

Effectiveness of therapeutic suits and intensive suit trainings in individuals with cerebral palsy and other neurological disorders: a scoping review

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Abstract

Introduction. This review aims to find if there is any effectiveness in the application of therapeutic suits or intensive suit trainings or both together, among people with cerebral palsy and other pathologies.

Methods. Articles published from 1997 to 2019 were reviewed. Fifteen articles met the inclusion criteria that involved: English, Spanish, or Polish language; published studies; studies about the effectiveness of suit therapies regardless of the used protocol (Adeli suit, Therasuit, Penguin suit, or suit therapy); studies conducted among people with cerebral palsy or other neurological disorders regardless of age, type of cerebral palsy, and severity level.

Results. There were some positive effects in gross motor functions, functional gait, and joint mobility. However, the evidence was not clear and there were numerous factors that could have affected the results and produced methodological limitations.

Conclusions. The findings justify further exploration of the potential of suit therapies in people with cerebral palsy and other neurological disorders.

Key words: cerebral palsy, Therasuit, Adeli suit, intensive training, intensive treatment, suit therapy

Introduction

Cerebral palsy (CP) is one of the most common causes of disability in children [1–7]. The incidence of CP is 2–2.5 per 1000 births [5, 8, 9]. CP is a term used to group a big heterogeneity of manifestations observed in people with brain disorders causing problems in motor abilities and other developmental aspects [4, 10–12]. In 2006, a committee of experts agreed on an international definition, as well as a classification for CP. According to Rosenbaum et al. [13], CP is a group of permanent developmental disorders related to movement and posture. These disorders cause an activity limitation attributed to nonprogressive disturbances that occurred in the developing foetal or infant brain. Motor disturbances usually are accompanied by perception disorders, cognitive and communicative difficulties, behavioural disturbances, and others [8, 14]. In addition, epilepsy and secondary musculoskeletal problems are frequent.

According to the same authors and their guidelines in order to classify CP, 4 elements should be taken into consideration: type of motor disturbance, the presence or absence of other limitations or disorders, anatomical distribution and neuro-image findings, and the time of injury.

The rehabilitation for people with CP has focused its efforts on minimizing difficulties, promoting general function, and improving the quality of life [7, 15, 16].

Treatments usually concentrate on several main goals. One of the most significant ones is preventing muscle weakness or, in other words, strengthening the muscular system. This is a very important aim because muscular weakness, altered muscle tone, deficient postural control [1, 17], limited passive joint mobility, and poor alignment [16] are common impairments in children and adults with CP [18]. Additionally,

people with CP, in comparison with healthy children and adults, move at a slower speed and show a poor balance [19].

The management of motor impairments resulting from CP consists of physical activity and a wide range of other therapies, more or less similar to physical therapy [11, 20]. There are numerous techniques applied in CP, even though very few techniques or approaches have a real scientific base. Even, some of these treatments are considered as alternative or complementary therapies [10, 13].

Suit therapy is one of these non-proved therapies. There are many names for this method: suit therapy, Penguin suit therapy, Adeli suit therapy, Polish suit therapy, Pediasuit therapy, Therasuit therapy, Spidersuit therapy [1]. Usually the designation alludes to protocols and suits [21].

The first suit was Adeli suit. It was developed by Russian scientists from the Soviet space program to help cosmonauts with their problems caused by the effects of zero gravity [1, 10, 11, 13, 16, 17, 21–23]. This orthotic device or dynamic orthosis consists of a vest, shorts, knee pieces, a head piece, and special shoes with hooks [1, 17, 18, 24, 25]. All these elements are linked, during the therapy, with elastic strings or bungee cords with varied levels of tension [14, 18, 24] to increase the body alignment and to provide proprioceptive information [3, 10, 11, 21, 23].

Mainly, the therapy with a suit, irrespective of the name, has 3 standards. The first one is the action of the suit *per se*; the second one has to do with the intensive training or therapy during several weeks; the last one is the requirement of active movement performed by the person with CP [11, 17, 26].

Suit therapies are very commonly linked with intensive training. To define intensive training or intervention with CP is a difficult issue. Some researchers state that training applied more than 2 times per week can be considered inten-

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sive [27]. However, the adjective ‘intensive’ refers to the duration of the training period (usually weeks), the frequency of trainings per week (days), and time spent each day (hours) [27]. The difficulty is related to the fact that a typical frequency of therapy or training for people with CP does not exist [3, 4]. Some guidelines have been developed in order to establish rules concerning the frequency and intensity of treatments or trainings [28, 29]. Bailes et al. [28] state that an intensive training is performed 3–11 times per week and, for instance, Hanson et al. [29] indicate a frequency of 3–5 times per week.

When suit therapies or trainings are taken into consideration, the trainings usually consist of a 3–4-week program, implemented 4–5 days per week, 2–4 hours per day [3, 11, 19, 24, 26, 30].

Suit therapies have their specific characteristics, in addition to the intensity of the intervention. A traditional protocol of a suit therapy consists of stretching exercises, isolated strengthening activities for specific muscles, and functional training [10, 30]. In spite of the protocol, trainings usually are not strictly determined, and there are adaptations depending on the person, the therapist, the goals, and many more.

Owing to this heterogeneity, it is difficult to determine the effectiveness of these trainings. Moreover, if the use of a suit is combined with the intensity of the training, both aspects are taken into consideration to measure the therapy success.

The aim of this review is to present the findings on the effectiveness of therapeutic suits and intensive suit trainings in people with CP and other neurological disorders on the basis of the research published so far. Comparisons of the characteristics of different types of interventions were conducted, as well as the characteristics that might explain the observed effect variances were investigated.

Subjects and methods

Search strategy

This scoping review focused on the literature pertaining to the effectiveness of exercises with a training suit among people with CP. An extensive literature search was conducted

in the MEDLINE (PubMed), PEDro, Cochrane Library, and Web of Science databases, with no year, gender, age, or type of article restrictions; papers published until August 2019 were considered.

The key words used in the online search included ‘Adeli suit,’ ‘Therasuit,’ ‘Penguin suit,’ ‘suit therapy,’ and ‘cerebral palsy’. The Boolean operator ‘AND’ was used to combine the search terms. The selection of these terms is justified because the therapeutic suits used in these kinds of therapies have different denominations depending on the registered trademark of the suit, even though all of them employ the same system. The term ‘cerebral palsy’ was selected to be sure that the therapies and suits were applied to treat this pathology or similar ones.

Selection criteria

The inclusion criteria were the following: (1) languages: English, Spanish, or Polish; (2) published studies; (3) studies on the effectiveness of suit therapies, regardless of the protocol: Adeli suit, Therasuit, Penguin suit, or suit therapy; (4) studies conducted in people with CP or other neurological disorders, regardless of age, type of CP, and severity level. These criteria were set to collect as much information as it was possible about the suit therapies implemented in people with similar neurological disorders and to be able to compare these interventions.

The exclusion criteria involved: (1) articles without original research; (2) the application of another type of orthosis or orthotic equipment; (3) research without enough data or information concerning the protocols or measurements; (4) articles not available.

Selection of studies and data extraction

After reading titles and abstracts, studies that did not meet the inclusion criteria were removed. Also, duplicate studies were excluded.

Owing to the diversity of protocols and a limited number of studies, all protocols and experimental designs were con-

Table 1. Summary of the search and selection of the bibliography

Database	Search strategy	Total number of results	Results after elimination of duplicate research	Results after exclusion criteria application
PubMed	Adeli suit	13	13	8
	Therasuit	6	6	4
	Suit therapy	10	7	0
	Suit therapy and cerebral palsy	32	17	12
	Penguin suit	9	8	0
Web of Science	Adeli suit	13	4	1
	Therasuit	2	0	0
PEDro	Adeli suit	3	0	0
	Therasuit	1	0	0
	Suit therapy	13	7	1
	Penguin suit	0	0	0
Cochrane Library	Adeli suit	5	2	0
	Therasuit	1	0	0
	Suit therapy	3	1	0

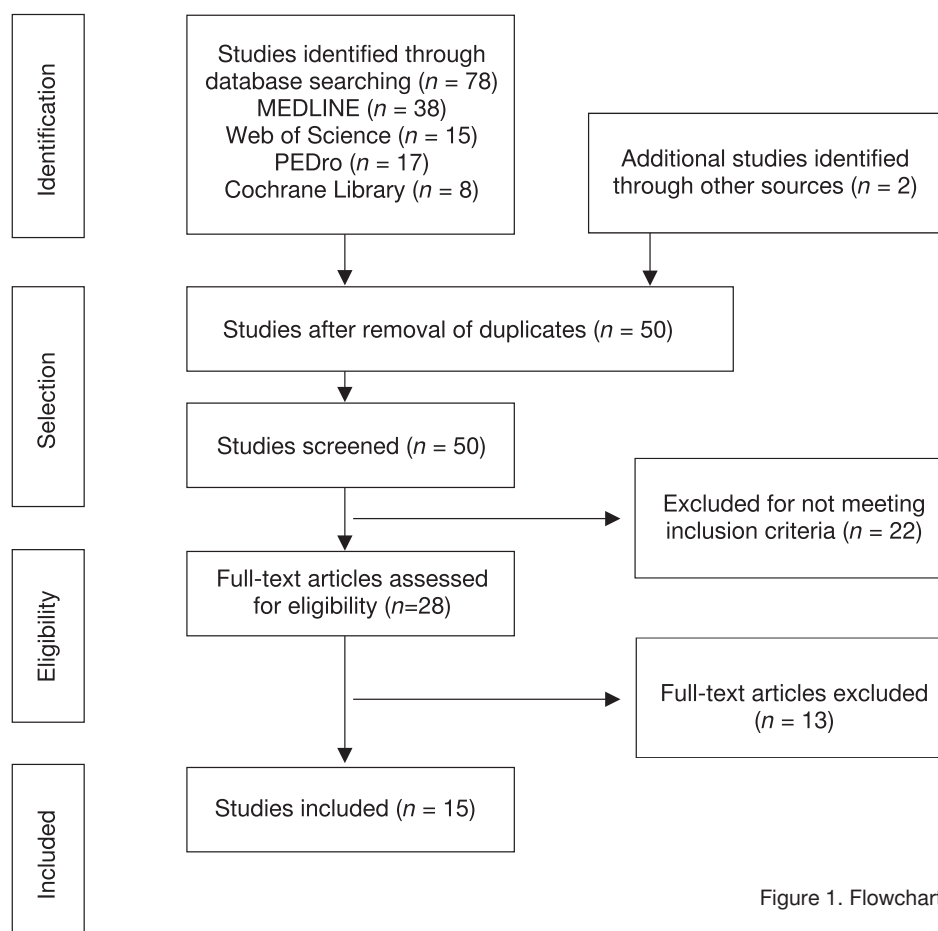


Figure 1. Flowchart of the article selection process

sidered. To identify other relevant articles, a manual search was conducted.

Two researchers read all the articles to determine which ones would be included in this review.

The searching and selection sequence are reflected in Table 1.

A specific strategy was followed to select as many appropriate studies as possible (Figure 1).

Quality assessment

Because of the diversity of the studies, 2 different tools were used to verify their quality. For randomized controlled trials, the Downs and Black [31] checklist was applied, as in other reviews [32–36]. For case reports, the Quality Assessment Tool for Case Series Studies was utilized from the National Heart, Lung, and Blood Institute [37], as in other research [38–41].

Ethical approval

The conducted research is not related to either human or animal use.

Results

From the initial 78 articles identified as potentially relevant studies, 15 met the criteria and were included in this review, as is shown in Figure 1. The included studies were published between 1997 and 2018.

There were a big variety of studies concerning the investigated issue: 1 retrospective study, 3 case reports, 5 single group designs, and 6 randomized clinical trials.

A big heterogeneity exists regarding the samples, protocols, and measurements. The inclusion and exclusion criteria are similar in most articles where these criteria could be found.

Data from the included studies were extracted by using a data extraction form involving: authors, study design, selection criteria, sample or study population, intervention protocol, measurements, and results. Table 2 shows a summary of these studies. Each research was numbered to facilitate the analysis in the successive sections and tables of this review.

Randomized clinical trials

The 6 randomized clinical trials presented a variability regarding all the surveyed aspects.

The inclusion and exclusion criteria were very similar. The samples consisted of children with different types of CP and diverse levels of severity. The subjects' age was between 4 and 12 years, although each study had a different range.

All samples performed an intensive exercise program in combination with a therapeutic suit. The training lasted from 3 weeks to 3 months, with the frequency of 3–7 days per week and the duration of the sessions from 30 minutes twice per day to 4 hours per day. Also, experimental and control group treatments were different. In 2 of the studies, the control groups received neurodevelopmental treatment (NDT). Also, in 2 of these studies, there was another control group: one received NDT + Adeli suit treatment (AST), and modified AST (MAST) was implemented in the other one. In 2 studies, the control group had a conventional therapy, and the study group followed a conventional therapy program with Thera-

Table 2. Summary of most important aspects of each study

Authors, study design	Selection criteria	Sample	Intervention protocol	Instruments/variables	Outcomes
Alagesan and Shetty [1] (1) Randomized controlled single-blinded study	Inclusion criteria: spastic diplegia, parents' consent Exclusion criteria: hip subluxation or dislocation, fracture of spine or limbs, severe scoliosis, seizures, mental retardation, severe spasticity, other congenital deformity	30 children, spastic diplegia, 4–12 years of age Experimental group: modified suit therapy with conventional therapy Control group: conventional therapy	3 weeks, 7 days/week, 2 hours/session with a 20-minute break after each session Control group: conventional therapy Experimental group: conventional therapy with modified suit	GMFM-88	After treatment: statistically significant difference between groups. Modified suit therapy with conventional therapy was more effective than conventional therapy alone for gross motor function improvement
Azab and Hamed [2] (2) Randomized controlled study	Inclusion criteria: 7–9 years of age, independent standing, 1+ to 2 score in modified Ashworth scale, ability to walk with support with abnormal pattern of gait Exclusion criteria: medical instability, epilepsy, visual or auditory problems	30 children, 7–9 years of age, spastic diplegia, randomly allocated to treatment groups	3 months, 3 times/week, 1 hour/session Control group: designed exercise program with emphasis on posture correction Study group: conventional therapy with modified suit	Back geometry by using For metric instrument system to assess lateral deviation, trunk imbalance, pelvic tilt, and surface rotation of vertebra	Improvement with significant differences in trunk imbalance, pelvic tilt, surface rotation, and lateral deviation in both groups. Therasuit had clear effect when added to treatment program in correcting the posture
Bailes et al. [16] (3) Case report	Inclusion criteria: CP diagnosis, GMFM level III, previous participation in Therasuit method, ability to follow instructions Exclusion criteria: no oral anti-spasticity medication, hip luxation > 35%, severe scoliosis, intrathecal baclofen pump, autism, attention deficit disorder, progressive encephalopathy, psychiatric or behavioural disorders, uncontrolled seizures	2 children with spastic diplegia	Therasuit method; 3 weeks, 5 days/week, 4 hours/day; activities in same sequence each day Therasuit: from 30 minutes on the first day to 2 hours and 30 minutes by day 5; individualized programs	PEDI; dimensions D and E of GMFM; 3-dimensional gait analysis: trunk, pelvis, and lower extremity joint motion during walking was tracked with a digital 10-camera motion analysis system	Minor changes in dimensions D and E of GMFM and PEDI. Both participants: small increase in some domains of PEDI. Gait analysis: Participant 1 improved walking speed, decreased double limb support time, and increased cadence. Improvements in some hip movements and in pelvis symmetry. Participant 2 improved walking speed, cadence, and single-limb support. Notable improvements in knee correction movements. More symmetry in lateral trunk motion and little change for pelvis
Bailes et al. [3] (4) Randomized controlled single-blinded study	Inclusion criteria: CP diagnosis, GMFM level III, no intensive therapy program before, ability to follow instructions Exclusion criteria: hip luxation > 35%, scoliosis > 25°, baclofen pump, history of selective dorsal rhizotomy, Botox injections within the previous 3 months, uncontrolled seizures, orthopaedic surgery within the previous year, serial casting within the previous month, diagnosis of autism, attention-deficit disorder, other musculoskeletal diseases, progressive encephalopathies, psychiatric or behavioural disorders	20 children with CP, 3–8 years of age, randomized to experimental or control group by a computerized minimization program	3 weeks, 5 days/week, 4 hours/day, both groups followed the Therasuit method Experimental group: Therasuit with elastic bungee cords Control group: Therasuit without bungee cords At the end of the 3 weeks: an individualized home exercise program to perform 1 hour daily for 4–9 weeks No other direct occupational therapy or physical therapy services during the study protocol	PEDI; GMFM-66; non-standardized investigator-developed questionnaire for parents' satisfaction	No significant differences between groups at baseline with regard to age, gender, weight, or initial GMFM-66 and PEDI scores. All scores improved across time Control group: differences in GMFM-66 at week 9 versus baseline Experimental group: significant differences in GMFM-66, PEDI self-care, and PEDI mobility Children from experimental group did not increase function more than children from control group

Bar-Haim et al. [17] (5) Randomized controlled single-blinded study	Inclusion criteria: diagnosis of CP, GMFM level II, III or IV, no orthopaedic surgery or spasticity reduction in the previous 6 months, not a candidate for surgery or other interventions for at least 1 year, parents' consent Exclusion criteria: hip dislocation or scoliosis, high degree of spasticity, poorly controlled epilepsy, hydrocephalus and progressive encephalopathies or myopathies	24 children, 17 males and 7 females, 6–12 years of age, randomly divided into 2 groups: AST (experimental) and NDT (comparison)	4 weeks, 5 days/week, 2 hours/day AST: suit and an intensive well-structured treatment protocol in accordance with the original Russian protocol NDT: structured program for each child	GMFM-66; metabolic cost of stair-climbing; body and limb mass, range of movement, step height, and relationship between walking velocity and step length	Significant improvement in GMFM-66 after 1 month in both groups. Sustained after 9 months of treatment. In AST group, increase from 1 month approached significance and after 10 months it was significant. AST can serve to optimize mechanical efficiency without a corresponding gain in gross motor skills, especially in children with higher levels of motor function
Christy et al. [30] (6) Single group design	Inclusion criteria: CP diagnosis, GMFM I–III Exclusion criteria: hip subluxation > 35%, severe scoliosis, uncontrolled seizures, selective dorsal rhizotomy < 1 year ago, intrathecal baclofen pump	17 children with CP, 8 males and 9 females, 4–12 years of age, 12 spastic, 3 hypotonic, 1 athetoid, 1 ataxic	3 weeks, 5 days/week, 4 hours/day; modified version of Therasuit protocol; specific exercise parameters; stretching, strengthening of isolated muscles groups, and functional training	GMFM-66; StepWatch activity monitor; Canadian Occupational Performance Measure, Pediatric Outcomes Data Collection Instrument	Improvements in GMFM-66, overall perception of general health (Pediatric Outcomes Data Collection Instrument), and performance and satisfaction concerning important activities (Canadian Occupational Performance Measure). StepWatch activity monitor data improved in both post-intervention tests but did not reach the level of statistical significance
Kim et al. [19] (7) Randomized controlled single-blinded study	Inclusion criteria: CP diagnosis, 4–7 years of age, GMFM I or II, no orthopaedic surgery or spasticity reduction in the previous 6 months, parental consent Exclusion criteria: hip dislocation or progressive scoliosis, poorly controlled epilepsy, medications for spasticity	17 children, 9 males and 8 females, randomly divided into 2 groups, 17 quadriplegia or diplegia	2 groups: NDT and NDT + AST NDT: 6 weeks, 5 days/week, 30 minutes/session, 2 sessions/day NDT + AST: NDT 6 weeks, 30 minutes/session, 2 sessions/day, 5 days/week + AST 30 minutes/session, 5 times/week	GMFM-88; PBS; TUG test; spatiotemporal parameters	NDT + AST: significant improvements in GMFM-88, TUG test; PBS improvement in walking speed, cadence, and stride length NDT: significant improvements in GMFM-88, TUG test; PBS improvement in step length More effectiveness in NDT + AST in spatiotemporal gait parameters, but not in GMFM, PBS, and TUG test
Ko et al. [18] (8) Single-subject case report	CP	One 8-year-old girl with diplegia	AST in accordance with the original Russian protocol, 18 weeks, 1 day/week, 50 minutes/session	GMFM; PBS; 10-meter walking speed; gait parameters: gait speed, stride time, stride length, and stride width	GMFM-88 improvements from 69.3% to 79.9%, PBS from 23 to 32. 10-meter walking speed: significant consistent improvement in gait speed. Significant improvements in gait speed (both sides), stride time, length, and width
Lee [25] (9) Case report	Children with CP	2 children, 6 and 3 years old, spastic diplegia	4 weeks, 5 times/week, 60 minutes/day with Adeli suit	GMFM-88; GAITRite Walkway System to measure gait function and Functional Ambulation Performance Score	Increase of gross motor function, cadence, and Functional Ambulation Performance Score in both cases. In one case, step length improved to better symmetry
Mahani et al. [26] (10) Randomized clinical trial	Inclusion criteria: CP diagnosis, no orthopaedic surgery or spasticity reduction intervention in the previous 6 months, GMFM level I–IV, not a candidate for surgery for at least 1 year, parental consent Exclusion criteria: hip dislocation and marked scoliosis, high degree of spasticity and disability, uncontrolled seizures, hydrocephalus, progressive encephalopathy and myopathies, systemic diseases: renal or cardiac disorders	36 children, 25 males and 11 females, divided into 3 groups: 21 spastic diplegia, 9 spastic quadriplegia, and 6 dystonic quadriplegia	4 weeks, 5 days/week, 2 hours/day AST: 1-hour preparation session, whole body massage, and post-isometric relaxation exercises, 1-hour Adeli suit NDT: 2 hours of passive and active movements MAST: 1 hour of passive stretching and facilitating normal movement patterns through handling, 1 hour of Adeli suit with functional activities in the context of play All children: occupational therapy for 16 weeks, 2 sessions/week, 45 minutes/session	GMFM	No significant difference between AST and NDT groups. 16 weeks after treatment: increases in scores in MAST group, but a decrease in NDT and AST groups. When the intensive program discontinued, the progress slowed down in MAST group and there was a regression in NDT and AST groups. MAST more effective than AST or NDT

<p>Martins et al. [42] (11) Single group design</p>	<p>Inclusion criteria: diagnosis of unilateral spastic CP, ability to walk independently, GMFm level I–II, 5–10 years of age, cognitive level and emotional state facilitating understanding and cooperation, no experience with dynamic orthosis</p> <p>Exclusion criteria: another medical diagnosis, congenital heart diseases and cardiorespiratory problems, structural deformities at lower limbs, trunk or ankles instability, epilepsy, botulin toxin in calf muscles in previous 6 months, surgical intervention in the previous 12 months, muscle tone scored ≥ 2 in modified Ashworth scale, severe affective or psychiatric impairments, serious hearing or visual problems</p>	<p>7 children, 4 males and 3 females, 5–9 years of age, 3 left hemiparesis and 4 right hemiparesis</p>	<p>All assessments conducted on the same day and with the same order</p> <p>Elastic cords of Therasuit were placed in accordance with the specific needs of each child</p> <p>Anthropometric measurements were performed, and 16 retro-reflective markers were fixed on the skin in anatomical landmarks</p>	<p>3D gait analysis in 3 different conditions: baseline, while wearing Therasuit without elastic cords, and while wearing complete Therasuit</p>	<p>Immediate effects of wearing Therasuit in angular displacements of the lower limbs during gait. Positive kinematic changes on gait patterns in the paretic lower limb. Decreased hip flexion angle at initial contact in both lower limbs. Increased extension pattern in the hip joint during stance phase in the paretic lower limb, and a decrease of flexion pattern during swing phase in both lower limbs. A decrease of the equine foot pattern at the ankle in the paretic lower limb during whole gait cycle, particularly in Therasuit condition (with elastic cords)</p>
<p>Méio et al. [6] (12) Retrospective study</p>	<p>Exclusion criteria: CP associated with other conditions or syndromes</p>	<p>53 children, 1–15 years of age; GMFm V (43.4%), quadriplegia (39.62%), diplegia (35.85%)</p>	<p>4 weeks, 5 days/week, 3–4 hours/session with 15-minute breaks</p> <p>Physical therapy exercises with additional intervention of multidisciplinary professionals; Peditasuit used with ludic therapy; participants performed 1–10 intensive neuromotor therapy modules</p>	<p>GMFM-88</p>	<p>Intensive neuromotor therapy improved gross motor abilities in children with CP. This effect was higher in the initial modules, with continuous improvement in all following modules. Significant difference in most modules and almost all dimensions of GMFM, except for module 6 for all scores and module 7 for the dimension scores</p>
<p>Pavão et al. [21] (13) Single group design</p>	<p>Inclusion criteria: ability to follow simple instructions, ability to sit on a bench without touching the floor and to touch an object in front of the body, attending physical therapy 2 times/week within the previous 6 months, no visual impairments</p> <p>Exclusion criteria: trunk deformities, orthopaedic surgical procedures and chemical blockages in the previous 12 and 6 months, suit orthosis therapy in the previous 6 months</p>	<p>29 children, 18 males and 11 females, 5–15 years of age, spastic CP, GMFm level I–IV, MACS levels I–III</p>	<p>Divided into 2 groups depending on arm impairment levels: MACS level I: 18, levels II and III: 11; no therapy</p>	<p>Participants seated on a force plate positioned on a bench. Hip and knee joints at 90°. The buttocks and thighs in contact with force plate and feet did not touch the floor. Reach for a pen 10 times with dominant arm with and without the suit, following a basic protocol, regardless of personal characteristics</p>	<p>Children at MACS levels II and III improved postural stability during the anticipatory phase of manual reaching while wearing the suit orthosis. Children at MACS level I, in contrast, increased postural displacement during the compensatory phase of the reaching task</p>
<p>Semyonova and Antonova [43] (14) Single group design</p>	<p>No mentioned</p>	<p>25 patients, 10–19 years of age, spastic diplegia</p>	<p>Adeli suit protocol, no more data</p>	<p>Electroneuromyography with skin electrodes. Bioelectric activity of lower limbs muscles at a physiological rest, during physiological movements with maximum effort, and in upright position</p>	<p>50% reduced pathologically high bioelectric activity in muscles with spasticity. Normalized ratio of activity in flexor and extensor muscles in plantigrade position</p>
<p>Shvarkov et al. [22] (15) Single group design</p>	<p>No mentioned</p>	<p>45 people with acute cerebrovascular lesions and 10 with hyperkinetic syndromes: 80% left-hemisphere insults and 20% right; 36 males and 19 females; 31 up to 50 years of age and 24 aged 50 years or over</p>	<p>Traditional rehabilitation methods with Adeli-92 therapeutic suit; 15 days with a special developed program, 1 session/day, 20–120 minutes/session; most of the time was spent walking in the suit; when signs of tiredness were seen, the session was interrupted</p>	<p>Measurement of range, strength, and precision of movements, equilibration of relation between tone and pose, increases in activity, and improvements in patient's mood and well-being also in their self-care ability; pyramidal syndrome points scale; topographic mapping methods for brain bioelectrical activity</p>	<p>71.9% of patients with sequelae of acute cerebrovascular lesions obtained a stable clinical effect. More than 50% restored equilibrium pose and increased muscle strength in paralyzed limbs, reduced muscle spasticity, and significantly improved or eliminated pathological synkinesis. The pyramidal syndrome severity decreased by 6–7 points in foot pathology and 3–4 points in hand pathology. More marked effects were seen in patients with more severe conditions. 17 people increased strength in paralyzed hands. Significant improvements in well-being, activity, and mood test</p>

AST – Adeli suit treatment, CP – cerebral palsy, GMFm – Gross Motor Function Measure, MACS – Manual Ability Classification System, MAST – modified Adeli suit treatment, NDT – neurodevelopmental treatment, PBS – Pediatric Balance Scale, PEDI – Pediatric Evaluation of Disability Inventory, TUG – Timed Up and Go

Table 3. Randomized clinical trials: methodological quality assessment checklist

Checklist items	Selected studies					
	1	2	4	5	7	10
Reporting						
1. Is the hypothesis/aim/objective of the study clearly described?	1	1	1	1	1	1
2. Are the main outcomes to be measured clearly described in the introduction or methods section?	1	1	1	1	1	1
3. Are the characteristics of the patients included in the study clearly described?	1	1	1	1	1	1
4. Are the interventions of interest clearly described?	1	1	1	1	1	1
5. Are the distributions of principal confounders in each group of subjects to be compared clearly described?	0	0	2	0	0	0
6. Are the main findings of the study clearly described?	1	1	1	1	1	1
7. Does the study provide estimates of the random variability in the data for main outcomes?	1	1	1	1	1	1
8. Have all important adverse events that may be a consequence of the intervention been reported?	0	0	1	0	0	0
9. Have the characteristic of patients lost to follow-up been described?	0	1	1	1	1	1
10. Have actual probability values been reported for the main outcomes except where the probability value is < 0.001?	1	1	1	1	1	1
11. Were the subjects asked to participate in the study representative of the entire population from which they were recruited?	0	0	0	0	0	0
12. Were those subjects who were prepared to participate representative of the entire population from which they were recruited?	0	0	0	0	0	0
13. Were the staff, places, and facilities where the patients were treated representative of the treatment the majority of patients received?	1	0	1	1	1	1
14. Was an attempt made to blind study subjects to the intervention they received?	0	0	1	0	0	0
15. Was an attempt made to blind those measuring the main outcomes of the intervention?	1	0	1	1	1	1
16. If any of the results of the study were based on 'data dredging,' was this made clear?	1	1	1	1	1	1
17. In trials or cohort studies, do the analyses adjust for different lengths of follow-up of patients, or, in case-control studies, is the time period between the intervention and outcome the same for cases and controls?	0	1	1	1	1	1
18. Were the statistical tests used to assess the main outcomes appropriate?	1	1	1	1	1	1
19. Was compliance with the interventions reliable?	0	1	1	1	1	1
20. Were the main outcome measures used accurate (valid and reliable)?	1	1	1	1	1	1
21. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?	1	1	1	1	1	1
22. Were study subjects in different intervention groups or were the cases and controls recruited over the same period of time?	1	1	1	1	1	1
23. Were the study subjects randomized to intervention groups?	1	1	1	1	1	1
24. Was the randomized intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?	0	0	0	0	0	0
25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?	0	0	1	0	0	0
26. Were losses of patients to follow-up taken into account?	0	1	1	1	1	1
Power						
27. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is < 5%?	1	1	1	1	1	1
Total score	16	18	25	20	20	20

Yes = 1 point, no or unable to determine = 0 points. For question 5: yes = 2 points, partially = 1 point, no = 0 points.
 Results ranges: excellent (26–28), good (20–25), fair (15–19), and poor (≤ 14)

Table 4. Quality Assessment Tool for Case Series Studies (National Heart, Lung, and Blood Institute [37])

Criteria	Selected studies								
	3	6	8	9	11	12	13	14	15
1. Was the study question or objective clearly stated?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Was the study population clearly and fully described, including a case definition?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
3. Were the cases consecutive?	NA	NA	NA	NA	NA	No	NA	NA	NA
4. Were the subjects comparable?	Yes	Yes	NA	NA	Yes	Yes	Yes	CD	Yes
5. Was the intervention clearly described?	Yes	No	Yes	Yes	Yes	Yes	Yes	No	No
6. Were the outcome measures clearly defined, valid, reliable, and implemented consistently across all study participants?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
7. Was the length of follow-up adequate?	CD	CD	Yes	CD	Yes	CD	Yes	CD	CD
8. Were the statistical methods well described?	Yes	Yes	Yes	NA	Yes	Yes	Yes	No	No
9. Were the results well described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Possible answers: Yes, No, CD – cannot determine, NR – not reported, NA – not applicable. For each item where ‘No’ was selected, a potential risk of bias can be considered. ‘Cannot determine’ and ‘not reported’ were also noted as representing potential flaws.

suit or a modified suit therapy. In the last trial, a comparison was made with the same protocol but using the suit with and without bungee cords.

Regarding the measurements, in 5 of the studies, Gross Motor Function Measure (GMFM) was applied exclusively or in combination with other scales like Pediatric Evaluation of Disability Inventory (PEDI), Pediatric Balance Scale (PBS), or the Timed Up and Go (TUG) test. Also, some studies took into consideration other parameters, like spatiotemporal or metabolic cost, and 1 study measured back geometry.

In all research, improvements were seen after the application of the treatment protocols. Alagesan and Shetty [1] established higher efficacy of conventional therapy in combination with suit therapy. Azab and Hamed [2] observed an improvement in back geometry in children from both groups. Bailes et al. [3] did not demonstrate any improvement in motor function in children wearing Therasuit in comparison with those wearing a control suit. Bar-Haim et al. [17] suggested that AST optimized mechanical efficiency in children with higher levels of motor function, without a corresponding gain in gross motor skills. Kim et al. [19] found a higher improvement in spatiotemporal gait parameters in the AST/NDT group, but no differences between groups in GMFM, PBS, or TUG test. Finally, Mahani et al. [26] noticed a greater effectiveness of MAST in comparison with AST and NDT.

The selected randomized clinical trials were surveyed in order to determine their quality by using a checklist for the assessment of the methodological quality of both randomized and non-randomized studies of health care interventions proposed by Downs and Black [31] in its modified version. The results are shown in Table 3. Using this checklist it can be determined that Bailes et al. [3] is good and the rest of them are fair, taking into consideration the result ranges.

Case reports, single group designs, and the retrospective study

Nine studies were included in this section.

The samples were 1, 2 (2 studies), 7, 17, 25, 29, 45, and 53 subjects. In all studies, the sample involved children with different types of CP, except in the last one, in which the study population consisted of adults after acute cerebrovascular lesions or with hyperkinetic syndromes.

Seven studies with treatment protocols were considered and 2 without treatment, only measurements. The treatment protocols were varied; nevertheless, 4 of them described a 3–4-week intervention with trainings on 5 days per week. Within these protocols, 3 had 3–4 hours of training per day, and there was only 1 hour in 1 study. Another protocol involved 18 consecutive weeks with one 50-minute long session once per week. There was 1 study with a 15-day treatment, 20–120 minutes per day, comprising traditional rehabilitation with an Adeli suit. The last treatment was very poorly described, the Adeli suit protocol was performed without any additional data.

The measurement tools were GMFM in 5 studies exclusively or in combination with other tests, like PEDI and 3D gait analysis [3]; StepWatch activity monitor, Canadian Occupational Performance Measure, and Pediatric Outcomes Data Collection Instrument [30]; and PBS, 10-meter walking speed and gait parameters [18]. Semyonova and Antonova [43] used electroneuromyography and Shvarkov et al. [22] measured the range, strength, and precision of movements, equilibration, and patients’ mood.

Although all of the studies showed improvements in measurements, almost all authors stated that further studies were necessary to confirm their findings.

There were studies without treatment protocols. These compared measurements in conditions with and without suits. These measurements applied a 3D gait analysis to evaluate the effects on gait, a force plate to assess postural stability. Martins et al. [42] concluded that some positive immediate effects were seen in gait kinematics when a suit orthosis was used, and Pavão et al. [21] observed that the suit improved postural stability in children with Manual Ability Classification System levels II and III during anticipatory postural adjustments.

To evaluate the quality of these studies, a quality assessment tool from the National Heart, Lung, and Blood Institute was used. In this tool, for each item where ‘no’ was selected, a potential risk of bias can be considered that could be introduced by that flaw in the study design or implementation. ‘Cannot determine’ and ‘not reported’ were also noted as representing potential flaws. The results are reflected in Table 4. There are similarities among most of the articles. We can consider the majority of them as a ‘good’ research; however, a lower quality can be observed in studies 14 and 15 [22, 43].

Discussion

This scoping review examined the current evidence of effects of therapeutic suits (Therasuit or Adeli suit), associated or not with intensive training protocols.

There is not much investigation accessible on this topic. Nevertheless, in most studies selected for this review, improvements in the measurements were observed. However, the evidence is not clear and there are numerous factors that can affect the results and produce methodological limitations.

The first limitation could be the fact that studies with statistically significant or positive findings are more likely to be published than trials with nonsignificant findings; then, the validity of a review conclusions can be threatened [44, 45].

Also, a limitation is the shortage of evidence and large heterogeneity in the existing trials regarding the type of study and their improvable quality, especially in oldest studies.

The samples were another limitation. They were very small (the largest one involved 55 people [22]) and there was a big variability among them. The samples were comprised of children of different ages, as well as adults in one of the studies, with very diverse characteristics: type of CP, severity, and GMFM level. This is an important point because age could influence the level of gross motor function and the improvement potential.

Inclusion and exclusion criteria, when mentioned, were very constrained; this aspect is also a limitation because CP and other similar neurological disorders are very commonly associated with other problems, for instance, cognitive, sensorial, or behavioural disorders [8, 13, 14]. Studies should preferably focus on more real samples to test the effectiveness of the treatment in most common patients and enable result generalization.

Regarding the measurements, the most frequently used one was GMFM in combination with other tests or examinations in some research. The majority of these tests and measurements are useful for quantitative evaluations, even though, especially in the most affected people, these improvements could be difficult to measure.

The diversity in the protocols, treatments, and comparisons among groups in each study was another limitation. It is complex to determine, in some of the studies, if the results were due to the suit, the protocol, or combination of both.

Case reports determined improvements in gross motor function, functional gait, and joint movements. However, all the researchers stated that more studies were needed to confirm their results and to clarify if the improvement was due to the suit by itself, the intensive training, or combination of both. Some studies seemed to show that the suit by itself produced improvement in postural stability and gait kinematics in children wearing the suits without any training protocol [21, 42]. Also the suit combined with intensive training protocols apparently produced better results than the intensive training in isolation [1], even though in other similar studies [2] the results were parallel in both groups, with and without suits.

Another important aspect to determine is if the effectiveness of the suit in combination with treatment protocols is always similar or if there are different factors that can affect it. Mélo et al. [6] mentioned that there were improvements in GMFM in all children in almost every module of treatment, even though they observed that the improvements were greater in the first modules than in the last ones of each child. This could be due to the age or the patients' getting used to the suit, the treatment, or both.

Therapists' opinions were not compiled in any of the studies and this could be an important dimension to take into account. The suit improved the alignment of patients by itself [3, 10, 16, 21, 23] and it would be a good assistance for the therapists to reduce their effort and fatigue during working time. If it were demonstrated, probably the use of the suit during intensive treatments could have a reasonable explanation, regardless the suit effects on patients.

The criteria for selecting the studies were met, with a language restriction. Only studies in English, Spanish, or Polish were included, which resulted in the exclusion of some, possibly pertinent, studies in Russian.

Finally, a good quality assessment tool for all studies was not found because of the diversity in their structure and format. Therefore, 2 different tools were necessary.

Owing to these limitations, the conclusions of the review were seriously limited, even though there are several interesting issues for future investigations.

Further research is necessary to confirm the effectiveness of this type of treatment, reducing the risk of bias and other limitations that have been highlighted before.

Also, a very important aspect that needs to be correctly measured is the quality of life in people with CP and the effects of the therapeutic intervention on this aspect. The measurement of the patients' quality of life reflects a holistic approach to patients with CP [46] and can be one of the main indicators of the effectiveness of the therapeutic methods [7]. Quality of life evaluation could provide important information about the patient's physical and mental state, necessary to perceive problems and to take actions aimed at solving them [47].

In connection with the previous idea, measuring the effectiveness of therapeutic suits and intensive trainings can be related to the improvement in other aspects that are usually affected in CP patients, like chronic constipation. Some of the several reasons for constipation are poor diet and decreased intestinal motility [48]; very likely, an intensive treatment with a therapeutic suit could help solve both these problems.

Conclusions

The results show that, nowadays, the evidence of the effectiveness of therapeutic suits like Therasuit or Adeli suit is weak. Therefore, more experimental studies with wider samples are required to confirm the results or to clarify the reasons for the method effectiveness.

Samples should be more homogeneous in each investigation, even though exclusion criteria should be less restrictive, including children with several disorders.

Additionally, it would be relevant to determine the impact of suits and intensive treatments in isolation.

Therapists' opinions should be surveyed to reinforce the usefulness of the suit, not only regarding the improvements in children's development, but also in the facilitation of the therapists' work.

Finally, the development of adequate assessment tools to test the quality of different types of trials could be interesting.

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Conflict of interest

The authors state no conflict of interest.

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