Efficacy of suit therapy on functioning in children and adolescents with cerebral palsy: a systematic review and meta-analysis

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ABBREVIATIONS

AST	Adeli suit treatment
CAM	Complementary and alternative medicine
MAST	Modified Adeli suit therapy
NDT	Neurodevelopmental treatment
PEDI	Pediatric Evaluation of Disability Inventory
PEDro	Physiotherapy Evidence Database
RCT	Randomized control trial

AIM This systematic review and meta-analysis presents an overview of the efficacy of suit therapy on functioning in children and adolescents with cerebral palsy (CP).
METHOD A systematic review with meta-analysis was conducted. A comprehensive search of peer-reviewed articles was performed on electronic databases, from their inception to May 2014. Studies included were rated for methodological quality using the Physiotherapy Evidence Database scale. Effects of suit therapy on functioning were assessed using meta-analytic techniques.
RESULTS From the 46 identified studies, four met the inclusion criteria and were included in the meta-analysis. Small, pooled effect sizes were found for gross motor function at post-treatment (g=0.46, 95% confidence interval [CI] 0.10–0.82) and follow-up (g=0.47, 95% CI 0.03–0.90).
INTERPRETATION The small number of studies, the variability between them, and the low sample sizes are limitations of this review. Findings suggest that to weigh and balance benefits against harms, clinicians, patients, and families need better evidence to examine and prove the effects of short intensive treatment such as suit therapy on gross motor function in children and adolescents with CP. Therefore, more research based on high-quality studies focusing on functioning in all dimensions of the International Classification of Functioning, Disability and Health perspective is necessary to clarify the impact of suit therapy.

Cerebral palsy (CP) designates a group of permanent disorders of the development of movement and posture, which causes activity limitations. These disorders are attributed to non-progressive disturbances that occur in the developing fetal or infant brain, and are often accompanied by other conditions such as: (1) disturbances of sensation, perception, cognition, communication, and behaviour; (2) epilepsy; and (3) secondary musculoskeletal problems.[1] In the general population, the estimated prevalence is two in every 1000 live births.[2,3]

From an International Classification of Functioning, Disability and Health perspective (ICF), CP affects a person's 'functioning', inclusive of body structures and functions, activities, and participation, which may in turn cause 'disabilities' such as impairments, activity limitations, and participation restrictions.[4] The limitations in activity require individual rehabilitation throughout the lifespan.[5]

Rehabilitation in children with CP aims to minimize the effect of physical impairments, promote independence, and improve the quality of life of children and their families who play a major role in the process.[6,7] The process of rehabilitation is influenced by the clinical type and severity of the CP, the existence of additional disabilities (e.g. visual, auditory, or cognitive), emotional problems, the physiological age of the child, and the family's socio-economic status.[8]

The management of motor disability in CP includes physical therapy and a wide spectrum of other therapeutic interventions.[9] Physical therapy focuses on function, movement, and optimal use of the child's potential. Physical therapists use different therapeutic approaches in the (re)habilitation of children with CP to maintain and restore physical, psychological, and social well-being.[10,11]

Context-focused therapy, bimanual training, constraint-induced movement therapy, neurodevelopmental treatment (NDT), goal-directed/functional training, muscle strengthening, and/or home programs for improving motor activities or self-care function are some of the therapeutic approaches used in CP rehabilitation by physical therapists

all around the world. However, no one treatment has been shown to be conclusively effective at more than one level of the ICF.[12]

In recent decades, different biomedical, surgical, and biomechanical innovations have led to the development of new intervention techniques[11] in the (re)habilitation of young people with CP, namely therapeutic garments with a roughly similar construction and intention of Adeli suit[13] such as dynamic movement orthoses or lycra body suit orthoses.[14] The designs of these orthoses range from full body suits to smaller garments such as sleeves/gloves and leggings.

Unfortunately, research studies evaluating the effects of orthoses for people with CP often lack a well-specified research question, sufficient detail of the methodology, and adequate description of the participants and/or the intervention. There is often a lack of clarity about what is being evaluated in orthotic research studies.[15]

The original suit was developed for Russian cosmonauts in the late 1960s. It was referred to as a 'Penguin suit' and designed to counteract the adverse effects of zero gravity including muscle atrophy and osteopenia, and maintain neuromuscular fitness during weightlessness experienced by cosmonauts. In 1991, the Adeli suit incorporated a prototype of a device developed in Russia for children with CP and popularized by the EuroMed Rehabilitation Center in Mielno, Poland.[13,16]

Since then, this dynamic orthotic has been popularized in different countries and different designations have been used according to their respective protocols (e.g. Adeli suit, TheraSuit, and PediaSuit).[17,18] The differences between these protocols are not clear in the literature, and most interventions use a combination of suits with intensive physical therapy (i.e. 2–4h sessions, 5 or 6d/wk, over 3 or 4wks). Suit therapy is considered appropriate for children from 2 years of age to adulthood.[18,19]

Adeli suit is a form-fitting garment with different attachment points for straps and bungee cords that offer the wearer support and resistance to movement.[17] It consists of a vest, shorts, kneepads, and specially connected shoes; hooks, rings, and elastic bands connect the pieces of the garment and are adjusted to optimally position limbs and joints. Therapists attempt to correct the abnormal muscle alignment by adjusting the bungee-like cords to mimic normal flexor and extensor patterns of major muscle groups. The elastic cords are assumed to create tension thereby strengthening the muscles, and the deep pressure at the joints is assumed to improve the sensory and proprioceptive information. The suit also aims to enhance the vestibular system and improve coordination.[16] The idea is that once the body is in proper alignment, intensive movement therapy can be performed that will re-educate the brain to recognize correct movement of the muscles.[13] The suit serves as a stability vest that produces a vertically directed load of approximately 15 to 40 kg.[20]

This intervention protocol includes a rigorous physical therapy protocol and treatment is based upon three principles: the effect of the suit (working against resistance loads, increased proprioception, and realignment); 1 month of intensive daily physical therapy; and active motor participation by the patient. Additionally, some protocols used ability exercise units or functional cages. These cages can be used in two ways: 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.[18]

What this paper adds

- Suit therapy interventions have limited and heterogeneous effects on gross motor function.
- Limitations of evidence on suit therapy should be considered when advising parents.
- Provides a basis for future research studies on the implementation and effectiveness of suit therapy in children and adolescents with CP.

Some of the available literature advocates that suit therapy has many benefits such as improving motor function and posture,[18] improving vertical stability (e.g. standing posture),[21] increasing range of motion,[22] normalizing electroencephalography signals,[23] providing proprioceptive input and improving the vestibular system,[15] improving symmetry, increasing walking speed and cadence,[24] improving trunk control,[25] motor function (in all dimensions of Gross Motor Function Measure [GMFM]),[26] and self-care[27] capacity in children with CP. However, most of these studies are case reports or descriptive studies in which the methodological quality limits the possibility of supporting or rejecting the use of the suit therapy in clinical settings.[21,28]

A narrative review of the literature on the effects of suit therapy,[29] which included all of its applications in neurological dysfunctions as well as a wide range of study designs (including case studies), concluded that the efficacy of suit therapy has no sufficient evidence in the literature on which to base clinical practice. In this review, the authors highlighted the need for more research on the effects of suit therapy in order to support evidence-based interventions.

Families who have children with disabilities risk spending valuable resources on complementary and alternative therapies that have not yet proven to be effective. Professionals should be cautious in encouraging families to pursue these therapies when they are still in the early phases of efficacy testing.[30–32] However, the introduction of complementary and alternative medicine (CAM) increases the complexity of clinical reasoning required by clinicians. Considering the current knowledge limitations regarding the benefits of suit therapy, the aim of this systematic review and meta-analysis was to examine the effects of suit therapy on functioning in children and adolescents with CP.

METHOD

This meta-analysis followed the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement[33] using a research question framed by the acronym

PICOS,[34] which stands for Population (children and adolescents with CP), Intervention (suit therapy), Comparator (another therapeutic approach), Outcomes (functioning or motor function), and Study design (randomized control trials [RCTs]).

Search strategy

A comprehensive literature search was conducted in the following electronic databases: Medline; CENTRAL (Cochrane Central Register of Controlled Trials); LILACS; OVIDSP; and PEDro (Physiotherapy Evidence Database). According to the aim of this study, the search expressions for Medline and CENTRAL were: 'cerebral palsy' AND ('motor function' OR 'functionality' OR 'functioning') AND ('suit' OR 'pedia suit' OR 'thera suit' OR 'adeli suit' OR 'modified suit' OR 'neuro suit' OR 'penguin suit' OR 'bungy suit'). The search expression was adapted for the others databases (PEDro, LILACS, and OVIDSP). Search strategies can be obtained from the authors. The search dates covered the period from the inception of the databases until 30 May 2014.

Inclusion criteria

Inclusion criteria were as follows: (1) RCTs reported in peer-review journals; (2) languages: English, Portuguese, Spanish and French; (3) studies investigating the effect of suit therapy regardless of the type of protocol used (PediaSuit, TheraSuit, NeuroSuit, Adeli suit, Penguin suit, or Bungy suit); (4) studies conducted with samples that comprised children and adolescents (from 0–18y) with a clinical diagnosis of CP regardless of the type and level of severity; and (5) studies reporting functioning as the primary outcome, assessed by means of standardized and internationally accepted instruments (e.g. GMFM – 66 or 88 items, and Pediatric Evaluation of Disability Inventory [PEDI]).

Exclusion criteria

Studies were excluded if: (1) the intervention used other types of therapeutic garments that did not use elastic cords; (2) participants had other diagnosed medical conditions (e.g. neuromuscular diseases) or were aged over 18 years; and (3) if the trial did not report at least one measure of functioning assessed at baseline, post-treatment, and/or follow-up.

Study selection

Relevant papers screened were entered into reference management software EndNote X7 (Thomson Reuters, Philadelphia, PA, USA) and duplicate articles were removed based on title and abstract matching. Studies were selected if they fulfilled the inclusion criteria. Results were conferred after each stage and the following stage would only initiate when full consensus was reached.

Reviews, correspondences, and editorials were specifically excluded, although their reference lists were hand-searched to identify potentially relevant studies. Records were then screened against the eligibility criteria before appraisal of methodological quality. See Figure 1 for a flowchart illustrating the review process.

Data extraction

Five researchers independently read and extracted data from all articles, and results were checked for accuracy by the first author. Reviewers were not blind to author (s), institution(s), or journals. Disagreements were resolved by consensus between researchers. The following information was retrieved from each study: author(s), year of publication, type of study design, sample size, instruments, intervention protocol, and outcomes. To calculate effect sizes for selected outcomes, we extracted sample sizes and baseline post-treatment, and follow-up means and standard deviations. Outcome variable was continuous. Authors of included trials were contacted when necessary to retrieve missing data in published studies.

Assessment of the methodological quality

Five reviewers independently rated the methodological quality of included studies using the PEDro scale.[35,36]

During a consensus meeting, scoring disagreements were resolved. Interrater agreement of quality assessment between the five reviewers was assessed using two-way mixed agreement and absolute agreement statistics, with a confidence interval of 95%. The value of the intraclass correlation coefficient was 0.99, indicating excellent agreements.[36]

According to Foley et al.,[37] studies scoring 9 to 10 on the PEDro scale were considered to be of 'excellent' methodological quality, studies ranging from 6 to 8 were rated as 'good' quality, studies scoring between 4 and 5 were considered to be of 'fair' quality, and studies scoring below 4 were rated as 'poor' quality.

Statistical analysis

Data was synthesized using a fixed-effect model, because of the limited number of studies (<5) available.[38] Effect sizes were the standardized mean difference with Hedge's *g* correction[39] for small samples, interpreted according to Cohen's[40] guidelines (values of 0.20, 0.50, and 0.80 correspond to small, medium, and large effects respectively), and 95% confidence intervals were also derived for each effect size. *Z*-values and corresponding *p*-values were considered as indicators of the significance of the pooled effects. Two analyses were conducted, one for each measurement point (baseline vs post-treatment, and baseline vs follow-up). For the study by Mahani et al.,[41] composite effect sizes were computed as more than one intervention arm (vs one control group) was included in the meta-analyses.

Analyses were inspected for heterogeneity using Cochran's Q statistic[42] for which a significant p-value ($p<0.05$) demonstrates that studies do not share a common effect size, and I^2 statistic[43] which assesses the proportion of observed dispersion that is caused by real differences in

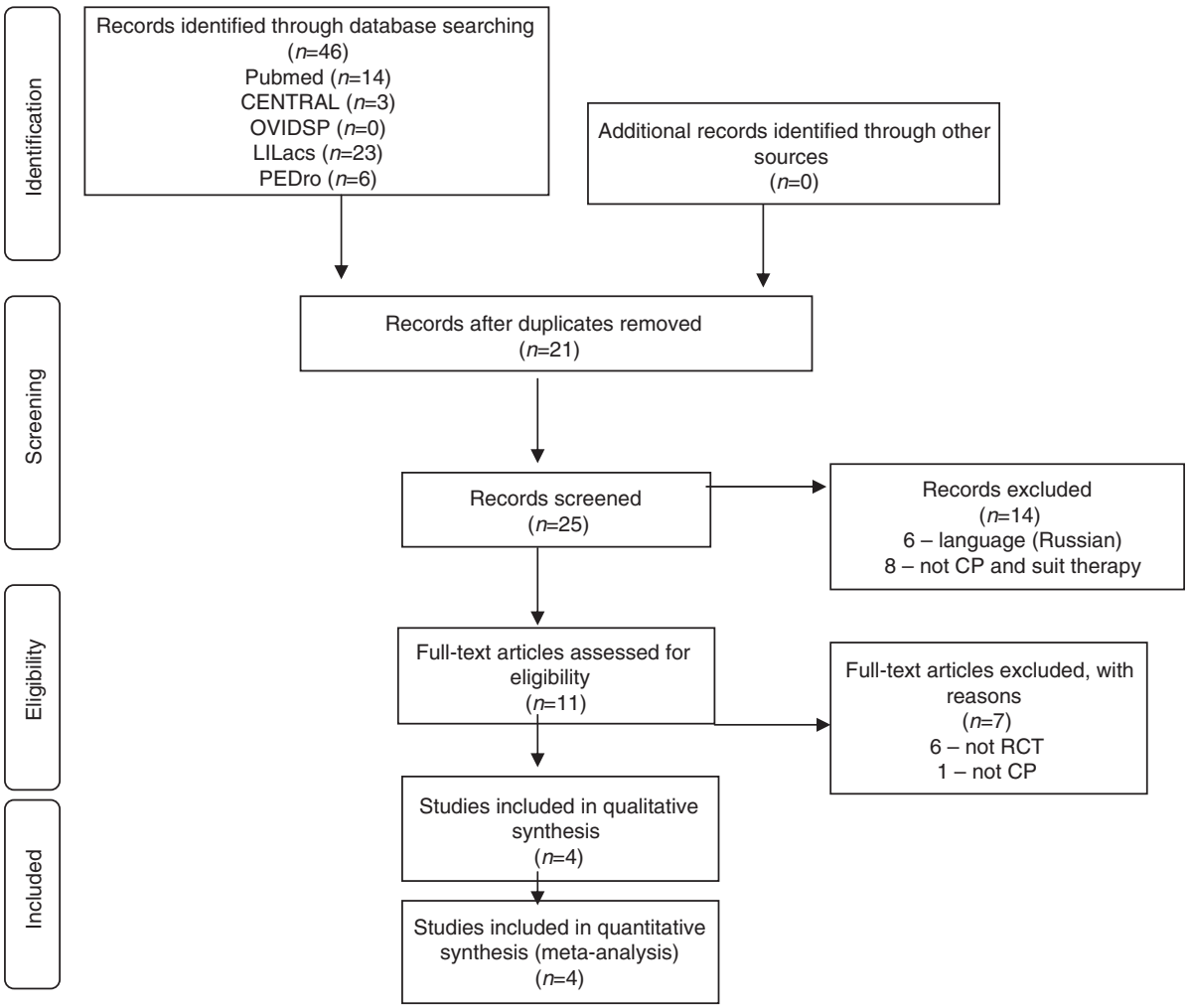

Figure 1: Flow chart of the article selection process. PEDro, Physiotherapy Evidence Database; CP, cerebral palsy; RCT, randomized controlled trial.

the true effect sizes. The I^2 ranges from 0% to 100% (values of 25%, 50%, and 75% correspond to low, moderate, and high heterogeneity).[43] Publication bias was examined by visual inspection for asymmetry of funnel plots and Egger's test[44] to confirm the visual impression.

To confirm the validity of the results obtained, the meta-analysis for the comparison between baseline and post-treatment was repeated excluding the study by Alagesan et al.,[45] which had used a different version of the measure (GMFM-88).

Analyses were conducted using the Comprehensive Meta-Analysis Software version 3 (Biostat, Englewod, NJ, USA).[46]

RESULTS

Study selection

In the first stage, 46 potentially relevant articles were identified from the search strategy. After removing duplicates, 25 articles remained. After removing six articles which were in Russian and screening the titles and abstracts of potential studies, 11 full text articles were retrieved for full reading. Seven of these articles were excluded for not meeting inclusion criteria (not RCTs). Four studies were eligible and included in the review for further analysis (Fig. 1).

The four studies included in this review were published between 2006 and 2011. Table I provides a descriptive summary of these studies. In total, these studies included 110 participants. The mean number of participants in each trial was 12.3 (SD 2.52) with a mean age of 6 years 11 months (SD 1y 10mo). Two RCTs compared Adeli suit treatment (AST) with NDT:[41,47] one study compared modified suit therapy with conventional therapy,[45] and the other compared TheraSuit with a treatment categorized as other therapy approach.[48]

Characteristics of included studies

The four RCTs presented variability regarding sample characteristics (age, subtypes, and level of severity of CP), instruments used to assess children and adolescent's

Table I: Summary of identified studies

Study	Selection criteria	Sample	Variables/instruments	Intervention protocol	Outcomes
Bar-Haim et al.[47]	Inclusion criteria: diagnosis of CP; 6–12y; GMFCS level II, III, or IV; no orthopaedic surgery or spasticity-reduction intervention in the previous 6mo; not a candidate for surgery or other interventions for at least 1y; parents' agreement for child allocation to either group by randomization. Exclusion criteria: hip dislocation or scoliosis; high degree of spasticity; poorly controlled epilepsy; hydrocephalus and progressive encephalopathies and myopathies	24 children randomly assigned to: AST (n=12) NDT (n=12)	Gross Motor Function Measure (GMFM-66); metabolic cost of stair climbing (Mechanical Efficiency Index)	AST in accordance with the original Russian protocol. NDT Both groups were tested at baseline and after 1mo of AST or NDT therapy, and again 9mo later after they had returned to their regular pre-study therapy. Both groups received daily treatment sessions for about 2h, 5d/wk for 4wk (40h). During this time they stopped routine physiotherapy treatments, but continued educational and recreational activities	GMFM-66: Significant time effect but no group or interaction effects. AST – significant increase between baseline and 1-mo scores (p=0.037); NDT – significant increase between baseline and 10-mo scores (p=0.006). Mechanical Efficiency Index: Significant time effect but no group or interaction effects; AST – significantly better at 10mo (p<0.05), greater improvement in children who had higher GMFM-66 scores at baseline. NDT – no significant change over time.
Alagesan et al.[45]	Inclusion criteria: children with spastic diplegic CP, between 4 and 12y. Exclusion criteria: subluxation or dislocation of hip, fracture of spine or limbs, severe scoliosis, seizures, intellectual disability, severe spasticity with contractures, and any other congenital deformity.	30 children randomly assigned Conventional therapy with Modified suit (EG) (n=15) Conventional therapy (CG) (n=15)	Gross Motor Function Measure (GMFM-88)	EG – conventional therapy while wearing Modified suit (vest, shorts, knee pad, and shoe attachments); CG – conventional therapy. Both groups were treated for 2h daily with short breaks of around 20min for duration of 3wks (30h).	Both groups displayed statistically significant improvement (p<0.001). In the post-treatment, results were significantly better in the EG than in the CG (p=0.03).
Mahani et al.[41]	Inclusion criteria: diagnosis of CP; no orthopaedic surgery or spasticity reduction intervention in the past 6mo; in GMFCS level I, II, III, and IV; not a candidate for surgery or other intervention for at least 1y; with parent's consent for child assignment in either group by randomization. Exclusion criteria: hip dislocation and marked scoliosis; high degree of spasticity and disability (GMFCS level); uncontrolled seizures; hydrocephalous, progressive encephalopathies, and myopathies; systemic diseases such as renal or cardiac disorders	36 children assigned to three groups by match pairs: G1 – MAST (n=12); G2 – AST (n=12); G3 – NDT	Gross Motor Function Measure (GMFM-66)	All children in the three groups received daily treatment for 2h/d, 5d/wk for a period of 4wks (40h). AST group – 1h passive intervention; 1h wearing the Adeli suit practising exercises for strengthening the weak musculatures and optimizing the correct posture and alignment. NDT group – 1h of passive intervention; 1h of functional activities such as sitting, standing up from sitting, and walking. MAST group – 1h of passive intervention; 1h of practice of functional and goal-directed activities in the context of play with the suit. After the treatment, all children received traditional occupational therapy services for 16wks, twice a wk, and 45min/session.	No significant difference in the GMF scores was found among groups at the baseline (p=0.965). The MAST group had significantly higher GMF scores than the other two groups after intervention (4wks) (p<0.001) and 16wks after treatment (p<0.001 between MAST and AST; p=0.001 between MAST and NDT). No differences were found between the AST and NDT groups at these stages.

Table I: Continued

Study	Selection criteria	Sample	Variables/instruments	Intervention protocol	Outcomes
Bailes et al.[48]	Inclusion criteria: children between 3 and 8y, able to follow instructions, with a diagnosis of CP, classified in GMFCS Level III on the GMFCS, with no evidence of hip subluxation >35% (migration index) and/or scoliosis greater than 25 (Cobb angle) on hip and spine X-rays, respectively, within 6mo of the start of intervention. Children could not have previously participated in an intensive suit therapy program. The parent/guardian needed to speak and read English, and physician approval was obtained. Exclusion criteria: intrathecal baclofen pump therapy, history of selective dorsal rhizotomy, or Botox injections within the past 3mo, orthopaedic surgery within the past y, serial casting within the past mo, uncontrolled seizures, and a diagnosis of autism, attention-deficit disorder.	20 children randomly assigned to: TheraSuit method (EG) (n=10); TheraSuit method with a 'control suit' (CG) (n=10).	Pediatric Evaluation of Disability Inventory (PEDI); Gross Motor Function Measure (GMFM-66).	Both groups received the therapy intervention for 4h daily, 5d/wk over a 3-wk period (60h). EG – TheraSuit method wearing the TheraSuit with elastic bungee cords attached to the vest, shorts, kneepads, and shoes. CG – TheraSuit method wearing a 'control suit', which consisted of only the TheraSuit vest and shorts, and did not have the elastic bungee cords attached. Each child's intervention was individualized to the goal of achieving the next functional activity level. At the end of the 3-wk intervention, each child was given an individualized home exercise program to perform not more than 1h daily from wks 4–9.	Between groups: no significant differences. Within-groups: GMFM-66 EG – Increase in scores between baseline and 9th wk (p=0.003); CG – Increase in scores between baseline and 9th wk (p=0.036). Within-groups: PEDI EG – 4th wk vs baseline – better in PEDI CA self-care (p=0.042); 9th wk vs baseline – better in PEDI FS self-care (p=0.044), PEDI CA self-care (p=0.015) and PEDI FS mobility (p=0.006); 9th wk vs 4th wk – better in PEDI FS mobility (p=0.032). CG – No significant differences.

CP, cerebral palsy; AST, Adeli suit therapy; NDT, neurodevelopmental treatment; GMFM, Gross Motor Function Measure; EG, experimental group; CG, control group; GMFCS, Gross Motor Function Classification System; MAST, Modified Adeli suit therapy; CA, Caregiver Assistance Scale; FS, Functional Skills Scale; PEDI, Pediatric Evaluation Disability Inventory.

functioning, and intervention protocols (duration, frequency, intensity) (Table I).

Sample

Studies included children with CP at different severity levels (in Gross Motor Function Classification System [GMFCS] levels I, II, III, IV, and V), subtypes of CP (spastic, ataxic, and dyskinetic), and topographic distribution of motor signs (hemiplegia, diplegia, and quadriplegia).

Outcome measures

The primary outcome measure was changes in functioning as measured by standardized outcome measures, namely the GMFM[49] and PEDI.[50] Both the GMFM and PEDI are considered sensitive instruments in detecting functional change over time in children with CP.[51,52] The intention was to assess the effects of suit therapy on functioning according to all ICF dimensions. However, all studies included in our review focused on the activity dimension, particularly in gross motor function. Only one study[48] used the PEDI, which assesses self-care, mobility, and social function. This scale includes 197 skills from all the nine domains of the activity and participation classification of the International Classification of Functioning, Disability and Health for Children and Youth (ICF-YC).

All studies included in this review[41,45,47,48] have in common the use of the GMFM (66 or 88 items). Determining the changes in motor function of CP children is of great clinical relevance because it allows quantification of the intervention results and standardization of information. Three studies[41,47,48] used the GMFM-66 and the remaining study[45] used GMFM-88.

Another widely used standardized classification system reported in three studies[41,47,48] is the GMFCS, which is based on the concepts of abilities and limitations in gross motor function. In these studies, the GMFCS was used to classify the severity level of CP. It was not used as an outcome measure because the GMFCS is not sensitive to minor changes in motor function. Distinctions between the different levels are based on functional capacities, the need for assistive technology, and also on movement quality.[53]

The GMFM reflects aspects of the activity dimension of the ICF and several studies have documented a very good

reliability, validity, and responsiveness of this measure.[54,55] According to Ostensjo, Carlberg, and Vollestad,[56] GMFM measures activities classified in the mobility domain of the ICF (d4), as well as a few neuromusculoskeletal and movement-related body functions (ICF b7). Both versions of the GMFM (66 or 88 items) were considered. GMFM is a clinical tool designed to evaluate change in gross motor function in children with CP across lifespan. The GMFM is a quantitative, easy to administer instrument that assesses gross motor functions based on the gross motor milestones of typically developing children. This instrument is widely used in clinical practice, especially by physical therapists. By providing a detailed description of the child's motor function, it allows the therapist to define realistic goals and to assess the efficacy of the intervention.[49,57]

Description of studies

Bar-Haim et al.[47] compared AST with NDT in 24 children with spastic CP (diplegia and quadriplegia) presenting with severity (GMFCS levels II, III, or IV). Results revealed significant improvements in GMFM scores after 1 month in the AST group and after 9 months in the NDT group. Regarding the mechanical efficiency index, there were improvements in the AST group after 10 months, particularly in children who had higher GMFM-66 scores at baseline, but not in the NDT group. However, when the retention of motor skills was tested 9 months after treatment there was no significant difference between the AST and NDT groups. Overall, this study showed that intensive treatment with AST results in significant improvements in gross motor function after 1 month of treatment (p=0.037). The decrease in gross motor function at the follow-up (9mo after treatment) suggests that patients receiving AST treatment may not retain the skills they developed in the long term. On the other hand, the NDT group only had significant improvements in gross motor function at the follow-up. This suggests that AST could result in short-term gains quickly, although long-term improvements in gross motor function may occur best with traditional NDT methods. The study does not address if treatment in the AST at a lower frequency (1–2 occasions/wk) would also result in improved gross motor function (Table I).

Alagesan et al.[45] compared the modified suit therapy, which consisted of conventional therapy while wearing Modified suit, with conventional therapy in 30 children with a diagnosis of spastic CP diplegia. The severity level of children with CP was not specified according to the GMFCS. The results showed a statistically significant difference between groups (p=0.030), which indicated that modified suit therapy was effective in improving the gross motor function in children with spastic diplegia CP (Table I).

Mahani et al.[41] studied 36 children with a diagnosis of spastic CP (diplegia and quadriplegia) and dystonic CP (quadriplegia) with severity (GMFCS levels I, II, III, and IV). There were three training groups: the Modified Adeli suit therapy (MAST), the AST, and the NDT groups. After 4 weeks of therapy the MAST group had significantly higher GMFM scores than the other two groups (both $p \leq 0.001$), whereas no significant difference was found between the AST group and the NDT group (p=0.272). These results were confirmed in the follow-up (16wks after the treatment). At this stage, there were significant differences between the MAST and the AST groups ($p \leq 0.001$) and between the MAST and NDT groups (p=0.001), whereas no significant difference was found between the AST and the NDT groups (p=0.379). This study showed that MAST along with conventional physiotherapy is effective in improving the gross motor function in children with spastic diplegia CP (Table I).

Bailes et al.[48] addressed the effects of the TheraSuit method compared with a control suit. A sample of 20 children diagnosed with CP (no specified subtype) and classified in GMFCS Level III were assigned to two training groups: the experimental group wore the TheraSuit with elastic bungee cords attached to the vest, shorts, kneepads, and shoes; and the control group wore a 'control suit' which consisted of only the vest and shorts of the TheraSuit and did not have the elastic bungee cords attached. No statistical significant differences were found between groups on the GMFM-66 or any domains of the PEDI, either 4 or 9 weeks after treatment. Significant within-group differences were found for the control group on the GMFM-66 and for the experimental group on four of the outcome measures: GMFM-66; PEDI Functional Skills self-care scale; PEDI Caregiver Assistance self-care scale; and PEDI Functional Skills mobility scale. This study does not provide statistical evidence that the use of the TheraSuit is more effective than an intensive therapy program wearing a control to improve motor function in children with CP classified as GMFCS level III (Table I).

The participant characteristics (GMFM scores), and number of sessions received during the treatment program for each study are presented in Table II.

Level and quality of evidence

PEDro score for each study is listed in Table III. The mean score of the four studies was 6.25 (interquartile range 5–8). One study[45] reported a score of 5, two studies a score of 6,[41,47] and the remaining study obtained a score of 8,[48] reflecting 'fair' to 'good' quality.[36]

As shown in Table III, all four studies specified the eligibility criteria (indicator 1) which is a guarantee of the external validity. Regarding the other criteria, all the studies[41,45,47,48] ensured the random allocation of participants (criterion 2), comparability of participant groups at baseline (criterion 4), the assessors were blind to the evaluation (criterion 7), the between-group statistical analysis was presented for at least one key outcome (criterion 10), and point estimates of variability were provided for at least one key outcome (criterion 11). Only the study by Alagesan et al.[45] did not reach more than 85% follow-up for at least one key outcome (criterion 8). Only Bailes et al.[48] met the

Table II: Improvement in Gross Motor Function Measure score (%) after suit therapy (experimental group vs control group)

	n		GMFCS		Baseline		Post-treatment		Follow-up		Hours of treatment (total)	
Studies	EG	CG	EG	CG	EG	CG	EG	CG	EG	CG	EG	CG
Bar-Haim et al.[47]	12	12	II, III, IV	II, III, IV	54.4	52.2	55	52.9	54.7	54.1	40	40
Alagesan et al.[45]	15	15	–	–	59.22	51.7	63.16	53.25	–	–	30	30
Mahani et al.[41]	12	12	I, II, III, IV	I, II, III, IV	42.92	42.92 41.41	59.59	51.01[a] 47.47[b]	62.62	49.49[a] 45.95[b]	40	40
Bailes et al.[48]	10	10	III	III	47.93	51.34	49.1	52.61	50.08	54.37	60	60

[a]CG=Group 2. [b]CG=Group 3. GMFCS, Gross Motor Function Classification System; CG, control group; EG, experimental group.

Table III: Quality assessment of the four randomized controlled trials according to the Physiotherapy Evidence Database scale

	Criteria of methodological rigour											
Study	1	2	3	4	5	6	7	8	9	10	11	Total
Bar-Haim et al.[47]	1	1	0	1	0	0	1	1	0	1	1	6
Alagesan et al.[45]	1	1	0	1	0	0	1	0	0	1	1	5
Mahani et al.[41]	1	1	0	1	0	0	1	1	0	1	1	6
Bailes et al.[48]	1	1	1	1	0	0	1	1	1	1	1	8

The Physiotherapy Evidence Database scale examines 11 aspects of the quality of methodology including: (1) specification of eligibility of participants; (2) randomization of participants; (3) allocation concealment of participants; (4) comparability of participant groups at baseline; (5) blinding of participants; (6) blinding of therapists; (7) blinding of assessors; (8) more than 85% follow-up of participants in at least one of key outcomes; (9) 'intention-to-treat' analysis; (10) between-group statistical analysis of at least one of the key outcomes; and (11) point estimate of at least one of the key outcomes. According to the Physiotherapy Evidence Database guidelines, a positive answer to each of the criteria 2 to 11 will yield 1 point, obtaining a Physiotherapy Evidence Database score between 0 and 10.[59]

PEDro criteria on concealed allocation and intention to treat analysis (criteria 3 and 9). Finally, no study[41,45,47,48] satisfied criteria 5 and 6 which relate to participants' and therapists' blinding respectively.

Meta-analysis of intervention studies

Figure 2 presents the forest plots for the meta-analyses. Gross motor functioning data was available for four studies at post-treatment and three studies at follow-up. A significant but small effect size was found at post-treatment (g=0.46, 95% CI 0.10–0.82; z=2.51, p=0.01). The trial conducted by Mahani et al.[41] showed the largest effect size (g=1.22), the trial by Alagesan et al.[45] presented a marginal effect (g=0.20), and the remaining trials[47,48] presented non-significant and trivial effects (g=0.03 and g=0.02 respectively). We conducted sensitivity analyses by repeating the primary analyses with the exclusion of the study by Alagesan et al.[45] which used a different version of the GMFM. Excluding this study led to an increase in the magnitude of treatment effects of 0.10. There was evidence of moderate heterogeneity between trials (Q=8.38, p=0.04, I^2=64%).

At follow-up, there was a similar overall effect (g=0.47, 95% CI 0.03–0.90). The trial by Bailes et al.[48] presented a trivial effect (g=0.15), the trial by Bar-Haim et al.[47] reported a negative effect (g=−0.43), and Mahani[41] reported a significant large effect (g=1.33). There was evidence of large heterogeneity between trials (Q=12.04, p=0.002, I^2=83%).

There was no indication of publication bias for any of the assessment points.

DISCUSSION

The aim of this systematic review was to determine the effect of suit therapy on functioning in children and adolescents with CP.

The four studies (all RCTs) included presented 'fair to good' quality evidence.[37] The mean score in PEDro scale[37,58] was 6.25, ranging between 5 to 8, suggesting that findings are credible. In this type of study it is not usually possible to blind the therapist or the participants.[59]

On the basis of previous studies, it was hypothesized that suit therapy would have a positive effect on gross motor function in children and adolescents with CP. The results of our research synthesis point to limited effects of suit therapy in gross motor function of children and adolescents with CP, presenting small combined effect sizes (g=0.46 for post-treatment and g=0.47 for follow-up), and considerable levels of heterogeneity between trials.

This review presents methodological limitations which advise caution when interpreting our results.

Methodological considerations

Some limitations can be mentioned, such as the restrictions of language; only articles published in English, French, Spanish, and Portuguese were reviewed, leading to potential bias on study selection – namely studies published in Russian. The fact that we had no possibility of access to a Russian translation might have compromised the inclusion of relevant studies. Other limitations include the few eligible RCTs studies with good quality data, and the use of meta-analytic techniques that present considerable advantages for inference on treatment effects (as compared to narrative analysis) but also present limitations and challenges. One must consider that the quality of a meta-analysis derives from the quality of the studies included, and the interpretation of results is to be conducted within a rigor-

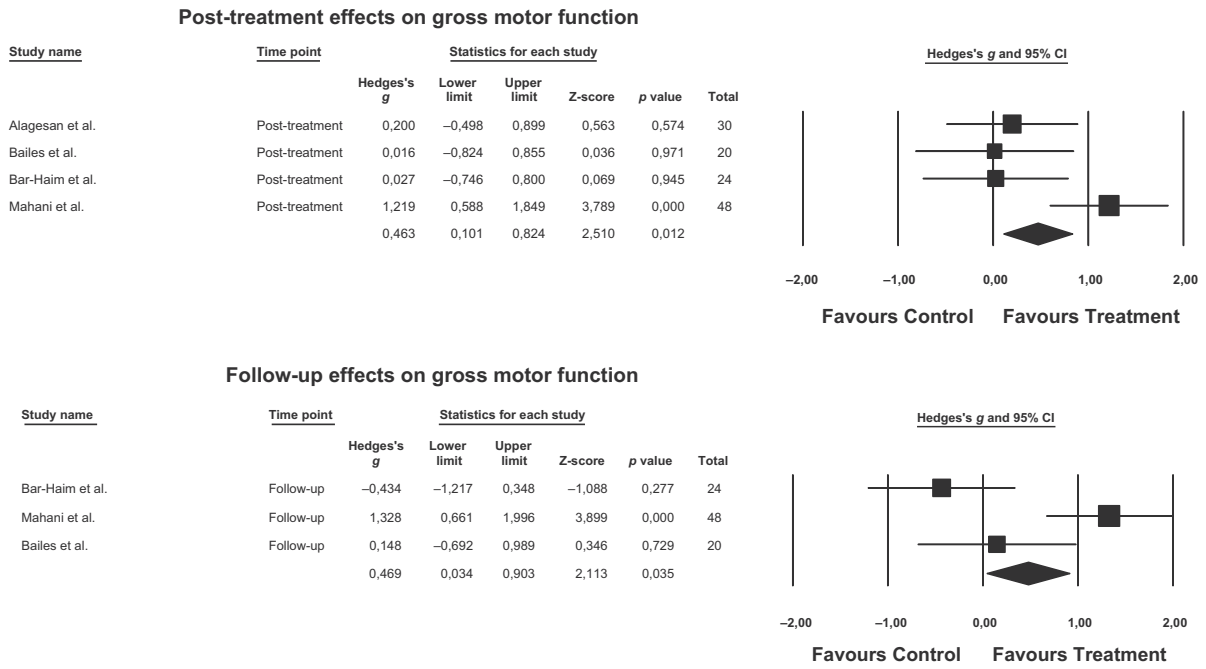

Figure 2: Forest plots of the effects of the interventions on functioning at post-treatment and follow-up. CI, confidence interval.

ous methodological and theoretical framework which allows a comprehensive analysis of the studies included.[60]

In the present review, the limited number of trials and very small sample sizes in each trial (ranging from 10 to 15 participants, with a total of 110 participants) seriously limit the conclusions that can be drawn from the effects of the trials for each assessment point, as non-significant effects may be because of low statistical power,[46] and in the context of a fixed-effect model, combined effects are largely influenced by studies with larger samples. In addition, publication bias is a serious threat to the validity of meta-analyses. Although inspection of publication bias did not reveal significant asymmetry in the present review, this may be because of low power in detecting real asymmetries as a result of the limited number of studies.[61]

In addition, we also assumed that studies report data on participants who received only the treatment offered in the intervention condition, but we should consider the possibility that participants could have gone through additional forms of treatment, especially in studies that had long intervals between pre- and post-interventions measurement.

Another important limitation is the variability in patient characteristics (GMFM scores) and number of sessions received during the treatment program (Table II).

An additional consideration relates to the severity levels of CP in GMFCS and the baseline score in GMFM-66/88 between studies. Only Bailes et al.[48] included children with similar functional level (GMFCS level III) in both (experimental and control) conditions. Two studies included participants with a large variation on severity levels from GMFCS levels I to IV,[41,47] and the study of Alagesan et al.[45] did not report on these levels (Table II). It is also important to consider the relationship between age and GMFCS level. A younger child with a GMFCS level I or II usually has a better developmental prognosis than an older child with a GMFCS level IV or V.[62] According to Rebel et al.,[63] the estimations on gross motor prognosis in children with CP require a prior assessment of GMFM. Further, other variables must be considered, namely the subtype of CP, the topographic distribution of the signs or symptoms, the co-existence of other associated problems (cognition, epilepsy, and status of sensory and perceptual systems) and other contextual factors (economic and social conditions, and the absence of treatment).

Finally, there are also concerns regarding the use of different versions of the GMFM (66 and 88 items) to assess gross motor function. In this review, most studies[41,47,48] used the GMFM-66 version. Although both versions evaluate changes in gross motor function over time, the GMFM-66 is a revised version of GMFM-88 in which scores are converted and plotted in an interval scale of gross motor function as opposed to the ordinal scaling of the original GMFM-88. According to Wang and Yang,[64] the responsiveness of the two versions of the GMFM for children with CP was analyzed and the results showed 'no great difference in responsiveness between GMFM-66 and GMFM-88 in discriminating between clinically meaningful motor improvement and no improvement. However, under this clinical condition, the correct negative responsiveness (specificity) of GMFM-66 was better than that of GMFM-88.' Taking this remark into consideration, the

results of the trial by Alagesan et al.[45] should be interpreted with caution, since the GMFM-88 version has a relatively higher rate of false-positive findings which might incorrectly report that a child undergoes motor improvement when in fact that improvement was not clinically meaningful.

PEDI is a useful measure that complements the GMFM information by framing functioning in the context of daily life activities. As only one study, Bailes et al.,[48] used PEDI as an additional measure, this could not be included in a meta-analysis. Future studies should consider using both measures as this knowledge is of great importance for rehabilitation interventions, which often aim to improve a person's functioning in a controlled therapy setting with the aim of also improving functioning in his/her natural environment and daily routine. Considering this, the examination of the relations between capacity, capability, and performance for other ICF-YC domains is of interest. Agreement on standard instruments for use in research and its testing is crucial for an adequate comparison of results from trials across studies since, according to Kunz et al.,[65] the large diversity of instruments is a major barrier to meaningful comparisons across studies.

The use of valid and reliable instruments to measure outcomes related to activities and social participation should be encouraged in order to understand the impact of this therapeutic intervention on children's daily lives.

Therapy considerations

The content and intensity of therapy

Regarding the protocol description, three studies included in this review[45,47,48] did not fully specify the type of activities and exercises performed by participants in the experimental conditions who enrolled in different protocols of suit therapy, and those in the control conditions who enrolled in conventional treatment or NDT. It would be helpful to have access to detailed descriptions of the activities performed during therapy to know exactly what was done in each condition. Only the study of Mahani et al.[41] reported sufficient detail on the exercises applied during treatment sessions in the experimental condition. According to Anttila et al.,[8] providing detailed protocol descriptions allows the identification of the active components of treatment, promoting its replication and correct transfer to other settings. Type of treatment received during the intervention and follow-up periods also varied between trials. Only the study by Bailes et al.[48] reported that participants did not receive any other form of direct occupational therapy or physical therapy during the study protocol to control for the effects of co-interventions. The presence of potential co-interventions (such as additional interventions and home training of parents with their children) remained unclear in most studies and might have influenced outcomes. Even environmental factors such as parental support, home, and leisure time activities may have an effect on children's functional abilities.

A further limitation concerns the duration of the protocol. Even though all studies used short intensive interventions, their duration varied considerably, ranging from 2 to 4 hours per day over 3 to 4 weeks (Table II). There is no consensus about the adequate duration of suit therapy programs. Liptak[30] advocates that treatments can be administered from 30 minutes to 2 hours a day, 5 to 6 days a week for 4 weeks; Koscielny[19] proposes 2 to 4 hours sessions, 5 or 6 days a week, during 3 or 4 weeks; and Trahan and Malouin[66] advocated that an intermittent program of four treatments per week lasting 4 weeks was well tolerated when separated by rest periods. Motor function improvements resulting from this program persisted through rest periods. Results underline the need to reconsider the organization of physical rehabilitation programs in order to find a routine that is adequate in terms of intensity, without becoming tired, and also providing practice conditions for consolidating the motor skills learned during the intensive therapy.

The discussion on the benefits of intensive versus intermittent programs is not new. In a previous study, Christiansen and Lange[67] showed that intermittent or continuous physiotherapy were both effective and did not result in different GMFM-66 outcome measures between two groups of children with CP. The results of a study by Bower et al.[68] showed that intensive physiotherapy, in contrast to a treatment approach based on collaborative goal-setting, improved GMFM scores. However, this trend was not statistically significant and declined in the follow-up observation period. Ustad et al.[69] highlight that recommendations on the frequency of physical therapy for children and adolescents with CP can be challenging since it is important to consider age, medical problems, magnitude of motor delay, as well as family conditions and support.

Another potential source of influence on treatment outcomes is the therapist's expertise and clinical reasoning. Only Bailes et al.[48] provided information on the expertise level of the physical therapists involved. All other studies[41,45,47] did not report on the previous experience and skills of therapists. Jensen et al.[70] reported that experienced clinicians' knowledge was more extensive in comparison to novice clinicians and that they were more comfortable with their knowledge level. Studies show that physical therapists with higher self-awareness and confidence in their clinical judgement, problem solving skills, and the ability to communicate this to each patient (i.e. tailoring) are more responsive in their therapeutic interactions with patients, can better handle environmental interruptions without disrupting treatment, and are able to provide more frequent and integrated cues and encouragement.

Finally, another concern relates to the difficulty in adequately evaluating the efficacy of each suit therapy (AST, MAST, or TheraSuit). Studies that use the same methodology but different patents would be necessary to understand the differential effects of the suit. Only one study[48] analyzed the different components of suit therapy and evaluated the effects of the suit itself.

In conclusion, physical therapy for children with CP is complex, because a large number of components may act both independently and interdependently. It is influenced by a diversity of factors, such as the type of therapy and its intensity, the option for a standardized or individually tailored approach, and skills and experience of the therapists.[71] Furthermore, additional unspecific stimuli may affect the results and there might be differences between therapists in how successful they are in motivating, engaging, and advising children and parents. As multiple factors are involved, specific ingredients responsible for effects are frequently hard to discern.[72] Research on potential moderators of intervention effects is needed.

Recommendations for clinical practice

The effects of CP on gross motor function are variable. In general, the relative deprivation of experience associated with CP compromises the child's overall development. This condition mainly affects mobility and independence, but it also influences other aspects of development and learning (e.g. capacity to explore, to learn about space, and to play). CP cannot be cured, but different therapeutic interventions can improve the child's functional abilities and quality of life.[73]

Safer and more effective interventions have been developed for children with CP in the past decade as a consequence of an exponential growth in high-quality CP research. There are now at least 64 different therapeutic interventions for CP. However, rapid expansion of evidence-based interventions has made it difficult for health professionals to keep up-to-date and for families to know how to best help their child.[12]

According to Hurvitz et al.,[74] families of children with CP show a great interest in CAM treatments, with a usage prevalence of 56%. The importance of innovative and alternative therapies underlines the need to increase the awareness and understanding of these treatment modalities. The role of physical therapists in counselling families is fundamental, because while families appear to be better informed, they might not have the biomedical information and expertise required to make a proper evaluation of a treatment choice on their own. Therefore, health care professionals need greater education about CAM, before encouraging or discouraging the families of CP children to use these approaches. Ottolini et al.[75] noted that most paediatricians consider that their lack of knowledge interferes with their ability to discuss CAM with patients. They emphasize a need for greater education about CAM. Further studies are needed to determine which factors make CAM modalities desirable and effective, and to consider how these factors can be incorporated into 'standard care' of children with CP.

According to Sackett et al.,[76] clinicians are expected to integrate clinical experience with conscientious, explicit, and judicious use of research evidence in order to make informed decisions that maximize patients' well-being. In other words, clinicians are being told to embrace evidence-based practice.

The findings of our meta-analysis suggest that further studies are needed to examine the effects of suit therapy on gross motor function in children and adolescents with CP. Combining subjective and objective outcome measures which assess all dimensions of ICF-YC is recommended to guide treatment for children with CP and to weigh and balance the benefits and harms of this CAM intervention.

Implications for future research

This systematic review and meta-analysis has highlighted many methodological shortcomings in the studies reviewed. Future RCTs should further analyze the content of the therapy and consider the differential effects of its intensity in relation to the outcomes achieved and the actual effects of the suit alone.

Several questions are left unanswered and suggest the need for future research before AST and suit therapy can be accepted as an effective treatment. Considering the results of this review, future studies should include: (1) a detailed description of the intervention protocols specifying the frequency, duration, and treatment plan; (2) samples with appropriate sizes presenting power or sample size calculations; (3) more homogeneous groups regarding age, sex, type, and distribution of CP and GMFCS level; (4) valid and reliable measures that assess all domains of ICF; (5) longitudinal studies to assess the long-term impact of suit therapy and that translate into improving function in a person's daily life in their normal environment; (6) data that assess kinetic and kinematic parameters of postural control; (7) control of parasite variables (e.g. level of experience of the physical therapists); (8) cost-effectiveness analysis; and (9) assessment of the satisfaction of the patient and family with the devices.

Considering the lack of clarity regarding the effects of the elastic orthotic, leading to some speculation, it is necessary to compare not only intensive suit therapy with other physical therapy programs (conventional method or NDT), but also to analyze specific immediate and long-term effects of suit therapy on postural control using other measures, namely kinematic and kinetic analyses and some physiological markers, such as blood pressure, heart rate, and metabolic rate.

CONCLUSION

Cerebral palsy is now the subject of much research and evidence-based care recommended for this population is continually and rapidly changing. Thus, it is important that decision-making is guided by up-to-date evidence. This systematic review and meta-analysis provides a state-of-the-art synthesis of current evidence on the effects of suit therapy on functioning in children and adolescents with CP. The results showed that short intensive suit therapy interventions have small effects on functioning at post-treatment and follow-up, demanding some cautious interpretation of the findings. Thus, physical therapists

should take into consideration the lack of scientific evidence regarding the effectiveness of suit therapy when advising parents who are enquiring about this costly and time-consuming treatment option.

In sum, the results of this systematic review and meta-analysis do not support robust conclusions to prescribe or suggest this new and 'promising' approach to therapy.

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