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Effects of the Inerventions method on gross motor function in children with spastic cerebral palsy

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ABSTRACT

Aim of the study: To investigate the effect of the Inerventions method on gross motor function in children with spastic cerebral palsy (CP).

Clinical rationale for the study: The Inerventions method is the type of transcutaneous electrical nerve stimulation (TENS) delivered through a full-body garment (Mollii suit) that aims to prompt reciprocal inhibition via the antagonist to reduce spasticity in selected muscle groups. Although Mollii is approved by the European Union as a medical device, independent clinical tests have not yet been performed.

Materials and methods: 16 children with spastic CP, aged 4.7 ± 1.3 were recruited and then willingly assigned to the Inerventions method (n = 8) and control groups (n = 8). In the Inerventions method group, TENS was applied 1 h per session, 3 days weekly for 3 weeks. Children of the control group received functional exercises program for the same duration, frequency and length. Outcome measures included the Gross Motor Function Measure, passive range of motion (PROM), the Modified Tardieu Scale, and the Timed Up and Go test.

Results: While both groups experienced improvements in gross motor function and mobility, the difference in improvement between children treated with the TENS and physiotherapy did not reach statistical significance. No change occurred in PROM and spasticity in either group following the interventions.

Conclusions: There is no superior efficacy of the Inerventions method compared to conventional physiotherapy.

1. Introduction

Cerebral palsy (CP) is a non-progressive neurological disorder that affects muscle tone, posture, movements and motor skills. The motor disorders of CP are often accompanied by disturbances of sensation, cognition, communication, perception, behaviour, and seizure disorder [1]. Various therapeutic interventions have been developed for children with CP as well as their family members. Novak at al. (2013) in the systematic review have selected interventions that are evidence based: medications (botulinum toxin, diazepam, anticonvulsants, bisphosphonates), therapies (casting, hip surveillance, constraint-induced movement therapy, biman-

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ual training, context-focused therapy, goal-directed/functional training, occupational therapy following botulinum toxin, home programmes, fitness, and pressure care), and surgery (selective dorsal rhizotomy). Some other interventions, including electrical stimulation (ES), were attributed to the group of therapies with uncertain effect [2].

ES is a therapeutic treatment that applies an electrical current to stimulate nerves and muscles. If proved effective it might provide an alternative to stretching and strengthening exercises techniques for children with CP, or indeed it might improve treatment compliance in those children who find exercise programmes difficult. Unfortunately, lack of consensus on optimal treatment parameters and methods of delivering ES as well as unconvincing research data limits the use of this intervention in clinical practice [3]. Nevertheless, interest in the area of CP and ES is growing because it has potential as passive, non-invasive, home-based therapy [3,4].

There are two types of ES that can be used in clinical practice: functional ES (FES) and threshold ES (TES). FES is the application of an electrical current of sufficient intensity to elicit muscle contraction. Alternatively, TES is described as a low-level, sub-contraction ES.

A growing number of mainly small studies tend to support that the use of FES is beneficial and can lead to improvement in both gross motor function and mobility for children with CP. However, these findings must be interpreted with caution because of insufficient statistical power and other methodological limitations of the FES studies [3,4].

The application of TES for children with CP is even more questionable. There is relatively little research on the effects of TES, and the results of the studies are inconsistent. Pape et al. (1993) reported that leg muscles TES improved gross motor, locomotor, and receipt/propulsion skills for children with spastic diplegia [5]. Hazlewood et al. (1994) have found positive effect of TES on passive range of movement of the ankle and knee for children with spastic hemiplegia [6] while Steinbok et al. (1997) described the positive effect of TES on motor abilities of children with CP who had undergone selective posterior lumbosacral rhizotomy [7]. In addition, the study of Liron-Keshet et al. (2001) revealed that TES has improved gait quality and range of motion for children with diplegic CP [8]. However, studies by Sommerfelt et al. (2001), and Dali et al. (2002) have failed to find a statistically significant effect of TES on motor function in children with CP [9,10].Contradictory results of TES studies may be explained by differences in TES application methods and/or methodological limitations of the studies: a small sample size [6,8] and/or uncontrolled study design [5,6].

Since 2010, another method of delivering TES, so called the Inerventions method was developed as a new and refined strategy for treating patients with spasticity. The principle of this method is based on mild, low frequent ES which prompts reciprocal inhibition via the antagonist to relax spasticity in selected muscle groups [11]. Electrical rehabilitation suit, so called Mollii, was designed to provide this type of ES.

2. Clinical rationale for the study

Although Mollii is approved by the European Union as a medical device, independent clinical tests have not yet been performed. Its use has been growing in Sweden since 2010 and in Europe since 2012 [12], so there is considerable demand for research on the benefits of this method.

Therefore, we have decided to conduct a study to determine whether the Inerventions method would improve passive range of motion (PROM), spasticity, motor function, and mobility in children with spastic CP.

3. Material and methods

Pre/post cohort study with a conventional therapy control group was conducted between September 2016 and December 2016. Ethical approval was granted by the Kaunas Regional Biomedical Research Ethics Committee (registration number BIC – SR (M) – 60). Since all of the children in this study were younger than 18 years, informed consent was obtained from the parents of the children who agreed to participate in this study.

3.1. *Participants*

Children with spastic CP were recruited for the study from the Children Rehabilitation Department according to the inclusion and exclusion criteria. Inclusion criteria necessitated that children: (1) have the diagnosis of spastic CP; (2) be between the ages of 3 and 9 years; (3) be able to walk with or without support; (4) be able to accept and follow verbal instructions, and cooperate with therapeutic programming. Children were excluded from participation in the study if they had a ventriculoperitoneal shunt or a cardiac stimulator, o if they demonstrated uncontrolled epilepsy or behavioural disorders.

Based on the review of medical records of the Children Rehabilitation Department a total of 42 children were potentially eligible to participate in the study. One of the researchers made telephone calls to parents of all eligible participants in order to provide information about the study, answer any possible questions concerning the study, exclude potential participants who did not fulfil the inclusion criteria, and to ask for possible reasons if participation was declined. Parent's reasons for their children not participating in the study included: not wishing to use time on any trial participation; not having vitality, strength or energy to participate in an extensive study; being unwilling to have their child undergo non-evidence based treatment. In total 16 ambulatory children with spastic CP (10 unilateral, 6 bilateral: 8 girls and 8 boys), aged 3–9 years (mean 4.6 $\pm$ 1.3 years) whose GMFCS level was I, II or III (GMFCS level I/II/III: 9/6/1) participated in this study.

3.2. *Procedure*

The children were willingly assigned into the experimental (n = 8) and the control (n = 8) groups. Attempts were made to match groups based on demographic characteristics. Children of the experimental group were given skeletal muscle ES (antagonist to the spastic muscle) at a frequency of 20 Hz, a pulse width from 25 to 175 μs, and the voltage from 3 to 10 V depending on the child's age. ES was delivered to the quadriceps and/or the ankle dorsiflexors according to the

data of the clinical assessment. ES using the Mollii suit was applied 1 h per day, 3 times a week over a three weeks period. When wearing the Mollii suit, children were playing table games and interacting with peers and parents. The control group received conventional strengthening and stretching exercises 1 h per day, 3 times a week over a three week period. Both ES and physiotherapy sessions were conducted in a physiotherapy room at the Children's Rehabilitation Department. Considering our intervention protocol, it was not possible to blind the patients and/or the investigator who performed the ES and physiotherapy.

3.3. *Assessments*

PROM and spasticity were assessed using a classical two-arm goniometer. The muscle tone was assessed using the modified Tardieu scale (MTS). This scale is considered to be best suited for the measurement of spasticity as the resistance is compared during stretches at different velocities [13]. Research has shown that PROM and MTS have good to excellent intrarater and interrater reliability (ranging from 74% to 90% agreement rates between raters and measures) when assessing ankle plantar flexor spasticity in children with CP [14].

The muscle tone of the ankle plantar flexors was assessed in both knee flexion and extension. Hamstring spasticity was tested in a supine position with the pelvic-femoral angle to 90°. Two levels of the angle were measured after slow and fast stretches of the joint, referring to R2 and R1 angle respectively. R1 was defined as the point in the PROM where a catch or clonus was first felt during a quick stretch of the joint, while R2 was defined as the total PROM of the ankle. R2-R1 represents the dynamic component of spasticity. Spasticity was quantified according to the quality of muscle reaction for grades 0–5 during the fast as possible stretch [13,14].

Gross motor abilities were assessed using the Gross Motor Functions Measure, GMFM-88. The reliability of this test are sufficient (interrater reliability: intraclass correlation coefficient [ICC] = 0.75–1.00; test–retest reliability: ICC = 0.96–0.99). The GMFM-88 is responsive to changes in motor functioning and can be used to measure changes in gross motor skills over time in children with CP as well as evaluate physiotherapeutic interventions for these children [15,16].

All five dimensions were measured: A – lying and rolling (17 items); B – sitting (20 items); C – crawling and kneeling (14 items); D – standing (13 items); E – walking, running, jumping (24 items). Each item was scored on 1–3 point scale. The GMFM-88 total score was calculated as the mean score of all 5 dimensions.

The Timed Up and Go (TUG) test was used to evaluate basic mobility. Research has shown that the TUG has high reliability, with ICC of 0.99 for within-session reliability and 0.99 for test–retest reliability. This test is recommended as an outcome measure in intervention studies for children with CP, a measure of disability, and as a measure of change in functional mobility over time [17].

Participants were instructed to rise, walk as quickly and safely as possible for 3 m, turn around, walk back to the chair, and sit down on set cues. The fastest of 3 trials, measured to a tenth of the second, was used to calculate the mean score of all 5 dimensions (Table 1).

The physiotherapists with expertise in pediatric developmental rehabilitation performed all assessments. Measurement sessions took place on the day of the start of the treatment program, and between 1 and 2 days after the end of treatment.

3.4. *Analysis*

Data analysis was performed using SPSS 22. Descriptive statistics were used to describe characteristics of the participants in both study groups.

The repeated measures analysis of variance (ANOVA) was used to compare GMFM, TUG, and PROM before and after treatment in both study groups, and the one-way ANOVA was used to determine differences in treatment effect between groups. The differences between MTS taken at first and second assessment of the ES and control groups were compared by using the Wilcoxon signed rank test for related samples and Mann–Whitney *U* test for independent samples. A difference was accepted as statistically significant at $p < 0.05$.

4. Results

Sixteen children were enrolled in the investigation, and all of them completed the full 3 weeks treatment. Of the 16 children, 8 received ES with Mollii suit (i.e. Inerventions method) and 8 received conventional physiotherapy. The comparability of the ES and the physiotherapy groups was assessed by examining baseline measurements of all outcome measures, including GMFM, TUG, and the clinical measurements of PROM and MTS. There were no significant clinical, functional and demographic differences between the groups at baseline (Table 1).

The Inerventions method had the positive impact on a gross motor function of all children with CP (Table 1). Positive changes in standing, walking, running and jumping dimensions were registered by GMFM test. The mean change in GMFM in the ES group was 3.38% ($F = 16.715$; $p = 0.005$) and in the physiotherapy group 2.81% ($F = 17.257$; $p = 0.004$). However, the difference in mean GMFM improvement between CP children treated with the Inerventions method and conventional physiotherapy was non-significant, $F = 0.25$, $p = 0.63$.

After the ES treatment, all patients also experienced improvement in mobility (Table 1). The improvement of TUG scores ranged from 0.14 to 9.24 (mean 2.244, SD = 2.967) sec. in the ES group ($F = 7.177$; $p = 0.032$). The improvement of TUG scores in the physiotherapy group ranged from 0.11 to 3.41 (mean 1.885, SD = 0.961) s ($F = 30.971$; $p = 0.001$).

We found no meaningful change in PROM as well as spasticity of the ankle plantar flexors and hamstrings in both experimental and control groups (Table 1).

No adverse effects were noted with the Inerventions treatment.

5. Discussion

The Inerventions method is the innovative ES method using the sub-threshold sensory ES to cause reciprocal inhibition of

Table 1 – Mean baseline values and mean change between values at baseline and first week after treatment for all outcome measures in both ES and non-ES groups.

	Values at baseline (mean, SD)			Values after the end of treatment (mean, SD)			Differences in treatment effect between groups	
	ES	Non-ES		ES	Non-ES		Mean= SD=	
GMFM score (%)	Mean = 79.77	Mean = 84.6	$F = 0.21$	Mean = 82.42	Mean = 86.87	$F = 0.95$	Mean = 2.43	$F = 0.25$
	SD = 10.81	SD = 8.32	$p = 0.33$	SD = 10.62	SD = 7.41	$p = 0.35$	SD = 1.63	$p = 0.63$
TUG (s)	Mean = 17.23	Mean = 15.52	$F = 0.5$	Mean = 14.99	Mean = 13.63	$F = 0.47$	Mean = 2.07	$F = 27$
	SD = 6.10	SD = 3.06	$p = 0.49$	SD = 4.50	SD = 2.52	$p = 0.51$	SD = 2.14	$p = 0.75$
***Spasticity* (Tardieu scale)**								
L knee flexors	Mean = 1.66	Mean = 1.5	$U = 10$	Mean = 1.66	Mean = 1.2	$U = 10$	Mean = 0.01	$U = 14$
	SD = 0.51	SD = 0.57	$p = 0.76$	SD = 0.51	SD = 0.83	$p = 0.42$	SD = 0	$p = 1$
R knee flexors	Mean = 2.1	Mean = 1.83	$U = 15$	Mean = 1.66	Mean = 1.66	$U = 18$	Mean = 0.25	$U = 14$
	SD = 0.52	SD = 0.41	$p = 0.69$	SD = 0.51	SD = 0.51	$p = 1$	SD = 0.45	$p = 0.89$
Extended knee								
L ankle plantaflexors	Mean = 2.1	Mean = 2.5	$U = 6$	Mean = 1.83	Mean = 2.25	$U = 7.5$	Mean = 1.66 SD = 2.5	$U = 12.5$
	SD = 0.52	SD = 0.57	$p = 0.25$	SD = 0.41	SD = 0.5	$p = 0.35$		$p = 0.67$
R ankle plantar flexors	Mean = 1.83	Mean = 2.33	$U = 7.5$	Mean = 1.83	Mean = 1.83	$U = 9$	Mean = 0.5	$U = 18$
	SD = 0.41	SD = 0.51	$p = 0.35$	SD = 0.75	SD = 0.41	$p = 0.61$	SD = 0.52	$p = 1$
Flexed knee								
L ankle plantar flexors	Mean = 1.83	Mean = 2.5	$U = 6$	Mean = 1.5	Mean = 1.75	$U = 9$	Mean = 0.5	$U = 7$
	SD = 0.75	SD = 0.57	$p = 0.25$	SD = 0.54	SD = 0.5	$p = 0.61$	SD = 0.52	$p = 0.22$
R ankle plantar flexors	Mean = 1.83	Mean = 2.1	$U = 12.5$	Mean = 1.83	Mean = 1.83	$U = 18$	Mean = 0.16	$U = 12$
	SD = 0.41	SD = 0.41	$p = 0.39$	SD = 0.41	SD = 0.41	$p = 1$	SD = 0.38	$p = 0.13$
***PROM* (degrees)**								
L knee extension	Mean = 53.33	Mean = 60	$F = 0.868$	Mean = 48.33	Mean = 55	$F = 0.382$	Mean = 4.01	$F = 0.0001$
	SD = 11.25	SD = 10.8	$p = 0.379$	SD = 16.32	SD = 17.32	$p = 0.055$	SD = 6.14	$p = 1$
R knee extension	Mean = 58.33	Mean = 60.83	$F = 0.22$	Mean = 55	Mean = 60	$F = 0.75$	Mean = 1.25	$F = 1.8$
	SD = 11.69	SD = 5.8	$p = 0.649$	SD = 13.03	SD = 5.47	$p = 0.407$	SD = 2.26	$p = 0.209$
Flexed knee								
L ankle dorsiflexion	Mean = 7.5	Mean = –6.25	$F = 2.127$	Mean = 9.16	Mean = –3.7	$F = 1.741$	Mean = 2.5	$F = 0.229$
	SD = 14.40	SD = 14.93	$p = 0.183$	SD = 14.97	SD = 15.47	$p = 0.223$	SD = 2.63	$p = 0.645$
R ankle dorsiflexion	Mean = 2	Mean = 2.83	$F = 0.16$	Mean = 6.66	Mean = 5	$F = 0.54.5$	Mean = 4.25	$F = 1.301$
	SD = 8.2	SD = 13.93	$p = 0.901$	SD = 8.16	SD = 15.49	$p = 0.82$	SD = 3.51	$p = 0.281$
Extended knee								
L ankle dorsiflexion	Mean = 4.285	Mean = –1.25	$F = 0.747$	Mean = 5.714	Mean = 1.25	$F = 0.461$	Mean = 1.66	$F = 0.433$
	SD = 9.83	SD = 8.53	$p = 0.41$	SD = 12.90	SD = 6.29	$p = 0.514$	SD = 2.5	$p = 0.527$
R ankle dorsiflexion	Mean = 2.33	Mean = 1.5	$F = 0.35$	Mean = 5	Mean = 2.5	$F = 0.385$	Mean = 2.2, SD = 2.44	$F = 0.001$
	SD = 7.39	SD = 7.96	$p = 0.855$	SD = 7.74	SD = 6.12	$p = 0.549$		$p = 1$

GMFM, Gross Motor Function Measure; ES, experimental group; non-ES, control group; L, left; PROM, passive range of motion; R, right; TUG, Timed Up and Go test.

the muscles. The manufacturers claim that ES using Mollii suit improves muscle tone, range, control and movement and therefore differs from others TES and FES ES devices [11].

There are only a few studies that have investigated the use of the Mollii suit for children with CP. Auer (2009) has evaluated the combination of Conductive Education (i.e. the educational system to assist children in developing the ability to conduct activities of daily living) and the Interventions method for 24 children with CP. Investigators, as well as parents of children, noted positive effects of the suit, such as the reduction of spasticity, better mobility and everyday functioning [18]. Shi et al. (2012) evaluated the cost-effectiveness of Inerventions method and compared it with conventional medical treatments, e.g. baclofen, botulinum toxin, surgery, for children with CP in Sweden. This pilot study suggested the superior cost-effectiveness of the Inerventions method [19]. Westerlund et al. (2014) conducted a survey to explore experiences of patients who have used the Inerventions method for the treatment of various neurological conditions including CP. Up to 90% of patients in the study indicated an overall improvement of general condition. The most pronounced effect was felt on locomotion, general spasticity, the range of movements, such as hand/finger extension, raising the arm above head, placing heel on the ground [11]. None of the studies that investigated benefits of the Inerventions method for CP were published in peer-reviewed journals, and all of them share serious methodological limitations, such as a small or heterogeneous sample size, non-comparative observational study design, non-validated outcome measures, incomplete or/and inaccurate reporting.

The present study aimed to compare the effects of the Inerventions method and conventional physiotherapy on motor function in children with CP. To the best of our knowledge, this is the first independent comparative

experimental study of the effect of the Inerventions method. The muscles selected for ES were the rectus femoris and tibialis anterior. These muscles are very important for functional gross motor skills. The rectus femoris flexes the hip joint and extends the knee, and thus, together with other vasti muscles support body weight during standing and walking. The tibialis anterior, the main ankle dorsal flexors, prevents drop foot during the swing phase of gait. It was hypothesised that, since the Inerventions method decreases muscle hyperactivity (i.e. spasticity and muscle co-contraction), the children's motor function and mobility might improve following the treatment because of an expected increase in the range of motion as well as improvement in selective voluntary control. Results indicated that the effect of ES varied from one subject to the other. Nevertheless, mild improvement in gross motor abilities and mobility occurred as reflected by positive changes in GMFM and TUG test. The Inerventions method and conventional physiotherapy appeared to have similar effects on gross motor function and mobility. Neither ES nor physiotherapy affected spasticity and PROM.

Previous studies analysing the effect of TES on gross motor function for children with CP provided rather conflicting results. Pape et al. (1993) followed the development of 38 children treated with TES for one year. The investigators found positive effects of TES, including the growth of the quadriceps, better motor performance and results in the Peabody Developmental Motor Scale [5]. Steinbok et al. (1997) carried out a randomized control trial to determine the effectiveness of TES in improving the function of children with CP who have undergone selective dorsal rhizotomy and described the significant improvement in the GMFM for TES-treated children. Similar to ours, the study found no positive effects of TES on strength, spasticity, or PROM for children with CP [7]. In addition, the paper from Liron-Keshet et al. (2001) claimed that TES delivered to the quadriceps and dorsiflexors improved overall gait quality and range of motion for children with spastic diplegia [8].

In contrast, other investigators did not find a significant difference in TES–placebo effects. Hazlewood et al. (1994) revealed no changes in gait for 10 children with hemiplegic CP who received ES of the anterior tibial muscle daily for an hour for 35 days [6]. The crossover-study from Sommerfelt et al. (2001) also did not find any significant effect of TES on a motor and ambulatory function for 12 children with diplegic CP [9]. Finally, Dali et al. (2002) conducted a randomized double-blind placebo-controlled clinical trial to determine whether a group of 57 children with CP would improve their motor skills after 12 months of TES. Results of the study showed that ES didn't affect motor function, ROM or muscle size [10].

Inconsistent results obtained in previous studies may be due to different ES or/and treatment characteristics (e.g. frequency, amplitude, a number of sessions, treatment intervals). Moreover, the methodological limitations such as small sample size, non-validated outcome measure, and uncontrolled study design could influence the results and conclusions of the above-mentioned studies.

Our study also has some limitations which have to be pointed out. Despite the comprehensive assessment of treatment outcomes, the expected statistical power is limited due to the rather small number of participants. It is also conceivable that a more intensive ES would have resulted in more significant changes related to gross motor function. Manufacturers do not provide any recommendations for optimal length of treatment with Mollii suit except the statement that ES using the Mollii suit reduce muscle spasticity and improve movement for up to 48 h after each session while with regular use the effects may be extended beyond 48 h [20]. Based on this assertion we have decided that the 3-week treatment duration would be enough to see the difference. Moreover, a combination of the Inerventions method and physiotherapy could be more effective than using either of these treatments alone. Further studies, employing large sample sizes, extending the period of intervention, also comparing different treatment strategies (e. g., ES plus physiotherapy versus physiotherapy alone) are required to provide conclusive evidence for or against the Inerventions method.

6. Clinical implications/future directions

The Inerventions method has been shown to have the mild positive effect on mobility and motor function in children with spastic CP. However, there is no evidence for the superior efficacy of the Inerventions method compared to conventional physiotherapy. Nor the Inerventions method neither conventional therapy did not affect PROM nor degree of spasticity. Further studies are indicated to establish whether or not the Inerventions method cause improvement in children with spastic CP.

Conflict of interest

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