Clinic prior to the study; 79% were recurring patients.

Intervention

All patients underwent a two-week rehabilitation course in the International Clinic of Rehabilitation after baseline examination. Based on the results of the examination, all patients received an individual rehabilitation plan, tailored to their needs. The main components of the course are: biomechanical correction of the spine, joint mobilization, reflexotherapy, remedial exercises, full-body massage, rhythmic group exercises, wax and paraffin application, and mechanotherapy.

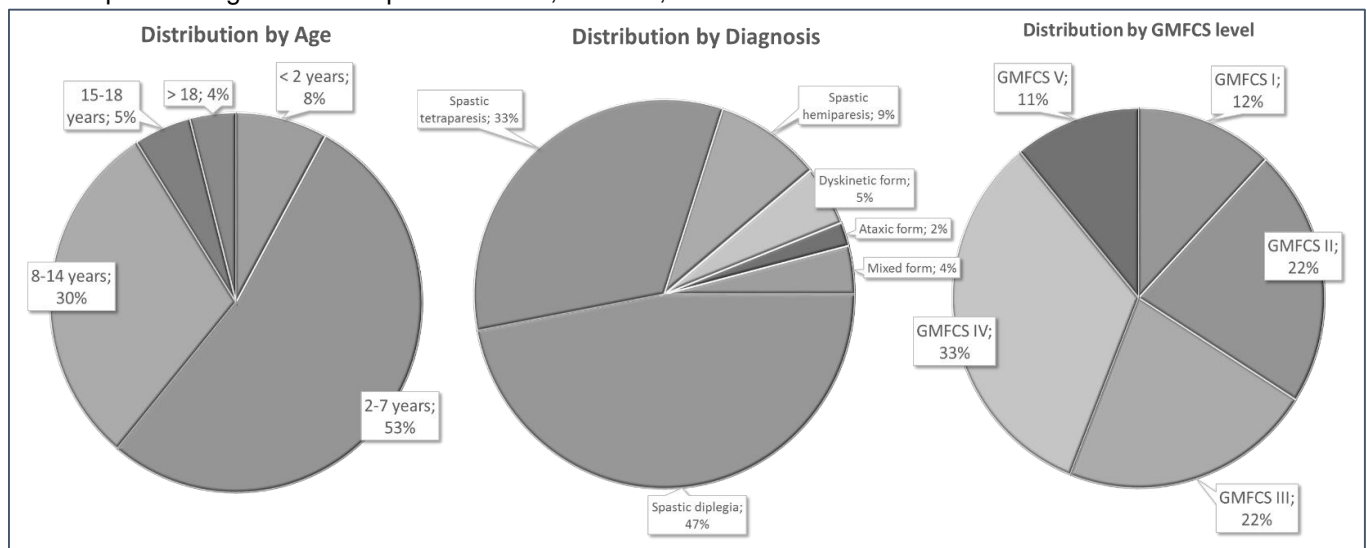
The program takes up to 4 hours daily. The detailed description of the treatment components can be found in the "Handbook of the manual therapist" [17]. All exercises and procedures were carried out by certified specialists.

An original technique of polysegmental *biomechanical correction of the spine (BCS)*, developed by prof. V.I. Kozyavkin, is the central element of the intensive rehabilitation. BCS helps to remove functional blockades of the vertebral sensorimotor segments and restore normal movements in the spinal joints. BCS is performed after manual examination and adequate "warm up" of all regions of the spine – lumbar, thoracic,

and cervical. In the lumbar region, all blocked segments are manipulated altogether by applying a proprietary technique called *backward rotation*. Blocked thoracic segments are manipulated sequentially from top to bottom by applying impulse while the patient exhales. Correction in the cervical region is performed through complex movements that have an instant effect on the blocked segments. In case of a blockade, impulse mobilization techniques may also be applied to the sacroiliac joint. Special relaxation techniques are used simultaneously with BCS.

Joint mobilization is used to restore joint mobility, correct muscle imbalance, improve trophic function, and facilitate acquisition of the new movement patterns. Large joints (hip, knee, and shoulder) are mobilized first, thereafter progressing to the smaller joints of the hands and feet. We use classic techniques as well as a proprietary mobilization technique that incorporates gently pulling the joint beyond the physiological range of motion by applying pressure to adjacent ligaments. We frequently apply traction combined with vibrating movements, as well as impulse techniques called "tapotement" (tapping movements) along the intra-articular gap, which are aimed at dewedging the blocked joints and pulling the articular surfaces towards their "central position".

Reflexotherapy is used to potentiate the achieved muscle relaxation in spastic CP, deactualize myofascial

**Figure 1. Distribution of the group by age, diagnosis and GMFCS level**

trigger points, and correct somatic and autonomic disorders. Conventional reflexotherapy methods are used in a mix with our proprietary techniques. A trained physician stimulates the biologically active points with a portable electric stimulator generating low-frequency impulses. Trigger zones of the muscular and articular system are stimulated simultaneously with isotonic or postisometric muscle tension, with the patient placed in a relaxed position. The intervention does not damage the skin and causes no pain.

Remedial exercises are aimed at improving the already achieved motor functions as well as forming the new ones in order to help the patient achieve more advanced forms of locomotion and develop the necessary daily skills. Remedial exercises are based on the fundamental kinesiotherapeutic techniques, tailored to the patient's individual situation. The key principle of the exercises - "from the center to the periphery" – denotes that movements of the trunk and in the proximal joints are trained first, with gradual progression to the fine distal joints. New motor skills are developed according to the principle – "from passive movements, through passive-active, to active" and "from simple movements to complex". Every session consists of breathing exercises, exercises, aimed to increase mobility in the joints of the spinal column and extremities limbs, and muscle-strengthening exercises.

As a part of the "warm up" before the BCS, we give a *full-body massage* to relax spastic muscles and deactivate myofascial trigger points. The massage system incorporates techniques of the classical, segmental, and periosteal massage, combined with the elements of postisometric and anti-gravitational relaxation. By using different massage relaxation techniques, a specialist prepares the musculoskeletal system so that the BCS can be effectively performed on the spine. Techniques to mobilize limb joints and

increase their mobility are used, as well as acupressure techniques to impact specific trigger points. Tonic massage methods have also been developed in order to activate hypotonic and inactive muscles.

The *group rhythmic gymnastics* are prescribed to improve motor skills, emotional well-being, as well as cognitive and communication skills. Sessions are based on the game with the use of music and dancing. Positive emotional environment facilitates acquisition of the new motor and communication skills. Parents are encouraged to participate. The exercises are aimed to improve the patient's motor ability, but they are even more helpful in facilitating social involvement of the child and motivating him or her for recovery.

We also administer *wax and paraffin applications* to stimulate the body's defensive mechanisms and improve local circulation, metabolism, and trophic processes. All patients are tested for allergy to bee products. Wax and paraffin are applied by enwrapping different muscle groups and joints in warm wraps, according to the doctor's prescription. Besides the thermal effect, such applications impact the musculo-articular system by means of diffusion of the biologically active substances through the patient's skin.

Mechanotherapy helps to build up muscle strength, improve coordination, and encourage proper movement patterns. Legs are usually trained with lever equipment, while upper limbs – with block-type devices. The physical therapist finds the best training regimen by adjusting the length of the levers, load weights, and the number of repetitions. Block-type devices are usually used to develop strength and muscle endurance in the upper limbs. Patients also train on treadmills and stationary exercise bikes in order to improve coordination and form proper movement patterns.

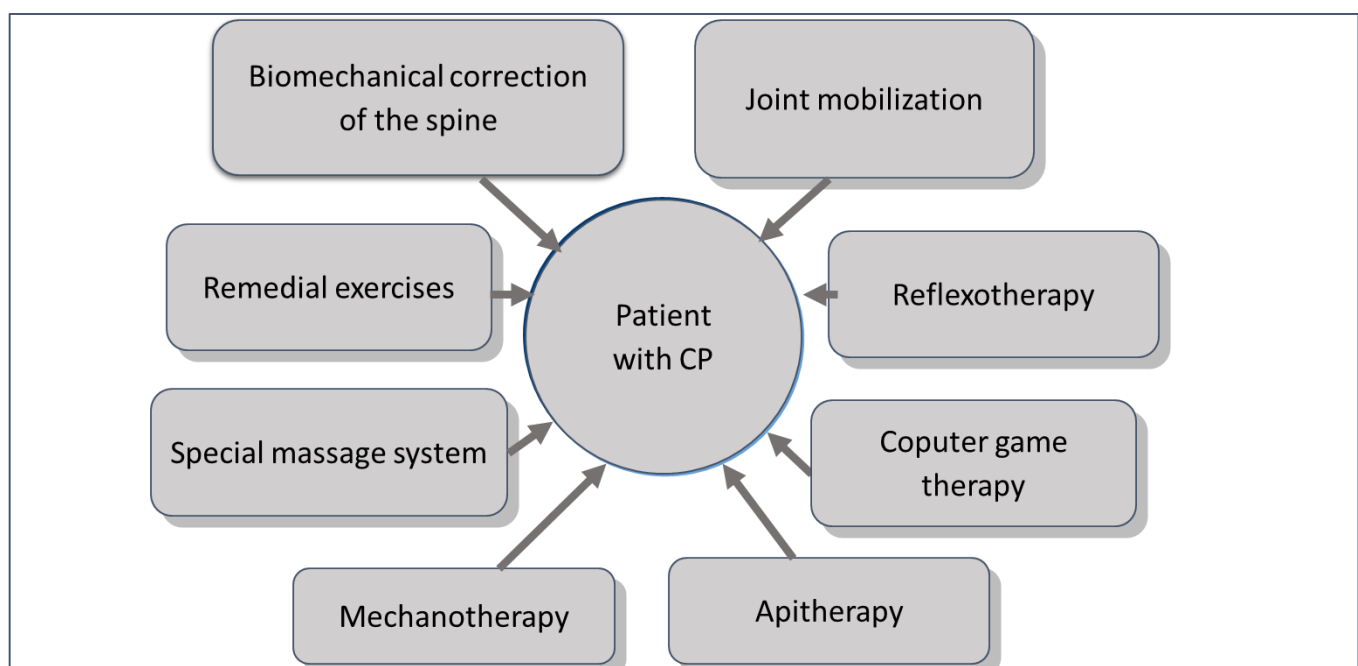


Figure 2. The main therapeutic interventions of Intensive Neurophysiological Rehabilitation System

Results and discussion

For the analysis, we retrieved a large amount of data from the patients' medical records. Only the most informative data is given in the article.

Impaired muscle tone, most frequently manifested as spasticity, is one of the important clinical syndromes of cerebral palsy. Of all CP patients, 87% had spastic forms, which amounted to 8371 patient/courses. Spasticity in shoulder flexor muscles, knee extensors, and ankle dorsiflexors was evaluated with the Modified Ashworth Scale (MAS). A 1-point reduction of spasticity was considered the cutoff value for clinically meaningful change [20].

Results of the muscle tone assessment in a group of patients with spastic cerebral palsy showed that Intensive Neurophysiological Treatment reduced the muscle tone in 93% of the cases. In 7% of the cases, the muscle tone remained unchanged; increase of the muscle tone in patients with spasticity was not registered.

The data is in line with the results of the previous research. A recent study uncovered that biomechanical correction of the spine affects spasticity. It used an instrumental method of spasticity measurement using the "Neuroflexor" device. This device quantitatively measures the spasticity level of the wrist muscles [21–23]. The assessment was performed before treatment, after one spinal manipulation and at the end of the two-week rehabilitation course. First spinal manipulation led to a significant decrease of spasticity and during the rehabilitation course, it decreased further.

The range of passive and active movements are other important criteria in determining the functional state of patients with motor disorders. The range of movements in shoulder, elbow, wrist, hip, knee and ankle joints was measured with a portable goniometer. A minimal clinically meaningful change was set to 10° [24]. Because the range of motion impairment is characteristic to spastic cerebral palsy, we analyzed this group of patients. After analyzing data of 8371

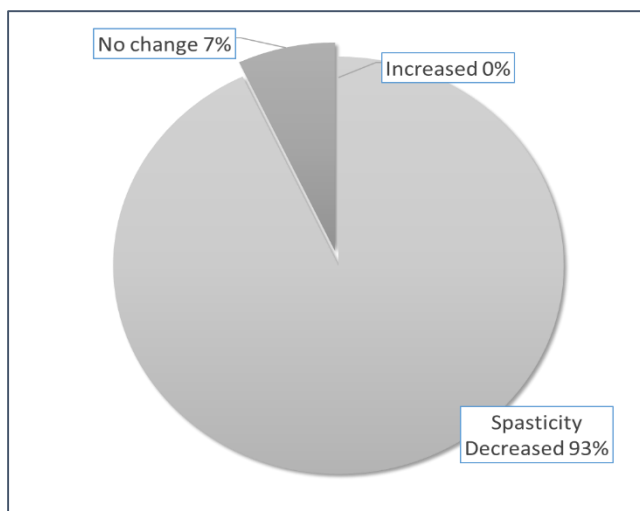


Figure 3. Change of the muscle tone in spastic Cerebral Palsy

patient/courses, the increase of passive range of movement was registered in 92% and the increase of active range of movement – in 84% of cases.

Information about the level of motor development of patients with CP was obtained from parents in conversation about their child's everyday motor activities. The motor activities of the patients were studied in categories: lying, crawling, kneeling, sitting, standing and walking. We analyzed only main motor functions according to patients' pre-treatment level of GMFCS.

Fig. 4 demonstrates the results of gross motor function analysis of 9622 patient/courses of CP patients. Improvement of head control was observed in 27% or 1161 from 4270 patient/courses in GMFCS level IV and V group. Crawling improved in 16% of the patient/courses in GMFCS level III group. Improvement of sitting was observed in 49% in GMFCS level II and III groups while standing improved in 68% in GMFCS level I and II groups. Finally, walking improved in 3352 patient/courses, which corresponds to 63% of patients in GMFCS level I, II and III groups.

These data correspond to the findings of the previous research. Study about changes in gross motor function after Intensive Neurophysiological Treatment included 61 patients with CP. Their gross motor skills were measured using GMFM-66 Item sets before and after a two-week course of treatment. The mean GMFM-66 score increased from 45.1 to 47.6 points. Most prominent changes were observed in GMFCS level II group [25].

Improvement of hand function is one of the main tasks in the rehabilitation of CP patients. Wrist rehabilitation holds a special place in the Intensive Neurophysiological Rehabilitation System. Most of the patients in the study had hand function impairments. According to MACS [26] patients were distributed as follows: level I – 13%, level II – 28%, level III – 26%, level IV – 21%, level V – 12%. Improvement of fine motor skills was observed in 3,078 patient/courses (32%).

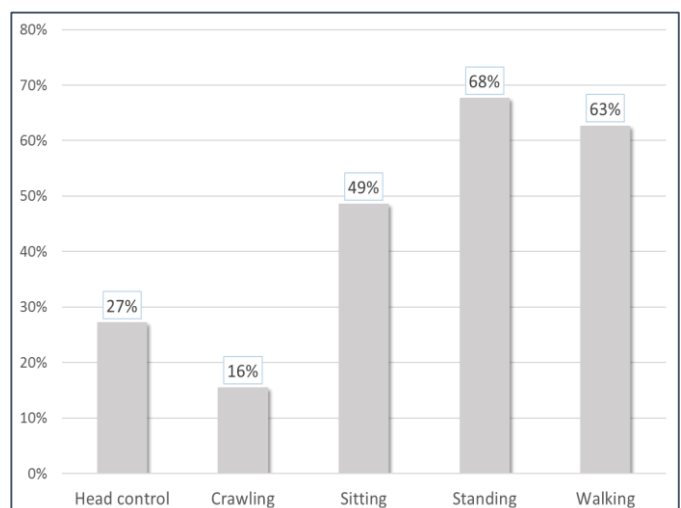


Figure 4. Development of gross motor functions

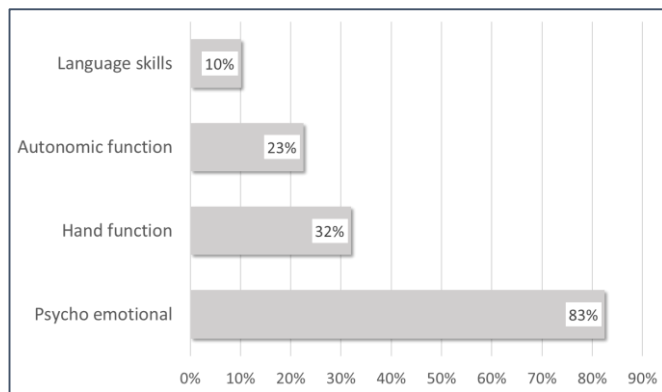


Figure 5. Improvement of other functions

A rapid development of motor functions after intensive rehabilitation course, described in our study can be explained by the publications of other researchers. A recent study demonstrates that the intensity of treatment significantly improves its efficacy. A 3-week program, which comprised of 6 hours of rehabilitation daily, more often caused hand function improvement than less intensive program [27].

Besides the development of motor functions, patients improved in other areas. Improvement of psycho-emotional state was observed in 7,938 patient/courses (83%), improvement of autonomic functions – in 2163 patient/courses (23%) and improvement of language skills – 969 patient/courses (10%).

These data can be used as preliminary to conduct more detailed studies aimed to understand the influence of the Intensive Neurophysiological Treatment System on different aspects of the functioning of CP patients.

Limitations

Our study has limitations, which are common to retrospective case series design. Evaluation of patients sometimes was conducted by the doctors and therapists directly involved in the rehabilitation process. It could have been a source of bias in some results. The study was descriptive, had no control group and no blinding. Therefore, results cannot guarantee that Intensive Neurophysiological Rehabilitation treatment course was a direct and sole cause of described improvements. Next limitation concerns the International Classification of Functioning, Disability and Health. We concentrated more on parameters, which belong to body functions and structure domain of ICF and less on activities and participation domains [28].

Conclusions

This study describes changes in motor function after the two-week course of Intensive Neurophysiological Rehabilitation. Our data suggest a possible influence of INRS on motor function and can be used as the base for subsequent research of the INRS, primarily randomized controlled trials.

Conflict of interests. Authors declare that they do not have any conflicts of interest.

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