



Review

The clinical aspects and effectiveness of suit therapies for cerebral palsy: A systematic review

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Received: July 29, 2018 Accepted: December 18, 2018 Published online: February 14, 2019

ABSTRACT

Objectives: The aim of this review to evaluate the clinical aspects and effectiveness of suit therapy for patients with cerebral palsy (CP).

Materials and methods: A literature search was performed in the PubMed, SCOPUS, Web of Science, and PEDro databases within the period from the establishment of the relevant database to July 2018. The articles were categorized according to their study design. We included studies published in peer-review journals focusing on the efficacy of suit therapies for CP and excluded review articles, duplications, non-related articles. A narrative synthesis approach was used, as it was not possible to classify extracted and analyzed data, and the overall effect size was unable to be calculated. Data regarding study subjects (number, age, CP type, Gross Motor Function Classification System [GMFCS] level), suit type, intervention including dose of suit therapy, outcome measurements, outcomes, adverse effects, and funding were extracted. The method introduced by Furlan, Pennick, Bombardier, and van Tulder was used to evaluate the risk of bias for the assessment of methodological quality of randomized-controlled trials (RCTs).

Results: A total of 29 studies were included of which 10 were Class I, eight were Class II-III, and 11 were Class IV studies. Studies were heterogenous in design, sample size, study population, and outcomes measured. The methodological quality score of RCTs varied between 4 and 10. The results of the high-quality RCTs showed that wearing the suit along with conventional therapy improved proximal stability, gross motor function, and gait. The Class II-III and IV studies supported the findings of the Class I studies.

Conclusion: The major improvements from the RCTs were seen in proximal stability, gross motor function and gait, although grading was unable to be done due to the heterogeneity of included studies. In order to obtain gains in the function, it is important to carefully consider intended use, patient selection criteria, and suit type.

Keywords: Cerebral palsy, dynamic elastomeric fabric orthosis, mechanism, orthotic garment, suit therapy.

Suit therapies involve the use of garments, which are a kind of dynamic orthosis.^[1] Suit therapies are alternative and complementary treatment methods which have been increasingly utilized in the pediatric rehabilitation settings. Although their use has become popular in recent years, scientific evidence supporting their efficacy still remains scarce.

Therapeutic suits were first designed for cosmonauts in the late 1960s to create forces on the body for stabilizing the torso to allow for more fluent and coordinated movement of all limbs to counteract the adverse effects of zero gravity such as muscle atrophy and osteopenia.^[2,3] Therapeutic suits are body splints made of lycra or a kind of elastomeric fabric

which has a circumferential base. They are very close-fitting and worn next to the skin. The orientation of fabric applies a dynamic correctional force to target body part(s).^[4] The fabric exerts a vertically directed load thus serves as a stability vest. The pressure exerted by lycra garment over trunk and thigh was found to be greater in the sitting position followed by standing and sit to stand positions.^[5] These suits are assumed to create tension, thereby strengthening the muscles, and the deep pressure at the joints and provide an additional proprioceptive information which enhances body awareness. Since receiving sensory cues during rehabilitation may improve postural control, the proponents of the suit therapy methods have claimed

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Cite this article as:

Karadağ-Saygi E, Giray E. The clinical aspects and effectiveness of suit therapies for cerebral palsy: A systematic review. Turk J Phys Med Rehab 2019;65(1):93-110.

This project was presented as workshop at 12th World Congress of the International Society of Physical and Rehabilitation Medicine (ISPRM 2018). July 8-12, 2018, Paris, France.

that, once the body and body segments are in a proper alignment, intensive therapy with the suit on enables reeducation of the brain to recognize and form the correct movement of the muscles: The more correct proprioceptive input result in the more proper alignment (Figure 1).^[6,7] It has been proposed that these orthotic garments provide stabilization of the trunk, shoulder and pelvis girdle and, thus, improve proximal stability and upper extremity function.^[4] They can also improve the movement fluency.^[8] Therefore, children with sensory deficits and poor muscle strength including children with neuromotor developmental disorders and hypotonia can benefit from the use of suit therapies.^[9] The developers of this kind of orthotic suits have claimed that these suits appear to be most beneficial for children with moderate to severe hypotonia, particularly axial hypotonia, deficits in dynamic stabilization, tone fluctuations, and unpredictable movement control from dyskinesia, moderate-to-severe hypertonia that is compensatory for poor deep sensation, whole body sensory awareness deficits, and some types of sensory integration problems. Severe restricted pulmonary function and refractory cyanosis are absolute contraindications for lycra-based orthosis use while having severe reflux symptoms, uncontrolled epilepsy, cardiovascular circulatory

disorders and being diagnosed with diabetes are relative contraindications.^[4,9] High degree of spasticity, hip dislocation or severe scoliosis, hydrocephalus, myopathies, progressive encephalopathies, and psychiatric or behavior disorders have been also defined as contraindications for Adeli suit and TheraSuit exercise protocols.^[10,11] The undesirable effects pertaining to the use of these orthoses are difficulty in donning/doffing, toileting problems such as constipation and urinary leakage, decrease in respiratory function, heat and skin discomfort (e.g. hyperthermia in summer, cyanosis).^[7,12-15]

The existing therapy garments in the literature include Penguin suit, Adeli suit, TheraSuit, full body suit (Kendall-Camp UK Ltd.), dynamic elastomeric fabric orthosis (DEFO), stabilizing pressure input orthosis (SPIO), UpSuit, Second Skin and PediaSuit (Figure 2).^[4,6,7,10,12,16-23] These suits are dynamic orthoses available in different designs. The designs range from full body suits to smaller garments such as sleeves/gloves and leggings.^[3] They may be prescribed for the upper limb, lower limb, or full body.^[1] Also, there is extensive variability in the design of orthosis depending on the purpose and the manufacturer.^[3,18,19] Suit therapy protocols include wearing only the suit or

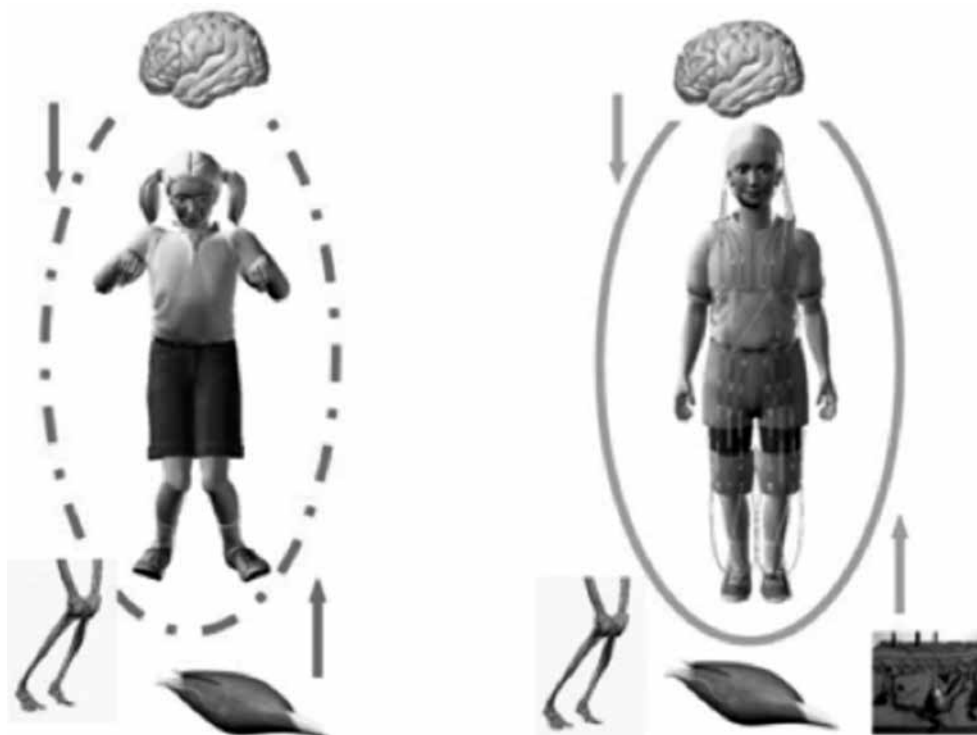


Figure 1. Mechanism of action of suit therapies (The vicious cycle (picture 1) can be interrupted and incorrect information is replaced by “new” correct information).^[6]



Figure 2. The existing suit types.^[4,6,9,14,18,20-23]

wearing the suit within an exercise treatment schedule. Adeli suit and TheraSuit include attachment points for straps and bungee cords. Therapist attempt to correct alignment by adjusting the bungee-like cords. TheraSuit is also a part of the TheraSuit Method®, which is based on an intensive and specific exercise program. The TheraSuit Method® utilizes various tools and exercises. Tools utilized during each exercise session consist of the Universal Exercise Unit, vibration and fitness machines, functional cages (the ‘monkey cage’ uses a system of pulleys and weights to isolate and strengthen specific muscles; and the ‘spider cage’ uses a belt and bungee cords to either assist upright positioning or practice many other activities that normally would require the support of more therapists) (Figure 3).^[3,6,10] Nonetheless, there is no standardized therapy protocol for suit therapies.

Recently, three systematic reviews have been conducted to evaluate the available evidence regarding the effects of suit therapies.^[1,3,24] In these reviews, the boundaries of what is known and what is not known have been defined; however, clinically relevant factors which allow guidance for reproduction of the intervention in daily practice still remain to

be elucidated. Families who have children with moderate-to-severe disabilities are at risk of spending valuable resources on alternative therapies, and professionals should be cautious in encouraging families to pursue alternative techniques in the early phases of research on their efficacy.^[3] To provide information for parents and for health professionals, who are frequently asked for advice on the effect of suit therapy for the management of cerebral palsy (CP), we thought it would be helpful to review the available literature and to provide a comprehensive discussion on the clinical aspects of suit therapies for the management of CP. Therefore, we aimed to review the available peer-reviewed reports of suit therapy to evaluate the clinical aspects and effectiveness of suit therapy for CP.

MATERIALS AND METHODS

Protocol and registration

The review protocol, registered on the Prospero database (CRD42018103053), is available http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018103053. The review is



Figure 3. Spider cage and universal therapy unit.^[6]

reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines.^[25]

Eligibility criteria

Criteria for considering studies for this review were based on the PICOS (population, intervention, comparison, outcome, and study) framework as follows:

1. Patients: Children (<18 years) with a diagnosis of CP
2. Intervention: Suit therapies
3. Comparison: Conventional therapy, neurodevelopmental therapy, or another therapeutic approach
4. Outcome: The clinical aspects of studies (number of participants, age, CP type, Gross Motor Function Classification System (GMFCS) level, suit type, intervention including dose of suit therapy, outcome measurements, outcomes, adverse effects, and funding)
5. Study: All types of trials published in peer-reviewed journals including randomized-controlled trials (RCTs) and non-RCTs and other studies (single case studies or case series)

Search strategy

A literature search was performed in the PubMed, SCOPUS, Web of Science, and PEDro databases within the period from the establishment of the relevant database through July 2018. Boolean operators of AND

and OR were used to combine keywords to ensure that the search was both sensitive and specific. The search strategy was based on Boolean combinations of the search terms “cerebral palsy, lycra, suit, suit therapy, garment, clothing, dynamic elastomeric fabric orthosis, Adeli, TheraSuit, Theratog”. Other potential studies for inclusion were identified by searching the reference lists of all included articles manually. Three additional articles were identified from the reference lists of the relevant articles.

Data collection and analysis

Two investigators independently extracted data regarding the number of participants, age, CP type, GMFCS level, suit type, intervention including dose of suit therapy, outcome measurements, outcomes, adverse effects, funding using a data extraction form. Any disagreement regarding data were resolved by discussion between the two review authors.

The articles were categorized according to their study design:^[26,27]

1. Class I: RCTs
2. Class II: Cohort studies and non-RCTs
3. Class III: Case-control studies
4. Class IV: Single-case studies and case series.

No studies were sufficiently homogeneous to justify useful meta-analysis. Also, the search results showed that current literature regarding the effectiveness of suit therapies for CP contained heterogeneous data, hindering grading the quality of evidence. Therefore,

a narrative synthesis approach was used. The data regarding the study subjects (number, age, CP type, GMFCS level), suit type, intervention including dose of suit therapy, outcome measurements, outcomes, and adverse effects were tabulated.

Methodological quality assessment

The method introduced by Furlan, Pennick, Bombardier, and van Tulder^[28,29] was used to evaluate the risk of bias for the assessment of the methodological quality of RCTs. The quality of the study was rated to be “high”, when at least 10 of the 12 criteria were met. The quality of the study was identified to be “low”, when the study met fewer than six of the criteria. The quality of studies were rated to be “moderate”, when six to nine criteria were met.^[28]

RESULTS

Study selection

A total of 375 articles were identified in the PubMed (n=120), Web of Science (n=91), SCOPUS (n=144), and PEDro (n=20). We included studies

published in peer-review journals focusing on the efficacy of suit therapies for CP and excluded review articles, duplications, and non-related articles. Once the duplicates were removed, 199 studies remained. Of the remaining articles, 169 were excluded, as they did not meet the inclusion criteria. A total of 30 full-text articles were accessed. Of these, one of them were excluded, as it was a conference abstract. Finally, 29 studies were included in the review (Figure 4).

Study characteristics

Types of studies

A total of 29 studies were included of which 10 (34.5%) were Class I,^[8,10,12,16,21,30-34] eight were (27.6%) Class II-III,^[4,14,15,17,20,35-37] and 11 (37.9%) were Class IV^[7,11,13,18,19,38-43] studies. Data regarding the study subjects (number, age, CP type, GMFCS level), suit type, intervention including dose of suit therapy, outcome measurements, outcomes, and adverse effects are presented in Table 1 and 2. Studies were heterogenous in design, size, study population, and outcomes measured (Table 1 and 2).

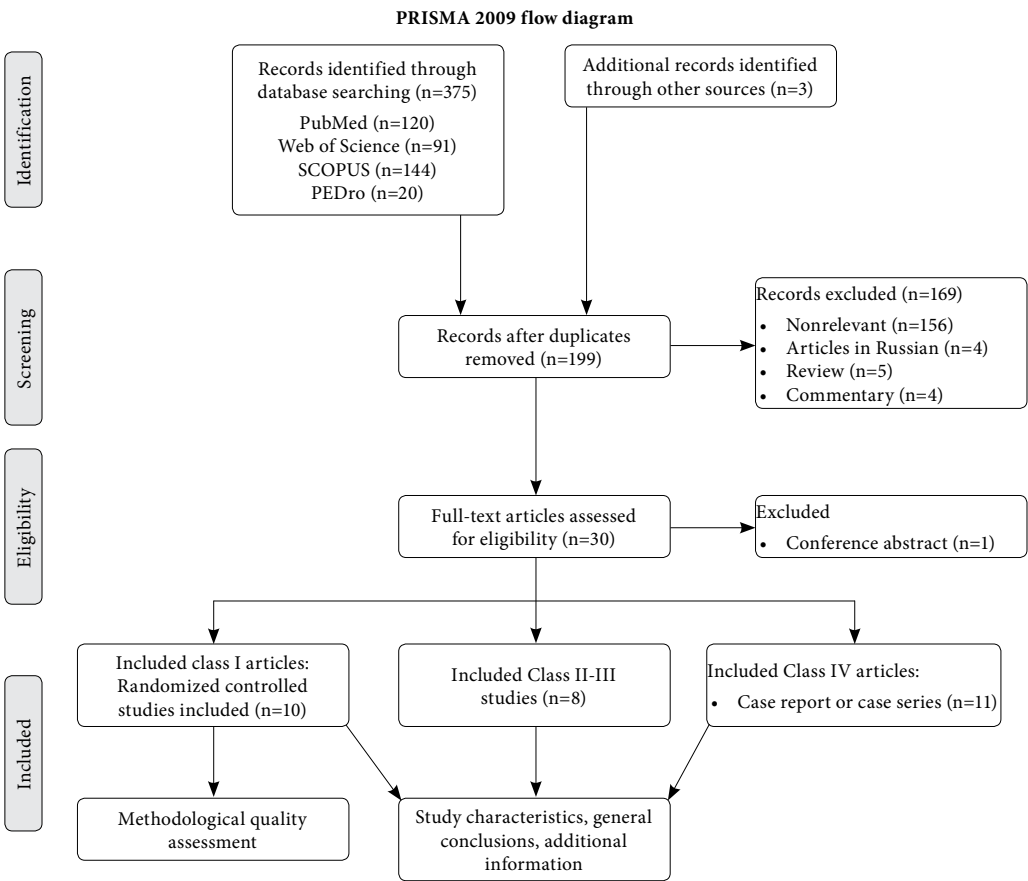


Figure 4. PRISMA flow diagram of the study.

Table 1. Study characteristics of identified studies part I

Study design	Sample size (n)	Age	CP type	GMFCS	Suit type	Intervention
Bar-Haim et al. ^[10]	RCT	24	Mean age 8.2 years, 5-12 years	Spastic diplegic, tetraplegic, mixed, ataxic	II-IV	Adeli suit (no further detail)
						Experimental (n=12) • Suit+NDT Control (n=12) • NDT 2 hours/day, 5 days/week for 4 weeks
Alagesan and Shetty ^[30]	RCT	30	4-12 years	Spastic diplegic CP	NS	TheraSuit Two hours a day for 3 weeks Experimental (n=15) • Modified suit therapy along with conventional therapy Control (n=15) • Conventional therapy
Elliott et al. ^[16]	RCT	16	9-14 years	Spastic dystonic, rigid	NS	Lycra arm splint Experimental group (n=8) • Lycra functional splint+goal-directed training. Control group • Goal-directed training only
Elliott et al. ^[8]	RCT	16	9.1-14.8 years	Hemiplegic, tetraplegic, dystonic, spastic, rigid	NS	Lycra arm splint (different splints for each individual) Six hours per day, 5 days per week for 3 month Experimental group (n=8) • Lycra arm splint wear during school hours Control group (n=8) • No intervention
Bailes et al. ^[1,2]	RCT	20	3-8 years	Not specified	III	TheraSuit Four hours/daily, 5 days a week, 3 weeks Experimental group (n=10) • TheraSuit with the elastic bungee cords attached. Control group (n=10) • "Controlsuit" (TheraSuit without the elastic bungee cords)
Azab and Hamed ^[31]	RCT	30	7-9 years	Spastic diplegic	NS	TheraSuit Experimental group (n=15) • Received conventional therapy while wearing suit Control group (n=15) • Received designed exercise on posture correction
Khayatzadeh et al. ^[32]	RCT	36	Mean age 7.78 years	Spastic, dystonic, diplegic, tetraplegic	I-IV	Adeli suit Two hours a day, 5 days a week, for 4 weeks Three groups: • MAST (n=12) • AST (n=12) • NDT with the suit on NDT (n=12)
Abd El-Kafy ^[33]	RCT	51	6-8 years	Spastic diplegic	I, II	Theratogs Two hours a day, 5 days a week for 12 weeks Experimental group 1 (n=16) • Theratogs with strapping system for lower extremity Experimental group 2 (n=17) • Theratogs plus solid GRAFO Control group (n=18) • Traditional PT
Kim et al. ^[21]	RCT	17	4-7 years	Diplegic, tetraplegic	I, II	Adeli suit Experimental (n=8) • Adeli suit (AST)+NDT 30 minutes/sessions, 2 sessions/day, 5 day/ week NDT plus 30 minutes/sessions, 2 sessions/day, 5 day/week for 6 weeks Adeli suit therapy session (individualized for each child) Control (n=9) • NDT group

Table 1. Continued

	Study design	Sample size (n)	Age	CP type	GMFCS	Suit type	Intervention
Giray et al. ^[34]	RCT	24	Mean age 61.1 months (35-105)	Spastic diplegic and tetraplegic	III, IV	Stabilizing input pressure orthosis (SPIO)	<ul style="list-style-type: none"> Control group (n=8) (received only conventional exercise therapy) SPIO 2-hour group (n=8) (two hours orthosis wear during therapy besides conventional therapy) SPIO 6-hour group (n=8) (four hours of orthosis wear in addition to two hours of wear during therapy besides conventional therapy) <p>Garment wear up to 8 hours/day, mean wear time 6.9 hour/day</p>
Blair et al. ^[4]	Repeated measures case study, cross-over design	24	15 months-14 years	Spastic (7), athetosis (5), dystonia (7), ataxia (4), hypotonia (1)	NS	UP suit (no details given, full body suit figure)	Garment wear up to 8 hours/day, mean wear time 6.9 hour/day
Rennie et al. ^[15]	Repeated measures case study	7	5-11 years	CP+Duchenne muscular dystrophy spasticity, athetosis, weakness, hypotonia, dystonia	NS	Full body suit	Two weeks familiarization (gradually increase garment wear up to 6 hours) 8 weeks in total
Nicholson et al. ^[14]	Repeated measures case study	12	2-17 years	Hemiplegia, diplegia, tetraplegic athetoid	NS	Variety of suit types according to child's needs	Two weeks gradually exposure to garment, up to 6 hours a day for a further 6 weeks plus therapy (30 minutes)
Flanagan et al. ^[17]	Quasi-experimental design	5	7-13 years	Diplegic CP	I	TheraTogs with individual adjustment (extra strapping system for some children)	10-12 hours per day, 12 weeks
Christy et al. ^[35]	Quasi-experimental design	17	4-12 years	Spastic, hypotonic, athetosis, ataxia, quadriplegic, diplegic and triplegic CP	I-III	TheraSuit	Four hours daily, 5 days a week, 3 weeks Intense therapy with suit (did not follow specific protocol amount of time spent in therapy differed among children!)
Degelaen et al. ^[36]	Quasi-experimental design	15	4-10 years	Spastic diplegic	I-II	Whole body pressure suit	Experimental group (n=15) Control group consisting of typically developing children (n=16)
Mélo et al. ^[20]	Retrospective cohort	53	1-15 years	Quadriplegia, diplegia, hemiplegia, dystonia, ataxia	I-V	PediaSuit	Three-four hours a day, 5 times a week, for a period of 4 weeks intensive neuromotor therapy modules with suit using spider cage and monkey cage
Romeo et al. ^[37]	Quasi-experimental design (non-randomized controlled study)	10	5-7 years	Spastic quadriplegia, diplegia	II-V	Lycra suit	Experimental group Suit wear (4 hours per day for 6 months. Control group Received no intervention with lycra garments
Hylton and Allen ^[7]	Case series	3	2-12 years	Mixed ataxic athetoid, diplegic, quadriplegic CP, cerebellar ataxia, Angelman syndrome	NS	SPIO different styles of orthosis depending on the patients need	Not specified
Cheng and Chan ^[38]	Case report	2	3-4 years	Hypotonic, athetoid CP	NS	Dynamic pressure garment	One hour of adjustment period for first week. Wear time gradually increased to 2.5 hours per day for 9 months (first case) and for 3 month (second case)
Knox ^[13]	Case series (repeated measures case study)	4	3-11 years	Spastic quadriplegia, diplegia, dystonic quadriplegia, choreoathetosis	Level 3 (n=1) Level 4 (n=2), Level 5 (n=1)	Camp lycra garment (total body, total body and gloves)	Camp lycra garment wear >4 hours per day for 4 weeks

Table 1. Continued

	Study design	Sample size (n)	Age	CP type	GMFCS	Suit type	Intervention
Corn et al. ^[39]	Multiple single subject experimental design	4	8-16 years	Ataxic hemiplegia, spastic hemiplegia, asymmetrical spastic quadriplegia, spastic quadriplegia	NS	Second skin upper limb lycra garment with different design	Splint wear up to 6.5 hours a day only at school not at home
Angilly ^[39]	Single case study	1	Not mentioned	Mixed dystonic, hemiplegic	NS	Second skin short bodice	Unclear
Matthews et al. ^[48]	Case report (repeated measures case study)	8	3-13 years	Spastic diplegic	NS	Dynamic elastomeric fabric orthotic (DEFO) leggings	Eight hours per day during waking hours during intervention phase Three phase A1 observation phase for 6 weeks B intervention phase for 6 weeks A2 intervention withdrawn
Bailes et al. ^[11]	Case report	2	8 years 3 months, 7 years 11 months	Spastic diplegic	III	TheraSuit with bungee cords	TheraSuit method of intensive suit therapy for 4 hours a day, 5 days a week for 3 consecutive weeks
Yasukawa and Uronis ^[40]	Case series	2	5 years, 3.6 years	Hemiplegic CP, obstetric brachial plexus palsy (OBPP)	NS	Dynamic movement orthosis (DMO) glove	Subjects began to wear DMO for 1-2 hours a day and wear time gradually increased up to 6-7 hours and continued to wear 6-7 hours a day for 6 months
Ko et al. ^[41]	Case report (single subject design)	1	8 years	Diplegic CP	III	Adeli suit therapy	Adeli suit therapy 50 minute sessions once a week for 18 weeks Usual physical and occupational therapy were maintained two times per week during study
Matthews et al. ^[42]	Retrospective cohort (case series)	180	Mean age 9 years	Cerebral palsy (n=79), Neuromuscular dystrophy (n=5), Developmental delay (n=42)	NS	Dynamic elastomeric fabric orthosis (DEFO)	Unclear
Lee ^[43]	Case report	2	6 years 3 years	Spastic diplegic	II	Adeli suit	Adeli suit therapy including garment wear and exercises (60 minute sessions, five session per week for 4 weeks)

CP: Cerebral palsy; GMFCS: Gross Motor Function Classification System; RCT: Randomized-controlled trial; NDT: Neurodevelopmental therapy; NS: Not specified; MAST: Modified adeli suit therapy; AST: Adeli suit therapy; GRAFO: Ground Reaction Ankle Foot Orthosis; SPIO: Stabilizing Pressure Input Orthosis; DEFO: Dynamic elastomeric fabric orthotic; OBPP: Obstetric brachial plexus palsy; DMO: Dynamic Movement Orthosis.

Table 2. Study characteristics of identified studies part II

	Outcome assessments	Follow-up points	Outcomes	Parent satisfaction, adverse effects	Funding/declaration of interest
Bar-Haim et al. ^[10]	<ul style="list-style-type: none"> GMFM-66 Energy cost during stair-climbing 	Baseline, after 1 month and 9 months	Significant improvements by time but no group differences	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effects Not reported 	None
Alagesan and Shetty ^[30]	GMFM-88	Baseline, after 3 weeks	Significant group differences	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effects Not reported 	None
Elliott et al. ^[16]	<ul style="list-style-type: none"> Goal attainment scale 3D upper limb and trunk kinematic 	Baseline, immediate, immediately upon splint removal, after three months	Attainment of movement goals, improvements in postural control and decreased compensatory movements	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effects Not reported 	Funded by second skin
Elliott et al. ^[8]	<ul style="list-style-type: none"> Melbourne assessments Fluency (three dimensional upper limb kinematics) 	Baseline, initial splint wear, immediately following splint removal, after three months	Decreased jerkiness, improved fluency in children with dystonia	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effects Not reported 	Funded by second skin
Bailes et al. ^[12]	<ul style="list-style-type: none"> GMFM-66 PEDI 	Baseline, 4 weeks, 9 weeks	No significant between group differences	Parent satisfaction <ul style="list-style-type: none"> Discomfort Too intense Want to enroll program again if it would be repeated No serious adverse effect 	TheraSuit LLC
Azab and Hamed ^[31]	Posture analysis system	Baseline, after 3 months	Significant group differences in posture (trunk imbalance, pelvic tilt, lateral rotation)	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effects Not reported 	None
Khayatzadeh et al. ^[32]	GMFM	Baseline, 4 weeks, 16 weeks	MAST>AST>NDT	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effects Not reported 	None
Abd El-Kafy ^[33]	Gait kinematic	Baseline, 30 minutes after removing Theratogs and post treatment (after 12 weeks) (assessments were done without suit)	Theratogs with GRAFO> conventional treatment with or without therasuit	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effects Not reported 	None
Kim et al. ^[21]	<ul style="list-style-type: none"> Gait analysis GMFM TUG PBS 	Pre and post-intervention (6 weeks)	Combined AST/NDT than NDT alone yielded improvements in spatiotemporal gait parameters but not GMFM, PBS and TUG	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effects Not reported 	None
Giray et al. ^[34]	<ul style="list-style-type: none"> SAS Cobb angle Kyphotic angle Migration Index 	Before treatment and at six months after treatment	Improved kyphosis, but not scoliosis and hip lateralization Using the SPIO vest for two and six hours also yielded similar outcomes	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effects Not reported 	None
Blair et al. ^[4]	Observer rated change from video recordings Respiratory function Grip strength Abdominal strength	Before intervention, day 4, day 7, day 10, day 16	Improvements in postural stability and dynamic function, reduced involuntary movements and increased confidence to attempt motor tasks	Parent satisfaction <ul style="list-style-type: none"> Gain in confidence to attempt tasks Adverse effects Respiratory compromise Hyperthermia 	Funded by second skin

Table 2. Continued

	Outcome assessments	Follow-up points	Outcomes	Parent satisfaction, adverse effects	Funding/declaration of interest
Rennie et al. ^[15]	<ul style="list-style-type: none"> • PEDI gait analysis 	Baseline, after 8 weeks (assessments with the garment on)	No improvements in proximal or distal stability, or PEDI scores	Parent satisfaction <ul style="list-style-type: none"> • Suit was easy to get on • Increased confidence during mobilizing • Seven of eight parents reported they would not use garment in the future Adverse effect <ul style="list-style-type: none"> • Skin chaffing in joint lines • Uncomfortably warm in summer and excessive perspiration and dehydration 	Funded by Kendall-Camp Orthopaedic Ltd.
Nicholson et al. ^[14]	<ul style="list-style-type: none"> • PEDI • Reach and grasp test by kinematic motion analysis (applied to only 5 selected children) 	Immediately before the garments were fitted and 8 weeks later wearing the garment	Improvements in proximal stability	Parent satisfaction <ul style="list-style-type: none"> • Difficult to don on/off • Severe constipation • Circulation difficulties, blue fingers • Difficulty in cleaning the suit (ideally a second suit should be available) Adverse effect <ul style="list-style-type: none"> • Difficult to don on/off 	Funded by Kendall-Camp Orthopaedic Ltd.
Flanagan et al. ^[17]	<ul style="list-style-type: none"> • Gait analysis • Gross motor abilities and balance (BOTMP, COPM) Parent satisfaction	Two and 4 months after intervention	<ul style="list-style-type: none"> • Correction of pelvic alignment • No change in gait parameters • Significant difference in BOTMP No significant improvement in COPM	Parent satisfaction <ul style="list-style-type: none"> • Parental report of improved walking and confidence Adverse effects <ul style="list-style-type: none"> • Difficulties in dressing and toileting and discomfort in hot weather 	None
Christy et al. ^[18]	<ul style="list-style-type: none"> • GMFM-66 • Step watch activity monitor • COPM • PODCI 	Baseline, 3 weeks, 3 months	Improved gross motor skills and participation, but not community ambulation	Parent satisfaction <ul style="list-style-type: none"> • Not specifically tested • PODCI results (well-being of child from caregiver perspective) Adverse effect <ul style="list-style-type: none"> • Not reported 	None
Degelaen et al. ^[16]	Kinematic analysis	Without garment, with garment	<ul style="list-style-type: none"> • Improved coordination between trunk and extremities Increased step velocity and cadance, improved interjoint coordination between hip-knee and knee-ankle in children without ankle joint contracture	Parent satisfaction <ul style="list-style-type: none"> • Not tested Adverse effects <ul style="list-style-type: none"> • Not reported 	None
Mélo et al. ^[20]	GMFM	Before and after each nodule	<ul style="list-style-type: none"> • Improvement at GMFM scores Improvement was higher in after first modules and continued over time	Parent satisfaction <ul style="list-style-type: none"> • Not tested • Adverse effect • Not reported 	None
Romeo et al. ^[27]	GMFM Computerized static balance assessment (center of pressure as a measure of trunk control)	At the beginning of the study and 6 months after the study (assessments were performed with and without the suit)	At 6 months study group showed better static balance than control group, while there were no differences between groups in terms of GMFM	Parent satisfaction <ul style="list-style-type: none"> • Difficulty in putting the suit on Adverse effect <ul style="list-style-type: none"> • No specific adverse effect • Skin chaffing over joint lines 	None

Table 2. Continued

	Outcome assessments	Follow-up points	Outcomes	Parent satisfaction, adverse effects	Funding/declaration of interest
Hylton and Allen ^[7]	Observational results	Not specified	<ul style="list-style-type: none"> “... He began to explore his environment in a more ordered and secure way...” “... Immediate improvement of hip/lower trunk/pelvic/upper leg stability was noted...” “... Gave him better ownership of his body...” 	Parent satisfaction and adverse effects <ul style="list-style-type: none"> Warmth in summer Not specifically reported 	The manuscript is written by the developers of the orthosis
Cheng and Chan ^[38]	Video recordings on gross and fine motor skills	Before, immediately wearing the suit, and at the end of trial	Observational results: “.. the frog position of the legs in lying was reduced...”	Parent satisfaction <ul style="list-style-type: none"> Not reported Adverse effect <ul style="list-style-type: none"> Skin sensitivity to lycra material 	None
Knox ^[13]	GMFM QUEST Parent questionnaire	Pre-intervention, post-intervention	<ul style="list-style-type: none"> Three participants had improved GMFM scores while one had a reduced score. Two participants showed improvement in QUEST score. Observational results: Improved sitting balance, “... felt less afraid when sitting...”, able to self feed when wearing the garment, reduced range of involuntary movements 	Parent satisfaction <ul style="list-style-type: none"> Child and parent questionnaire Adverse effect <ul style="list-style-type: none"> Garment being difficult and time consuming to put on/take off, hot and restrictive to wear, in some cases reducing function 	Supported by Kendall-Camp Company (UK) Ltd.
Corn et al. ^[39]	Melbourne Assessment of quality of upper limb movement (video recordings)	Assessments were performed two times a week during Baseline (non-wearing phase) and intervention phase (wearing phase)	<ul style="list-style-type: none"> Long-term wearing resulted in decreased function in one child. Significant improvements were found while wearing the splint initially but was not maintained over time 	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effect <ul style="list-style-type: none"> Not reported 	None
Angilley ^[9]	GMFM Video recording during Bruininks Oseretsky test of motor proficiency, dressing and eating skills Qualitative assessments including monthly taped interviews and daily diary that were completed by the mother of the participant	Before intervention, monthly and 6 months after intervention	<ul style="list-style-type: none"> No change in GMFM or in the domains of fine motor skills of Bruininks Oseretsky test of motor proficiency Involuntary movements of shoulder seemed to be decreased in video recordings 	Parent satisfaction <ul style="list-style-type: none"> Adverse effects <ul style="list-style-type: none"> Skin reactions on axillary region The suit was uncomfortable to wear in hot weather Cleaning the suit was problematic because it took a day for the suit to become dry after washing 	The subject was selected by second skin and glove was provided by second skin
Matthews et al. ^[40]	GMFM <ul style="list-style-type: none"> 10 meter walking test VAS scoring of perceived change in gait PSFS Diary kept by patients and carers concerning number of hours of orthotic wear and perceived changes in mobility	Three phase <ul style="list-style-type: none"> A1 observation phase for 6 weeks B intervention phase for 6 weeks A2 intervention withdrawn 	Beneficial effects on gait and perceived performance	Parent satisfaction <ul style="list-style-type: none"> Tested via diary Adverse effects <ul style="list-style-type: none"> Soreness to thighs from increased heat Difficulty in don and doff of leggings	D.M. Orthotics Ltd provided the leggings free of charge
Bailes et al. ^[11]	PEDi <ul style="list-style-type: none"> GMFM Three-dimensional gait analysis	Pre- and post-intervention	<ul style="list-style-type: none"> Small changes in GMFM and PEDi Improved walking speed, cadance, symmetry, joint motion, and posture detected in gait analysis 	Parent satisfaction <ul style="list-style-type: none"> Not tested Adverse effect <ul style="list-style-type: none"> Not reported 	None

Table 2. Continued

Outcome assessments	Follow-up points	Outcomes	Parent satisfaction, adverse effects	Funding/declaration of interest
Yasukawa and Uronis ⁽⁴⁰⁾ Melbourne assessment of quality of upper limb movement (video recordings)	Baseline, after 1 month of wearing the DMO, after 3 months of wearing the DMO and after 6 months of wearing the DMO	Functional improvement over time in Melbourne Assessment of quality of upper limb movement	Parent satisfaction • Not tested Adverse effects • Not reported	None
Ko et al. ⁽⁴¹⁾ • 10 meter walking test • GMFM • PBS	Baseline and each week	Statistically significant changes in 10-meter walking speed, GMFM and PBS after intervention compared to baseline	Parent satisfaction • Not tested Adverse effects • Not reported	None
Matthews et al. ⁽⁴²⁾ Cobb angle	Unclear	A scoliosis progression of -6.3° (SD -6.7°) in three children Maintenance of the scoliosis with no progression in five children	Parent satisfaction • Not tested Adverse effects • Not reported	First author is Director of DM Orthotics
Lee ⁽⁴³⁾ GMFM Gait analysis FAPS	Before intervention, 4 weeks after intervention	Improvements in GMFM, gait velocity and cadence and FAPS	Parent satisfaction • Not tested Adverse effects • Not reported	None

GMFM: Gross Motor Function Measure; PED: Performance on the Pediatric Evaluation of Disability Inventory; LLC: Limited liability company; MAST: Modified Adeli suit therapy; AST: Adeli suit therapy; NDT: Neurodevelopmental therapy; TUG: Timed up and go; PBS: Pediatric Balance Scale; GRAFO: Ground Reaction Ankle Foot Orthosis; SAS: The Sitting Assessment Scale; AST: Adeli suit therapy; NDT: Neurodevelopmental therapy; SPIO: Stabilizing Pressure Input Orthosis; BOTMP: Brunninks-Oseritsky Test of Motor Proficiency; COPM: The Canadian Occupational Performance Measure; PODCI: Pediatric Outcomes Data Collection Instrument; QUEST: Quality of Upper Extremity Skills Test; VAS: Visual Analog Scale; PSFS: Patient Specific Functional Scale; PBS: Pediatric Balance Scale; FAPS: Functional Ambulation Performance Score;

Types of participants

Age of the children with CP included in RCTs ranged between 3 and 14 years. The sample size of the RCTs ranged from 16 to 51. Among 29 studies, only nine (31.04%) of them included only a specific type of CP. Fourteen (48.28%) of the studies did not report the GMFCS level of the participants.

Types of interventions

Intervention protocols varied among studies. Also, in most of the studies co-interventions varied among individuals (each child's therapeutic program was individualized with the goal of advancing the patient to the next level of function;^[21] for instance, some children spent more time than others using the TheraSuit, cage, and weights.^[35] Suit designs also differed among studies and varied among study participants in some of the studies.^[13,14] Strapping system design that varied among participants were also detected (a strapping system was individually designed for each child by consensus of the team).^[17] Nine (31.03%) of the studies investigated the effect of suit on upper limb function,^[4,7,8,13,14,16,19,39,40] while 10 of them investigated effects on lower limb function (e.g. gait analysis parameters, balance or walking performance tests).^[11,15,17,18,21,33,36,37,41,43] Suit therapy protocols included wearing only the suit or wearing the suit within an exercise treatment schedule. Suit therapy protocols included wearing the suit within exercise treatment schedule in all RCTs and effects of suit therapy protocol, compared to the effects of only exercise treatment schedule. Some of the Class II-IV studies investigated the effects of only wearing the suit (without receiving exercise treatment).^[15,17,18,36] In some of the studies, children continued their regular treatment and they only wore suit and received no intervention, while wearing the suit.^[13,14,37,38]

Types of outcome measures

The Gross Motor Function Measure was the most reported outcome. Outcomes mainly consisted of body structure and function and/or activity level outcomes. The evaluation of the effects of suit therapies on participation component of the International Classification of Functioning, Disability, and Health (ICF) are limited. Follow-up points differed among studies. Seventeen (58.62%) of the studies did not report parental satisfaction or adverse effects. Some of the studies immediate effect of suits were assessed immediately after the patients put on the orthosis.^[4,7,8,16] Eleven (37.9%) of the identified studies used kinematic assessments to evaluate the effects

Table 3. Methodological quality assessment

Study	A		B		C		D		E		F		Scoring	Methodological quality
	1	2	3	4	5	6	7	8	9	10	11	12		
Bar-Haim et al. ^[10]	Y	Y	N	N	N	Y	Y	Y	Y	N	Y	Y	8	Moderate
Alagesan and Shetty ^[30]	Y	Y	N	N	Y	N	Y	Y	Y	Y	Y	Y	9	High
Elliott et al. ^[8]	N	N	N	N	N	N	Y	N	Y	N	Y	Y	4	Low
Elliott et al. ^[16]	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	7	Moderate
Bailes et al. ^[12]	Y	Y	N	N	Y	Y	Y	Y	Y	N	Y	Y	9	Moderate
Azab and Hamed ^[31]	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	5	Low
Khayatzaideh et al. ^[32]	Y	N	N	N	N	N	Y	Y	Y	Y	Y	Y	7	Moderate
Abd El-Kafy ^[33]	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y	10	High
Kim et al. ^[21]	N	N	N	N	N	Y	Y	Y	Y	N	Y	Y	6	Moderate
Giray et al. ^[34]	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Y	Y	10	High

Table to show the methodological quality assessment rating and scoring of the included randomized controlled studies. Y: Yes (criteria achieved). N: No (criteria not achieved). Internal validity criteria refer to characteristics of the study that might be related to selection bias (criteria 1, 2, 9), performance bias (criteria 3, 4, 10, 11), attrition bias (criteria 6, 7), and detection bias (criteria 5, 12). Each criterion should be scored as yes, unclear, or no, where yes indicates the criterion has been met and therefore suggests a low risk of bias. The quality of the study is rated to be “high” when at least 10 of the 12 criteria were met. The quality of the study is identified to be “low” when the study met fewer than 6 of the criteria. The quality of studies are rated to be “moderate” when 6-9 criteria were met.

Key to abbreviations:

- A 1 Was the method of randomization adequately generated?
- B 2 Was the treatment allocation adequately concealed?
- C 3 Was the knowledge of all the allocated interventions adequately prevented during the study?
- 4 Was the patient blinded to the intervention?
- 5 Was the care provider blinded to the intervention?
- D 6 Was the outcome assessor blinded to the intervention?
- 7 Were incomplete outcome data adequately addressed?
- E 8 Was the drop-out rate described and acceptable?
- F 9 Were all randomized participants analyzed in the group in which they were allocated?
- 10 Are reports of the study free of suggestion of selective outcome reporting?
- Other sources of potential bias.
- 9 Were the groups similar at baseline regarding the most important prognostic indicators?
- 10 Were co-interventions avoided or similar?
- 11 Was the compliance acceptable in all groups?
- 12 Was the timing of the outcome assessment similar in all groups?

of suits.^[8,11,14-17,21,31,33,36,43] Kinematic assessment was performed in only one of the high quality RCTs.^[33]

Methodological quality

The methodological quality score of RCTs varied from 4 to 10. Two (20%) of the RCTs were rated to have low methodological quality, five RCTs (50%) were rated to have moderate methodological quality, and three (30%) of them were rated to have high methodological quality (Table 3). Most of the RCTs failed in blinding care providers, patients or assessors, and only 50% of the trials reported adequate concealment of allocation. Co-interventions were not similar in 40% of the RCTs.

Synthesis of results

There is high quality evidence from one RCT showing that full body suit in addition to conventional therapy is beneficial for improving gross motor function in children with diplegic CP.^[30] There is high quality evidence from one RCT suggesting that children with diplegic CP at GMFCS level I, II benefit from the use of TheraTogs strapping system plus ground reaction ankle foot orthosis (GRAFO) to improve gait speed, cadence, stride length, hip and knee flexion angles during walking, compared to conventional therapy with and without suit.^[33] There is high quality evidence from one RCT showing that vest type suit therapy in addition to conventional therapy result in improvement in the trunk posture of children with diplegic and tetraplegic CP at GMFCS level III-IV.^[34] There is moderate quality of evidence from four RCTs showing that suit therapy in addition to conventional therapy yields no significant change in GMFM compared to conventional therapy only in children with diplegic and tetraplegic CP. There is moderate quality of evidence from one RCT suggesting that lycra arm splints provide improvement in attaining movement goals, postural control and compensatory movements.^[16] The Class II-III and IV studies support the findings of the Class I studies. None of the studies investigated the feasibility (e.g adherence/compliance), and cost-effectiveness. Eleven of the included studies were funded by orthotic companies. Undesirable or adverse effects pertaining to the use of suit were reported in only 11 of the included studies. The reported undesirable effects were difficulty in donning/doffing, toileting problems such as constipation and urinary leakage, decrease in respiratory function, heat and skin discomfort (e.g. hyperthermia in summer, cyanosis).^[7,12-15]

DISCUSSION

In this review, 10 RCTs were identified. The studies are heterogeneous in design, include different outcome measures which are measured at different follow-up times. The studies investigating the effects of such kind of orthoses mainly consist of quasi-experimental designed studies, case reports, and case series. For systematic reviews and meta-analysis, the Cochrane Collaboration and PRISMA guidelines recommends presenting overall quality of evidence using the GRADE-approach (Grading of Recommendations Assessment, Development, and Evaluation).^[44] Due to the heterogeneity of included studies, meta-analysis and creating a GRADE table was not possible in the present review.^[27] Thus, all conclusions should, thereby, be considered with caution. We detected significant improvements in the proximal stability, gross motor function, and gait from the high quality RCTs. Recently, three systematic reviews have been conducted to evaluate the available evidence regarding the effects of suit therapies. However, current systematic reviews are often limited in their usefulness for guidelines, as they rate risk of bias by studies across outcomes rather than by outcome across studies.^[25,44,45]

Patient characteristics

It is not possible to draw firm conclusions regarding the important question which children with CP may benefit more than others from suit therapies due to limited evidence and heterogeneity of the included studies. Only in one study, improvements were more prominent in children with higher motor function (GMFCS levels II and III).^[10] However, it seems reasonable that children with diplegic and tetraplegic CP at GMFCS level III-IV are more suitable for suit therapies aiming to improve proximal stability while children with diplegic CP at GMFCS level I, II are more suitable for suit therapies targeting to improve gait and balance.

Treatment characteristics

Additionally, no firm conclusions could be drawn with regard to specific details of suit therapy what may be more or less effective due to the differences among therapeutic suits and the time regimens in which they were implemented. Proceedings from 2011 American Physical Therapy Association Section on Pediatrics Research summit define dose as frequency, intensity, timing, and type of intervention.^[46] Dose of suit therapies are variable. Bailes^[46] suggested that dosing parameters

relate to the ingredients in intensive suit therapy programs; therefore, describing the specific protocol is crucial while evaluating packaged programs such as suit therapy that consist of multiple ingredients. The frequency of the therapy was reported to be five days a week for three to 12 weeks in the included studies. Timing of suit therapies ranges two hours to 12 hours a day. The intensity, which refers to how hard the child works within the intervention, was not reported in any of the studies. Type of interventions have not been adequately addressed.^[46] Only one RCT compared the effects of two- and six-hours daily wear of the vest type suit in addition to conventional therapy and found no difference between the efficacy of two- and six-hours daily wear on the improved trunk posture. The optimal intensity of wear to guarantee efficacy of suit therapy is still uncertain.^[24] The results of RCTs with high and moderate quality have shown that wearing suit during treatment is more effective than conventional treatment. Despite reported undesirable effects, feasibility of the suit therapies has not been studied before. No serious adverse effects were reported. However, given the fact that possible side effects were not sufficiently addressed in all of the included studies and limited evidence on positive effects of suit therapies, widespread uncritical use cannot be supported. In addition, none of the studies investigated the cost-effectiveness of suit therapies.^[3]

Strength and limitations of the study

The main strength of the present review is that it focused on clinical aspects of suit therapies which is useful for guidance for reproduction of the intervention in daily practice and drawing attention to important points that should be considered in the design of future researches. Also, the present review provided a compressive overview on suit therapies by adding recently published articles that have not been assessed previously. Nonetheless, this review has some limitations. It was impossible to give precise guidance on the right target group and best effective therapy protocol due to heterogeneity of the included studies. We used the method introduced by Furlan, Pennick, Bombardier, and van Tulder^[28,29] for the evaluation of the risk of bias to examine the methodological quality of RCTs. However, scales for the assessment of the methodological quality that numerically summarize multiple components into a single number are judged as misleading and unhelpful by the GRADE guidelines.^[45] However, due

to heterogeneity of the studies, it was not possible to develop a GRADE approach and, therefore, we used a scale that numerically summarize methodological quality assessment to give an overview of the methodological quality of the RCTs evaluating the effects of suit therapies.

Implementing evidence into clinical practice and future research

Randomized-controlled trials are more powerful than others in their ability to answer research questions on the effectiveness of interventions.^[47] Systematic reviews only include RCTs to reduce bias.^[44] The results from other type of research studies have left unmentioned. As indicated in a recent paper in the *British Medical Journal*, parachutes reduce the risk of injury after gravitational challenge, although their effectiveness has not been proved in RCTs.^[48] Therefore, systematic reviews can define the boundaries of what is known and what is not known. Systematic reviews may be helpful; however, they can never replace sound clinical reasoning. Cerebral palsy is a heterogeneous condition blending motor, sensory, and cognitive disorders, often accompanied by other medical symptoms. It is impossible to make recommendations for the entire group of CPs at different functional levels.^[49] Since researchers measure the average responses in the heterogeneous condition of CP, the results of systematic reviews should be interpreted with caution. Systematic reviews can never make individual recommendations for clinical care; rather, they provide a summary of average responses to intervention as reported in systematic literature review.^[50]

The implementation of evidence into clinical practice and future research is of utmost importance. Suit therapies may be costly and time-consuming.^[1,3] Due to the lack of definitive treatment for CP, it is not surprising that alternative approaches to management arise and attract attention of parents of children with CP.^[51] Families who have children with moderate to severe disabilities are at risk of spending valuable resources on alternative therapies.^[52]

Cerebral palsy is heterogeneous which involves different parts of the brain with different etiologies and pathophysiologies and, thus, it would be surprising to have one therapy be beneficial for everyone with CP.^[53] Suit therapies can be implemented in case of appropriate patient selection criteria, a specific neurological need and intended functional outcome. Children at GMFCS level III may have difficulty with

functional upright activities in the suit due to their level of impairment and, therefore, suit therapies for improving such function can be beneficial for children at GMFCS level I and II.^[54] The benefits from the treatment should be assessed via ICF based outcome measurement. Success of an intervention can be defined as promoting functioning and ease disability. Therefore, the final aim of implementing suit therapies should be improving function and disability. Any therapy, whether complementary or therapeutic, should be evaluated in terms of its effects on body functions and structures, activities, and participation.^[53] For the evaluation of outcomes, immediate effect of the suits should be taken into account and the evaluations should be done without suit on. The only significant improvements from the high quality RCTs were in proximal stability, gross motor function and gait. Children with impaired proximal stability and who require trunk control to ease performing everyday activities may benefit from the use of vest type orthotic garment. Children with diplegic CP may benefit from the use of full body suit in addition to conventional therapy to improve gross motor function. Children with diplegic CP at GMFCS level I, II may benefit from the use of strapping system plus GRAFO to improve gait speed, cadence, stride length, and hip and knee flexion angles during walking compared to conventional therapy with and without suit.

In conclusion, in order to obtain gains in the function, it is important to carefully consider intended use, patient selection criteria, and suit type. The issue is about doing the right things with the right child at the right time, as suit therapies are highly individual.^[55] Therefore, ONE size does not fit ALL children with CP. To draw a final conclusion on the effects of dynamic elastomeric fabric orthosis vest, further studies including large numbers of children with CP at different functional levels and ages in order to establish impact of this orthosis type in children with CP at different functional levels and ages via subgroup analysis; kinematic assessment of evaluated body segment; and assessment of activity and participation in addition to body structure and function must be conducted.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The authors received no financial support for the research and/or authorship of this article.

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