# Effects of suit therapy programs in children with cerebral palsy: systematic review with meta-analysis

*Efeitos de programas com* suit therapy *em crianças com paralisia cerebral: revisão sistemática com meta-análise* 

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ABSTRACT: Purpose: examine literature on the effects of suit therapy (ST) programs on motor and functional performance of children with cerebral palsy. Methods: this is a study of systematic review with meta-analysis, whose search of articles occurred in three databases using the alternated combination of the keyword "cerebral palsy" with "occupational therapy", "physical therapy", and "physical therapy modalities". The articles were evaluated using three scales of methodological quality: PEDro Scale, Jadad Scale and Study of Quality. Results: the search resulted in 4,060 articles, from which 1,425 were excluded for having been published prior to January 2006, 3,005 because were not clinical trials, and 818 for not addressing suit therapy programs. Thus, only five articles were included in this study, from which only two showed methodological homogeneity. The studies showed controversial results and did not show any positive evidence in favor of ST. Conclusions: this study reveals the need for research on clothing with dynamic elements, since we did not identify any study indicating significant motor skill improvements in children with cerebral palsy.

**KEYWORDS:** Cerebral palsy; Rehabilitation; Clothing; Technology; Child.

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RESUMO: Objetivo: verificar na literatura os efeitos de programas com suit therapy (ST) no desempenho motor e funcional de crianças com paralisia cerebral. Método: esta é uma pesquisa de revisão sistemática com meta-análise, cuja busca de artigos foi realizada em três bases de dados utilizando a combinação alternada da palavra-chave "cerebral palsy" com "occupational therapy", "physical therapy" e "physical therapy modalities". Os artigos foram submetidos à avaliação de qualidade metodológica por meio das seguintes escalas: PEDro Scale, Jadad Scale e Study of Quality. Resultados: a busca resultou em 4.060 artigos, dos quais 1.425 foram excluídos por terem sido publicados antes de janeiro de 2006, 3.005 por não serem ensaios clínicos e 818 por não abordarem programas de ST. Assim, somente cinco artigos foram incluídos neste estudo, dos quais apenas dois apresentaram homogeneidade metodológica. Os estudos apresentaram resultados adversos e não mostram evidência a favor da ST. Conclusão: este estudo evidencia a necessidade de mais pesquisas sobre vestimentas com elementos dinâmicos, visto que não foram identificados estudos que indiquem melhora significativa nas habilidades motoras de crianças com paralisia cerebral.

**DESCRITORES:** Paralisia cerebral; Reabilitação; Vestimenta; Tecnologia; Criança.

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# INTRODUCTION

Suit therapy (ST) programs as intensive treatment protocols have become distinguished as a potential resource in the rehabilitation process of children with cerebral palsy, as they aim for the inhibition of primitive reflexes, postural organization and an increase of motor control in the torso as well as upper and lower limbs<sup>1</sup>.

The use of therapeutic suits was inspired by the dynamic clothing used by Russian cosmonauts in the 1960's. The "Penguin" or "Penguin Suit" was the name attributed to the clothing created to maintain physical conditioning in weightless environments<sup>2</sup>. Based on these experiences, Semenova created the first suit at the end of the 1990's, in Poland, named Adeli Suit (AS)®, a dynamic proprioceptive correction orthosis capable of promoting torso alignment through elastic tensions applied on different body segments (feet, knees, hip and torso)<sup>3</sup>.

Besides the AS, other suit therapy programs emerged, such as the TheraSuit (TS)<sup>4</sup> and the Pediasuit<sup>5</sup>, which are internationally recognized treatment protocols. Due to their widespread dissemination, rehabilitation professionals (physical and occupational therapists) have been increasingly using these suits as therapeutic resources in the treatment of children with cerebral palsy.

We highlight that the first and third authors have clinical and academic experience in the suit therapy field and, in consonance with the evidence-based practice approach, they identified the need to obtain theoretical support for the use of dynamic clothing in intensive interventions for children with cerebral palsy. Therefore, the objective of this study is to examine literature on the effects of suit therapy programs on motor and functional performance of children with cerebral palsy.

# METHODS

#### **Search Strategies**

The selected virtual platforms were: PubMed, PEDro (Physiotherapy Evidence Database) and Cochrane. Based on

the search in Health Sciences Descriptors (http://decs.bvs. br/), the following combination of terms was used: (cerebral palsy) and (occupational therapy); (cerebral palsy) and (physical therapy); (cerebral palsy) and (physical therapy modalities). Two independent researchers simultaneously performed the search in the databases.

#### **Selection of Studies**

For eligibility purposes, we performed a selection process based on the reading of articles' titles and abstracts. Using the combination of descriptors in virtual databases, we performed the reading of articles' titles and triage of studies by means of the following inclusion criteria: works that presented titles and/or abstracts with the terms "Theratogs", "Adeli Suit", "Neurosuit", "TheraSuit", "Suit Therapy", "Spio", "Pediasuit", "Polishsuit", "suit" and "vest suit", published between January 2006 and October 2018, and articles characterized as clinical trials. The choice of period for inclusion aimed to encompass possible modifications in the designs of the clinical trials and updates in the methodological procedures.

In the second selection process, researchers read the articles' abstracts. An inclusion criterion was adopted wherein works were selected if they had analyzed the efficiency of dynamic suits in physical-functional treatments for children with cerebral palsy. The articles were included when they presented 100% agreement between the researchers during selection.

The exclusion criteria used were those studies that did not use dynamic suits in the treatment of children with cerebral palsy, systematic reviews of literature, and studies published prior to 2006 (Figure 1).

The articles were analyzed and categorized with regard to objectives, study type, participants (classified according to the gross motor function classification system), interventions, data collection instruments and results. Furthermore, all selected articles were submitted to methodological quality evaluation by means of the following scales: PEDro Scale (PS), Jadad Scale (JS), and Quality of Research Score Sheet (QoRSS).

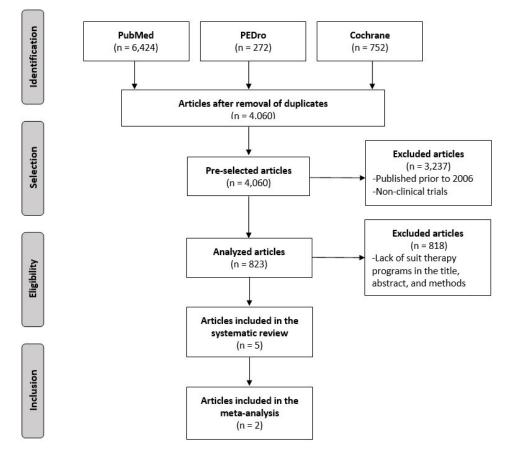


Figure 1 – Flow chart of the articles' selection

#### **Statistical Analysis**

The data was treated according to the Cochrane manual for systematic intervention evaluations.

The outcomes are presented as continuous data using data extracted from the eligible studies and including the mean value of the outcomes in each intervention and control group, standard deviation of the outcomes in each intervention and control group, and the number of participants by which the result was measured in each intervention and control group. The standard deviation was calculated for each study based on the change score method.

Heterogeneity between included studies was explored qualitatively (comparing characteristics of the included studies) and quantitatively (using the chi-square heterogeneity test and I<sup>2</sup> statistic). The funnel plot shows the mean of differences, which was used as the qualitative method to examine heterogeneity when more than two studies were analyzed. If applicable, the results of the included studies were combined with each result to give a global estimate of treatment effect. A fixed-effect model metaanalysis was used being based on the qualitative evaluation of heterogeneity and the low bias risk. All analyses were performed using Review Manager Version 5.0.

# RESULTS

The search in the virtual databases resulted in the sample of 7,448 articles, from which, after the removal of duplicates, lasted 4,060. Of these, 3005 studies were excluded for addressing studies that were not characterized as clinical trials, including systematic reviews of literature and theoretical articles, and 1,425 due to having been published prior to January 2006. Afterwards, 818 articles were excluded for not addressing suit therapy programs for children with cerebral palsy. In the end, five articles were selected for this review, which were made available in their entirety by the virtual platforms or by the authors themselves (Figure 1).

#### **Characteristics of the Included Studies**

The selected studies consist of clinical trials with comparison between groups, including control groups with or without other intervention approaches, such as neurodevelopmental treatment (NDT). Only Bailes et al.<sup>1</sup>, and Alagesan and Shetty<sup>6</sup> used experimental group and control group (Table1).

#### **Methodological Quality**

As for the methodological quality analysis of the selected articles, above-average score rates were identified (Table 1). The majority of studies presented randomization procedures as to the grouping of subjects. However, the majority also did not show any system for blinding of evaluators or participants when measuring results. All studies showed a description of eligibility criteria and the process for selection of participants. According to the QoRSS, the scores ranged from 9 points<sup>6</sup> to 12 points<sup>2</sup>. On the JS, the articles held the same score (3 points), with the exception of Bailes et al.<sup>1</sup>, which obtained the highest score (4 points). On the PS, the scores varied between 5 points<sup>7</sup> and 8 points<sup>1, 2, 6</sup>.

#### **Participants**

The participants presented varied functional levels, which varied between I and IV, according to the Gross Motor Function Classification System (GMFCS). Two studies selected children with cerebral palsy classified in levels I to IV<sup>2, 8</sup>, one conducted the research with children in levels I to III<sup>7</sup> and one selected only children in the level III<sup>1</sup>. Alagesan and Shetty<sup>6</sup> did not report the participants' functional levels. The topography of impairment as well as the type of cerebral palsy is diverse in the studies, even though it is not always reported.

Table 1 - Characteristics of included studies - clinical, demographics and testing description

Studies	QRSS/ J/P	Instruments	GMFCS	Ν	Age (Years)	Frequency/Modality/Intensity
Bar-Haim et al. <sup>2</sup>	12/3/8	GMFM-66 and Mechanical Efficiency Index	II to IV	24	5 years 11 months–12 years 11 months	AST Group/ NDT Group: measured at baseline and after 4 weeks and 10 months after baseline; Both groups: 2 hours, 5 days per week for 4 weeks (20 sessions)
Alagesan; Shetty <sup>6</sup>	9/3/8	GMFM-88	-	30	4 to 12 anos	Control group: conventional therapy / Experimental group: conventional therapy while wearing Modified Suit. Both groups were treated for 2 hours daily with short breaks of about 20 minutes for 3 weeks
Mahani et al. <sup>8</sup>	10/3/7	GMFM-66	I to IV	36	MAST 7.78 ± 1.93 AST 7.48 ± 2.13 NDT 7.40 ± 2.15	All children in the three groups received daily treatment for 2 hours, 5 days per week for a period of 4 weeks (20 sessions). They were tested at baseline, immediately before and 16 weeks after treatments
Bailes et al. <sup>1</sup>	11/4/8	GMFM-66; PEDI	III	20	4.9 ± 1.4	All participants (control and experimental) were assessed at baseline (3–10 days before the intervention), at 4 weeks (3–10 days after the intervention), and at 9 weeks (1 month after the intervention)
Christy et al. <sup>7</sup>	11/3/5	GMFM-66, SAM, COPM, and PODCI	I to III	17	7.6 ± 2.9	All children received daily treatment during four hours per day, five days per week, three weeks, a modified version of the TheraSuit <sup>™</sup> protocol

Legend: GMFCS= Gross Motor Function Classification System; GMFM=Gross Motor Function Measure; AST= Adeli Suit Treatment; NDT= Neurodevelopmental Treatment; COPM= Canadian Occupational Measure; PODCI= Pediatric Outcomes Data Collection Instrument; SAM= Step watch activity monitor; PBS= Pediatric Balance Scale; PEDI= Pediatric Evaluation of Disability Inventory; MAST= Modified Adeli Suit Therapy; QRSS= Quality of Research Score Sheet; J= Jadad Scoring; P= PEDro Scale.

#### **Evaluation Instruments**

With regard to the instruments utilized for data collection, it was observed that all of the selected studies used the Gross Motor Function Measure (GMFM) as the evaluation measure during pre- and post-treatment. Moreover, a preference was observed for this scale in its reduced version (GMFM-66). Other instruments are described in Table 1.

# Sample

The sample value used in the studies held the interval of seventeen and thirty-six subjects. The studies also showed heterogeneity regarding the age of the participants, which varied between four and eight (Table 1).

#### **Characteristics of the Interventions**

The studies describe therapeutic interventions, with the forming of a baseline from the use of evaluation measures of motor and functional components. The methodological design adopted by the majority of the studies presented a control group or comparison between more than two groups. The subjects were evaluated in intervals of four to eight weeks. During these periods, the participants were submitted to intensive intervention procedures, between three and six hours of physical therapy and/or occupational therapy (Table 1).

# **Description of Studies**

In comparing the effects of the AS® with the NDT on 24 children with cerebral palsy in levels II to IV, according to the GMFCS, by means of the GMFM and the Mechanical Efficiency Index (EIHB), Bar-Haim et al.<sup>2</sup> verified that in both methods the improvement in motor abilities in these subjects was not significant. However, with regard to the EIHB, there was a significant difference with regard to the children that were treated with AS at the tenth month.

With the objective of examining the effects of the AS® on the gross motor function of 30 children with spastic diplegia, based on a randomized clinical trial with a control group, Alagesan and Shetty<sup>6</sup> verified that in the intra-group comparison there was a statistical difference in the experimental group in the pre- and post-test. The comparison between the groups showed that there was a statistical difference for both of the post-treatment groups.

Mahani et al.8 examined the effects of the Modified AS® Therapy (MAST) on the development of gross motor function in children with cerebral palsy. Thirtyfive children with cerebral palsy were selected and divided into three groups: 12- MAST, 12- AS Therapy (AST), and 12- NDT. All of the children in each group received two hours of treatment daily, five days a week for one month. The participants were evaluated at the baseline and after four and sixteen weeks of intervention by means of the GMFM-66. The results of this study showed that after four weeks there was a significant difference between the MAST and AST groups, however the same did not occur between the AST and NDT group. After sixteen weeks, an increase in the GMFM score was observed only for the MAST group. There was no statistical difference between the AST and NDT groups.

Another study performed by Bailes et al.<sup>1</sup> examined the effects of ST during an intensive therapy program on the motor function of children with cerebral palsy. Twenty children were selected between the ages of three and eight and classified as level III, according to the GMFCS. The participants were divided into two groups (control and experimental) and evaluated by the Pediatric Incapacity Evaluation Inventory (PEDI) and by the GMFM-66 before the intervention and after four and nine weeks of treatment. The results showed that there was no statistical difference between the groups. However, there was a statistical intragroup difference at the ninth week. In the control group there was differences only in the GMFM (p=.0364). In the experimental group there was differences in the GMFM (p=.0026) an in the PEDI – functional skills/self-care (p = .0436), caregiver assistance/self-care (p = .0152), and functional skills/mobility (p = .0058).

Based on a clinical trial without a control group, Christy et al.<sup>7</sup> observed the effects of intensive physical therapy on gross motor function, on mobility, and on social participation in children with cerebral palsy. Seventeen children were evaluated who participated in intensive intervention (four hours daily, five days a week for three weeks) using the modified TS version. The participants were evaluated immediately and after three weeks of intervention by means of the GMFM-66, the Step Watch Activity Monitor (SAM), the Canadian Occupational Performance Measure (COPM) and the Pediatric Outcomes Data Collection Instrument (PODCI). Immediately after the intervention, a significant change was observed in the scores of the GMFM-66, SAM, COPM, and PODCI. After three months, improvements were detected only in the GMFM scores.

#### **Meta-analysis Results**

Figure 2 presents the forest plot of this meta-analysis. The data of the GMFM were used by two studies in posttreatment of children with cerebral palsy. The study conducted by Bailes et al.<sup>1</sup> showed a mean difference of -0.10 [-5.42, 5.22]. Meanwhile, in the study of Alagesan and Shetty<sup>6</sup> a mean difference of 2.42 [-5.87, 10.71] was found, P=0.78 in favor of the group that used the ST program (Figure 2).

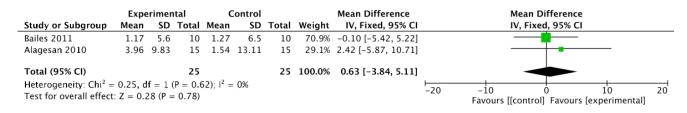


Figure 2 – Forest plot of the effects of programs that use suit therapy on children with cerebral palsy evaluated by GMFM

# DISCUSSION

The articles were found in search databases, with free access, except for the study by Christy et al.<sup>7</sup>. There were no studies with language different from English.

Taking into account that the objective of this study was to verify the literature on the effects of ST programs on motor and functional performance of children with cerebral palsy, it was found that the majority of the studies<sup>1,2,6,8</sup> showed positive evidences regarding the intra-subject comparison after the intervention protocols that use ST.

The type of studies, clinical trials, showed variations. Some researchers used control groups for comparison with the group that used the dynamic suit<sup>1, 6</sup> whereas other studies chose to compare with other intervention methods<sup>2, 8</sup>. Only one study selected intra-group comparison regarding preand post-intervention<sup>7</sup>.

The five studies presented in this review showed satisfactory methodological quality in the PS, with an average of 7.2 points, which shows high reliability, according to the criteria established for this instrument<sup>9</sup>. In the JS, the average was 3.2 points, and in the QoRSS the average was 10.6. In the presented studies it was identified that the researchers did not adopt any system for blinding of evaluators or participants because of the impossibility related to the characteristics of this type of research. The daily use of the suit makes it impossible to blind the participants, as well as their caregivers.

The studies in this review created hypotheses that the use of these suits contribute to the improvement of the motor and functional performance of children with cerebral palsy. However, the results of these clinical trials showed that the effects of these interventions were limited and controversial, lacking consistency of post-treatment effects.

The limitations of the presented studies refer to the size of the samples, ranging from 17 to 36 participants, subdivided into groups that varied from 10 to 12 children. Moreover, these studies did not describe the additional rehabilitation treatments provided for the participants, especially regarding the long-term treatment protocols.

The level of functionality of the participants reported by the studies also must be highlighted. The ST was not used with children in the level V, according to the GMFCS. The intervention protocols were used with patients with moderate limitations on ambulation and posture transfers. Even though it was not described, it seems to exist a predilection for children with less motor impairment.

For the meta-analysis, only two studies were selected, considering their homogeneous characteristics. Bailes et al.<sup>1</sup> and Alagesan and Shetty<sup>6</sup> conducted studies with similar research protocols: use of control groups and of the GMFM-88. However, the scarcity of studies limits the interpretations of comprehensive results and the statistical potential regarding the efficiency of the ST.

The article written by Alagesan and Shetty<sup>6</sup> shows favorable evidence concerning the use of the dynamic suit. Conversely, the research conducted by Bailes et al.<sup>1</sup> did not show data in favor of the ST.

Taking into account the growing emergence of dynamic suits, there is a need for new studies, with larger samples to validate the efficiency of the ST. Furthermore, this theme requires more homogeneous and more diverse research protocols, aiming to expand the contributions of this method.

# CONCLUSION

The present study concludes that the clinical studies that use ST programs show controversial scientific evidence with regard to motor and functional gains for children with cerebral palsy. There exists a statistical difference between the pre- and post-treatment for children that use ST, however, with regard to the inter-group comparison (control and other intervention methods), the results are still controversial and limited, due to the reduced number of studies and heterogeneous protocols.

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