

Gait parameters in children with bilateral spastic cerebral palsy: a systematic review of randomized controlled trials

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WORD COUNT: 4856

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ABSTRACT

Aim: To identify the gait parameters used to assess gait disorders in children with bilateral spastic cerebral palsy (BSCP) and evaluate their responsiveness to treatments.

Method: A systematic search within Pubmed, Web of Science and Scopus (English, 2000-2016) for randomized controlled trials of children with BSCP who were assessed by instrumented gait analysis (IGA) was done. Data related to participants and study characteristics, risk of bias and outcome measures were collected. A list of gait parameters responsive to clinical interventions was obtained.

Results: Twenty-one articles met the inclusion criteria. Eighty-nine gait parameters were identified and fifty-six of them showed responsiveness to treatments. Spatiotemporal and kinematic parameters were widely used compared to kinetic and surface electromyography data. The majority of responsive gait parameters were joint angles at the sagittal plane (flexion-extension).

Interpretation: The IGA yields responsive outcome measures for the gait assessment of children with BSCP. Spatiotemporal and kinematic parameters are the gait parameters used most frequently. Further research is needed to establish the relevant gait parameters for each clinical problem.

SHORTENED FORM OF THE TITLE: Gait Analysis in Cerebral Palsy Children.

WHAT THIS PAPER ADDS

- Fifty-six responsive gait parameters for children with bilateral spastic cerebral palsy were identified.
- Most responsive gait parameters belong to joint angles time-series at sagittal plane.
- Spatiotemporal and kinematic parameters are widely used compared to kinetic and sEMG parameters.
- Further efforts improving the clinical management of kinetic and sEMG data are required.
- Further research to establish the relevant gait parameters for each clinical problem is needed.

1. INTRODUCTION

Cerebral palsy (CP) is the most common cause of chronic childhood motor disability¹ with a prevalence of above 2.0 per 1000 live births². CP describes a group of permanent disorders affecting movement and posture and causing activity limitation that are attributed to non-progressive lesions in the developing fetal or infant brain³. The motor disorders of CP often occur together with disturbances of sensation, cognition, communication and behaviour, with epilepsy and with secondary musculoskeletal problems³.

Spasticity is often the dominant motor disorder⁴, along with loss of selective motor control and impaired balance⁵, and it can be classified according to different topographical patterns such as quadriplegia, diplegia and hemiplegia, with additional terms such as monoplegia and triplegia, or unilateral and bilateral⁶. Secondary musculoskeletal problems like muscle contractures, bony deformities and joint instability appear as a consequence of growth and development of the musculoskeletal system⁵. Their interaction, occurring at multiple levels, affects the quality and efficiency of gait and other aspects of motor function, contributing to activity limitation and participation restriction^{5,7}.

The Gross Motor Function Classification System (GMFCS) has been universally adopted to describe the movement ability of children with CP⁸. Its expanded and revised version uses five ordinal levels across five age bands, with emphasis on the typical performance in different settings⁹. The general headings for each level are: walks without limitations (I); walks with limitations (II); walks using a hand-held mobility device (III); self-mobility with limitations, may walk with physical assistance or use powered mobility (IV); and transported in a manual wheelchair (V)¹⁰. Children with unilateral CP almost always develop independent locomotion; in the case of bilateral CP, some children walk independently, some walk with aids and others can never achieve this function¹¹. Considerable research effort has been directed towards improving or maintaining walking ability of children with CP through different clinical interventions such as surgery, pharmacology, orthotics or physical therapy^{5,12}. Using reliable, valid and responsive outcome measures to evaluate the success of these interventions is crucial¹².

The Instrumented Gait Analysis (IGA) allows a precise quantification of gait characteristics, through objective data that cannot be appreciated visually or measured on a static physical examination¹³. The IGA provides detailed information on four main types of data recorded simultaneously: spatiotemporal, kinematic, kinetic and surface electromyography (sEMG) parameters^{14,15}. The IGA is often used in the assessment of ambulatory children with cerebral palsy¹⁶, for multiple purposes including the identification and understanding of gait deviations, the refinement of clinical decision-making and the evaluation and understanding of the effects of treatments on gait deviations^{5,13,14}. However, the reliability, validity and clinical utility of the IGA have not been well established⁵ and its clinical use remains variable and controversial^{15,17}.

One of the handicaps of the IGA is the large amount of data collected and analyzed, that makes it an instrument complicated to use and difficult to interpret¹⁸. A methodology for properly interpreting data from the IGA has not been defined clearly¹⁵ so clinicians and researchers have the challenge to extract the clinically relevant information from this large amount of data¹⁹. Kinematic and kinetic data analysis can be performed in two different ways: scalar gait parameters analysis and full gait waveforms analysis¹⁹. Scalar gait parameters analysis (which refers to specific vector components in

specific time instants of the gait cycle) is the most frequently used in intervention studies, but there is no consensus on which parameters should be evaluated¹⁹. Different methods have been used to select relevant gait parameters, from conventional manual procedures based on subjective available clinical expert knowledge to novel automated procedures based on objective mathematical techniques²⁰.

Two requirements for a clinically relevant gait parameter are: 1) its capability to distinguish between physiological and pathological gait (clinical problem characterization), and 2) its capability to separate between two therapy stages within the same patient group (responsiveness to treatments)²⁰. The responsiveness (ability to assess significant changes) of gait parameters to interventions should be established with caution due to the risk of type I (false positive: the mistake of inferring an experimental effect when none exists in reality)²¹ and type II (false negative: the mistake of missing real effects)²² errors. Evidence to support the responsiveness of gait parameters is needed¹².

The objective of this systematic review is to critically evaluate and summarize the current evidence base related to the clinical use of the IGA for the assessment of gait disorders in children with bilateral spastic cerebral palsy (BSCP). We aim to identify the gait parameters most widely used and evaluate their responsiveness to treatments for children with BSCP.

2. METHOD

2.1. Search strategy

In order to identify the key articles on this topic, a systematic search was undertaken within the following online databases: PubMed, Web of Science and Scopus. Constraints were applied for year of publication (2000-2016), language (English) and document type (clinical trial). Search through PubMed was also limited for species (humans) and text availability (abstract). The user query used was: (cerebral palsy OR spastic diplegia) AND (child OR adolescent) AND (gait OR walking OR ambulation OR locomotion) AND (spatiotemporal parameters OR kinematics OR kinetics OR electromyography OR three-dimensional gait analysis OR 3D gait analysis OR instrumented gait analysis OR quantitative gait analysis OR computerized gait analysis).

2.2. Eligibility criteria

Articles were included if they satisfied the following criteria: 1) Randomized controlled trials (RCT) with statistical analysis of the results; 2) Percentage of subjects with diagnosis of BSCP > 60%; 3) Mean age of the sample between 6 and 18 years old; 4) IGA for obtaining outcome measures, including spatiotemporal, kinematic, kinetic and/or sEMG parameters.

2.3. Risk of bias

To check the validity of the RCT selected, the Cochrane risk of bias tool²³ was used. This tool allows analyzing the adequacy of different features related to the risk of bias: random sequence generation, allocation sequence concealment, blinding, incomplete outcome data and selective outcome reporting. Included studies were asked to be RCT so we firstly analyzed the way randomization was carried out (participants' selection bias). On the other hand, this review aimed to evaluate the responsiveness of gait parameters to treatments so we secondly analyzed the risk of type I and type II errors due to the gait parameters' selection bias. The analysis of the risk of bias involves answering "low risk of bias", "high risk of bias" or "unclear" (lack of information or uncertainty over the potential for bias)²³.

2.4. Data collection

A data extraction sheet was developed, pilot-tested on the 14 first included studies and refined accordingly. Firstly, information related to participants and study characteristics was extracted in order to establish the comparability of the included studies: eligibility criteria, participants, study design, intervention and assessment. Secondly, gait parameters were classified, according to their nature, in spatiotemporal, kinematic, kinetic, sEMG and summary indexes, and their significant results (intra- or intergroup statistical analysis) were collected in order to determine their responsiveness to interventions. Both text and tables data were considered. Only outcomes which were statistically analyzed, and significant results obtained from randomized interventions were included. Significant results obtained from a combination of experimental and control group data, and kinematic parameters calculated from video observation were excluded. Finally, results were summarized in tables.

2.5. Additional analysis

From the data collection, an additional analysis was performed to study the responsiveness of gait parameters to different treatments. In this analysis, interventions were grouped into different types and the gait parameters that showed significant results for each type of intervention were determined.

3. RESULTS

3.1. Study selection

The search of Pubmed, Web of Science and Scopus databases provided a total of 334 citations, taking into account the above-mentioned user query and the search constraints. The last search was run on August 10th, 2017. After adjusting for duplicates, 199 remained. After reviewing the title and the abstract, 150 studies were discarded because they clearly did not meet the inclusion criteria. The full text of the remaining 49 studies was examined in more detail. Finally, 21 studies met the inclusion criteria and were included in the literature review²⁴⁻⁴⁴. In one article³⁴, only one of the studies (phase I) was included. All the studies finally selected for the review were RCT published in English in the period 2000-2016. See the flow diagram in Figure 1.

3.2. Trial's eligibility criteria

The inclusion criteria of participants in the different studies include information related to diagnosis (21 studies), age range (16), gross motor function (20), range of motion (nine), severity of motor disorders (spasticity and/or muscle weakness; six), secondary musculoskeletal problems (contractures and deformities; 14), medical history (surgery, drugs and/or rehabilitation; 19), sensory impairments (visual, auditory or perceptual; seven), degree of comprehension (13), anthropometric measures (height and/or weight; three) and treatment contraindications (four).

3.3. Participants

The included studies involved a total of 528 children with spastic cerebral palsy. The majority of the participants had a diagnosis of BSCP (n = 488, 92%), at least 419 (79%) spastic diplegic, and the mean age of the children was 8 years 7 months. The ability to walk of the participants was mainly defined through the GMFCS. Seven studies only included participants with independent walking (GMFCS levels I and/or II), 10 studies included participants able to walk with or without walking aids (GMFCS levels I,

II and/or III) and four studies additionally included participants able to walk with external support (GMFCS levels I, II, III and/or IV) (see Table 1).

Other characteristics were detailed only in some studies, for example, gender (15 studies), anthropometric measures like weight, height or body mass index (10), the gait pattern (five), the use of walking aids or orthosis (three) and the history of surgery, physical therapy or botulinum toxin A (BTX-A) injections (three).

3.4. Study design

Eighteen studies used a parallel group design: different interventions were applied to at least two different groups (experimental and control groups). The other three studies used a cross-over design: there were two different interventions (A and B) and all the children received both interventions in a randomized order. Two studies defined a healthy control group but only data from the cerebral palsy groups was taken into account in the review (see Table 2).

3.5. Intervention

A big variety of interventions were studied in the included studies: surgical procedure (single event multilevel surgery (SEMLS), distal rectus femoris transfer and/or selective dorsal rhizotomy; four studies), BTX-A (four), casting (four), orthopedic device (ankle-foot orthosis, strapping system and/or postural insole; three), individually defined physical therapy (one), strength training program (whole body vibration training, resistance and/or active exercises or neuromuscular electrical stimulation; five), balance training program (one), gait training program (gait trainer, treadmill training or partial body-weight-supported treadmill training; three), hippotherapy (one) and transcranial direct current stimulation (one) (see Table 2).

3.6. Instrumented gait analysis

All included studies assessed participants at least twice. Eight studies made pre- and post-intervention assessments, seven studies made pre-intervention and follow-up assessments and four studies made pre-, post-intervention and follow up assessments. Three studies made assessments in different conditions: with and without the intervention device (see Table 2).

When performing the IGA, different measurement tools were used synchronously (integrated solutions) or independently: three dimensional gait analysis (3DGA) system, force plate, sEMG and video recording. 3DGA was used in 19 studies to obtain kinematic and/or spatiotemporal parameters. The number of infrared cameras went from five to 16 (six being the most common) and the recording frequency from 100 to 120Hz. The markers were reflective with a diameter between 9 and 25mm. Eight studies used force plates to obtain kinetic data and the number of platforms went from one to three (two being the most common). Five studies used sEMG to obtain muscle activation data, and information about channels supported, sample frequency, amplifier, transmitter, filters (high-pass and low-pass) and electrodes (type, area and inter-electrodes distance) was reported. Eight studies used a video system as a complement to the other measurement tools (see Table 2).

In all the studies, participants were asked to walk on a walkway. In 12 studies, the length of the walkway was specified, with a mean value of 8m. In 11 studies, the minimum number of walking trials (collected and/or selected) was reported, ranging from two to six trials. Two studies reported the maximum number of walking trials (eight and 10 respectively). Fifteen studies reported the walking

speed that was indicated to participants. In all cases, self-selected walking speed was chosen. Some studies also described whether participants walked barefoot (eight studies) or with usual footwear (two), with orthosis or insoles (four) and/or with walking aids (five). Ten studies used data from children with typical development as normative reference.

All the studies used the IGA for obtaining outcome measures (it was one of the inclusion criteria of the review). Additionally, the IGA was used to define the gait pattern of the participants (two studies), the rehabilitation devices setup (two) and the BTX-A target muscles (two).

3.7. Risk of bias

The risk of bias assessment was focused on the participants' selection and the gait parameters' selection. When assessing the participants' selection bias, the random sequence generation and the allocation concealment were studied. Different techniques were reported in the included studies. Regarding the random sequence generation, the following criteria was applied when analyzing the risk of bias: 1) computer random number generation, minimization and block randomization with block size masked were considered as "low risk of bias"; 2) alternation was considered as "high risk of bias"; and 3) envelopes and block randomization without specifying the sequence generation technique were considered as "unclear risk of bias". In relation to the allocation concealment: 1) sequentially numbered, opaque, sealed envelopes and central randomization (performed by a person independent to the study) were considered as "low risk of bias"; 2) alternation was considered as "high risk of bias"; and 3) envelopes with one or two of the requirements (sequentially numbered, opaque and sealed), computer randomization without specifying the allocation method and random allocation schedule without specifying that it was not open were considered as "unclear risk of bias". Three studies showed a low risk of bias in both features and seven studies showed a low risk of bias in one of them (with the other one classified as unclear). In 10 studies, the whole randomization process was classified as unclear and one study showed a high risk of participants' selection bias (see Table 1).

The assessment of the gait parameters' selection bias was based on the ideal hypothesis testing defined in Pataky et al.²¹ and the following criteria were applied: 1) directed hypotheses (claim response in specific gait parameters) followed by analyses of the same specific gait parameters and non-directed hypotheses (broadly claim kinematic, kinetic or sEMG response) followed by full gait waveforms analyses were considered as "low risk of bias"; and 2) specific gait parameters analyses following non-directed hypotheses (broadly claim spatiotemporal, kinematic, kinetic or gait response) and directed hypotheses followed by analyses of more specific gait parameters than those defined in the hypotheses were considered as "high risk of bias". We considered as hypothesis the last paragraph of the introduction section of the included studies, independently of the terminology used (hypothesis, aim, objective, goal or purpose). Sixteen studies showed high risk of gait parameters' selection bias, and five studies showed low risk.

No subgroup analyses of the results were done considering the risk of bias results because it is not possible to know if the bias really existed and any judgment could be unfair.

3.8. Outcomes

This section summarizes the gait parameters used as outcome measures in the included studies. The reported parameters were classified in spatiotemporal, kinematic (“joint angles” referring to ankle, knee and hip, and “segment angles” referring to foot and pelvis), kinetic, sEMG and summary indexes.

Only three included studies provided detailed parameters definitions^{26,28,30}. Gait parameters with different terminology were grouped together if they had a similar meaning (e.g. “minimum knee flexion in stance”³⁰ and “maximum knee extension in stance”⁴³) and a common terminology was provided in order to homogenize the definition criteria. Sometimes, it was difficult to establish the correct definition for each gait parameter. For example, it is not clear if the gait parameter “ankle angle at initial swing”³¹ refers to a specific time instant of the gait cycle (toe off) or to the mean value during a gait subphase (initial swing). Some spatiotemporal parameters were defined according to Grecco et al.²⁸. The nomenclature of kinematic and kinetic parameters was divided in three different items related to their definition: value, time-series and gait phase (e.g. the minimum value of the hip flexion-extension angle at stance phase was named MIN_HipFlexExt_St), based on Wolf et al.²⁰, and a short definition was given for each item. The definition of the summary indexes was also provided (see Table 3). sEMG data was cataloged by muscles, independently of the statistical parameter used in each study.

For each parameter, it was determined whether statistically significant differences were observed, either in the intra- or intergroup analysis, considering a p -value < 0.05 .

3.8.1. Spatiotemporal parameters

Eighteen studies analyzed spatiotemporal data. Seven different parameters were reported: gait speed (17 studies), cadence -also expressed as cycle time- (15), stride length -also expressed as step length- (17), step width (two), time of toe off -also expressed as stance phase or swing phase- (six), single support (one) and double support (one). Gait speed was calculated in m/s, cm/s or m/min (15 studies) and it was also normalized to account for leg length (one). Cadence was calculated in steps/min or cycles/min (10 studies) and, when expressed as cycle time, in s or ms (four). Stride length was calculated in m or cm (13 studies) and percentage of height (one). Time of toe off, single support and double support were calculated in percentage of cycle. Statistically significant changes ($p < 0.05$) within groups (intra-group analysis) and/or between groups (inter-group analysis) were observed for five spatiotemporal parameters: gait speed (11 studies), cadence (seven), stride length (nine), time of toe off (one) and single support (one) (see Table 4).

3.8.2. Kinematic parameters

Fifteen studies analyzed kinematics of the lower limb, including segment angles: foot (four studies) and pelvis (five); and joint angles: ankle (12), knee (13) and hip (10); in the three planes: sagittal (15), frontal (four) and transverse (four). Four studies analyzed kinematics at the five levels (foot, ankle, knee, hip and pelvis) and in the three planes (sagittal, frontal and transverse). There were 64 different kinematic parameters explicitly reported: foot (four parameters), ankle (14), knee (18), hip (19) and pelvis (nine); sagittal plane (44), frontal plane (eight) and transverse plane (12). Significant changes were found in 38 kinematic parameters: foot (three parameters), ankle (10), knee (13), hip (eight) and pelvis (four); sagittal plane (30), frontal plane (three) and transverse plane (five) (see Tables 4 and 5).

3.8.3. Kinetic parameters

Five studies analyzed kinetics, including ankle, knee and hip moment (five studies) and power (three) in the sagittal plane. Joint moment was calculated in N·m/kg (normalized to body mass) (four studies) and joint power in W (one) or W/kg (two). Eight different parameters were reported: PlantDorsFlexMo_IC (one study), MAX_PlantDorsFlexMo_LR (two), MAX_PlantDorsFlexMo_POFF (five), MIN_AnkleGenAbsPo_LR (one), MAX_AnkleGenAbsPo_POFF (three), MIN_KneeGenAbsPo_LR (one), MIN_HipGenAbsPo_St (one) and MAX_HipGenAbsPo_St (one). Significant changes were observed in four kinetic parameters: MAX_PlantDorsFlexMo_LR (one study), MAX_PlantDorsFlexMo_POFF (two), MIN_AnkleGenAbsPo_LR (one) and MAX_HipGenAbsPo_St (one) (see Table 4).

3.8.4. sEMG parameters

Four studies analyzed sEMG data. Each one used different parameters related to sEMG: root mean square difference, mean asymmetry score (in mV), dynamic EMG score (in percentage of number of patients in which muscle is active during gait cycle) and maximal linear envelope of EMG (dynamic rectified EMG recordings in mV). Eight muscle groups were studied: gastrocnemius (three studies), soleus (one), tibialis anterior (two), rectus femoris (two), vastus lateralis (one), lateral hamstrings (one), medial hamstrings (two) and adductor (one). Significant changes within or between groups were found in all the muscles (at least in one study) except in vastus lateralis (see Table 4).

3.8.5. Summary indexes

Five studies analyzed one of these two summary indexes: the Gillette Gait Index (GGI) (three studies), and the Gait Profile Score (GPS) (two). Significant changes were found in both indexes (see Table 4).

3.9. Gait parameters responsiveness to different treatments

Interventions were grouped in eight different types: surgery, BTX-A + casting, orthopedic devices, strength training, balance training, gait training, individualized therapy and hippotherapy. Surgery produced significant changes in kinematic parameters, mainly at knee (nine parameters), and one summary index (GGI). BTX-A and/or casting showed significant differences in spatiotemporal, kinematic (foot, ankle, knee, hip and pelvis), kinetic (ankle and hip) and sEMG parameters. Orthopedic devices showed significant results in spatiotemporal, kinematic (ankle, knee and hip) and ankle kinetic parameters. Strength training significantly changed spatiotemporal and kinematic (ankle and knee) parameters. Balance training produced significant results in spatiotemporal parameters. Gait training showed significant results in spatiotemporal and kinematic parameters, mainly at hip (five parameters), and one summary index (GPS). Individualized therapy significantly changed spatiotemporal and kinematic (knee and pelvis) parameters. Hippotherapy showed significant changes in sEMG data (adductor muscle activity) (see Table 6).

4. DISCUSSION

This work presents a literature review of 21 RCT, published in English between the years 2000 and 2016, that used the IGA to obtain spatiotemporal, kinematic, kinetic and sEMG outcome measures. We identified the gait parameters used to evaluate gait disorders in children with BSCP and analyzed their responsiveness to clinical interventions.

A total of 89 gait parameters were statistically analyzed in the included studies. Spatiotemporal parameters were the most frequently used (18 included studies) followed by kinematic (15), kinetic (five), summary indexes (five) and sEMG data (four). If the parameters are analyzed individually, gait speed, stride length and cadence were the most frequently used (in 17, 17 and 15 studies, respectively) while the rest of parameters were used only in one study (47% of the gait parameters), two studies (31%) or between three and six studies (15%). It should be studied why kinetic and sEMG data are not usually used in intervention studies although they are considered necessary to clarify the gait patterns commonly seen in individuals with CP and plan an appropriate intervention¹³. Further research is needed to establish the relevance of kinetic and sEMG parameters as outcome measures.

Fifty-six gait parameters showed significant results. Kinematic were the type with more responsive parameters (38) followed by sEMG (seven), spatiotemporal (five), kinetic (four) and summary indexes (two). 81% of responsive kinematic parameters were joint angles (ankle, knee or hip) and 79% were from sagittal plane. This makes sense since the widest movements involved in gait are ankle plantarflexion/dorsiflexion, and knee and hip flexion/extension. Most of the gait pattern classifications are based on sagittal plane kinematics¹⁴ and many gait deviations observed and treated in children with CP occur in the sagittal plane⁴⁵. However, deviations in the transverse and frontal planes are also considered important in clinical decision-making and intervention planning, and analyses in these planes could improve content validity of gait classifications⁴⁶.

The selection of an appropriate outcome measure depends on many factors including the type of intervention⁴⁷. Responsiveness is intervention-specific so we analyzed the gait parameters that showed significant results for each type of intervention. Gait speed, cadence and stride length showed to be responsive to the majority of interventions or, analyzed from another point of view, the majority of interventions had an effect on them. On the other hand, from the number of gait parameters with significant results, we observed that some interventions had their main effect at a certain level: BTX-A + casting and orthopedic devices on the ankle, surgery on the knee and gait programs on the hip. The studies included in this review were not selected for the analysis of the relationship between gait parameters and interventions. Neither a rigorous scientific methodology was followed to statistically analyze this relationship. Therefore, these results should be considered only as additional observations that could inspire new hypotheses and future research studies on this field.

There is no consensus on the relevant gait parameters for each clinical problem¹⁹. Only three included studies specified the parameters selection criteria^{35,39,43} (based on the expected changes or a study of the literature), so the selection probably could have been done subjectively in all cases. From the fifteen studies that used kinematic and/or kinetic data, thirteen analyzed specific gait parameters and two analyzed the full time-series through the Gait Variable Score (also called Movement Assessment Profile)^{26,28}. There are two main risks when using scalar gait parameters: 1) the rationale behind the selection of the gait parameters is often unclear. Reducing the large amount of data subjectively may introduce post hoc regional focus bias (type I or type II error resulting from expanding or reducing the scope of the clinical hypothesis after seeing the data) and potential clinically relevant parameters could be omitted^{19,21,48}; 2) there exist covariance among vector components of multidimensional kinematic and kinetic data. Conducting scalar statistical testing on multiple dependent gait parameters may

introduce inter-component covariation bias (type I or type II error resulting from the failure to consider the covariance among vector components), especially in small sample sizes^{19,48,49}.

Some solutions have been proposed to avoid these risks. First of all, a clear hypothesis should be stated a priori and an adequate statistical approach should be selected in accordance to this hypothesis¹⁹. In case of non-directed hypotheses⁴⁸, statistical methods such as the Bonferroni correction are often applied to deal with the risk of detecting a false positive when testing a large number of dependent gait parameters, but some of them can increase the probability of obtaining a false negative result^{19,22}. The statistical parametric mapping (SPM), which belongs to full gait waveforms analysis, is a promising statistical alternative to scalar gait parameters analysis with regard to the interpretation of multidimensional biomechanical data^{19,21,48}. SPM is able to perform hypothesis testing on kinematic and kinetic data in a continuous manner, avoiding the need for subjective a priori data reduction, and it also takes into account the dependency between different time instances of the gait cycle¹⁹. So, SPM overcomes both bias sources⁴⁸. In case of directed hypotheses⁴⁸, performing a scalar gait parameters analysis overcomes the risk of bias^{21,48}.

There is another handicap related to scalar gait parameters: they are usually defined on the basis of normal kinematic and kinetic waveforms and they can be difficult to extract from pathological gait waveforms⁵⁰. Furthermore, the definitions of scalar gait parameters are often unclear, making it difficult for researchers to reproduce or confirm results¹⁹. SPM could be a solution since it avoids the need to define gait parameters. Otherwise, a clear definition of the scalar gait parameters (like the one proposed in this review) could help clinicians to understand, interpret, reproduce and compare results.

The IGA is expensive, complex and time-consuming to learn and to use in real practice⁵. Consequently, it is not always accessible for clinicians^{51,52}. The quotidian application of expensive healthcare technologies cannot be justified until the evidence unequivocally demonstrates its utility⁵. Conclusions about the usefulness of the IGA can only come from multiple high quality scientific studies free from bias¹⁶. However, these studies are scarce^{15,17}. Our review provides evidence from RCT supporting the responsiveness of the gait parameters to interventions. Our results may also guide clinicians and researchers to select the most relevant gait parameters according to the clinical hypothesis and the treatment selection. The IGA is one of the many inputs into the clinical decision-making process¹⁶ and we recommend using it together with usual clinical assessment. In the identification of walking problems, differences are detected when using the IGA or the clinical assessment⁴⁵; the IGA is not a substitute for the clinical assessment but should be used to provide evidence and enhance clinical decision-making¹³. The use of a diagnostic and assessment protocol, based on different sources of information and including the IGA, is crucial to achieve an evidence-based practice to optimize the gait pattern and the gait function of children with cerebral palsy.

Some limitations should be considered when interpreting the findings/results of this review: 1) the scope of this systematic review was limited to English-language RCT, which might have under-represented the set of gait parameters used worldwide, 2) only one reviewer was involved in the study selection and data collection processes, which might have increased the risk of misinterpretation, and 3) there was a big heterogeneity with regards to the selection and definition of the gait parameters, which made difficult the analysis and comparison of results.

In conclusion, the IGA yields responsive outcome measures for the gait assessment of children with BSCP. Spatiotemporal and kinematic parameters are widely used in comparison to kinetic and sEMG data. Further research is needed to determine the role of kinetic and sEMG parameters in the gait analysis and to establish the relevant gait parameters for each clinical problem.

ACKNOWLEDGEMENTS: The authors would like to thank Olga Araujo Gutiérrez for her assistance as librarian and Amy Croft for her help in copyediting this review.

CONFLICT OF INTEREST: The authors have stated that they had no interests which might be perceived as posing a conflict or bias.

FUNDING: This study received the support of a predoctoral grant in physiotherapy from the University of Vic - Central University of Catalonia. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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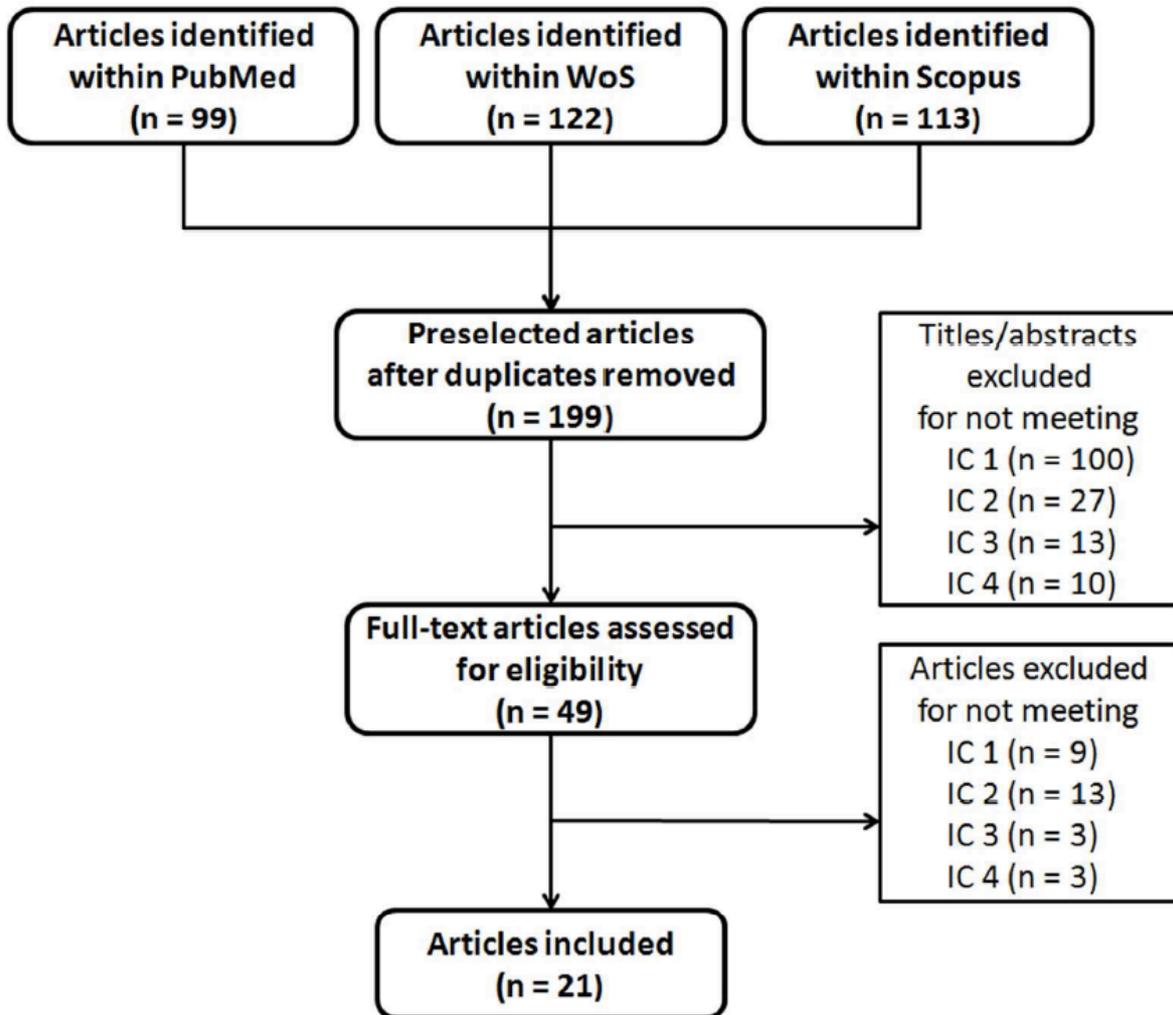
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FIGURES

Figure 1. Study flow diagram. WoS = Web of Science, IC = Inclusion Criteria.



TABLES

Table 1. Participants' characteristics and selection risk of bias

Table 1
Participants' characteristics and selection risk of bias

Study	Sample size (n)		Mean age (yr/mo)	Sex (n)		Diagnosis (n)				GMFCS (score)	Participants' selection risk of bias	
	E	C		M	F	SD	SQ	SH	ST		RSG	AC
Neto et al. (2014) ²⁴	5	5	8	—	—	10				I, II	?	?
Abd El-Kafy et al. (2014) ²⁵	15	15	8/10	13	17	30				I, II	+	?
Franki et al. (2014) ²⁶ [^]	5	5	6/2 ^a	6	4	<i>b</i>	<i>b</i>			I, II, III	+	+
Abd El-Kafy (2014) ²⁷	19/19 ^c	19	7/4	31	26	57				I, II	+	+
Grecco et al. (2014) ²⁸	12	12	7/11	7	17	24				II, III	?	+
Lee et al. (2013) ²⁹	15	15	9/10	15	15	<i>b</i>	<i>b</i>			<i>d</i>	?	?
Dreher et al. (2012) ³⁰	17	15	11/2	20	12	32				I, II, III	+	?
Smania et al. (2011) ³¹	9	9	13/4	10	8	11	7			I, II, III, IV	+	?
Van der Houwen et al. (2011) ³²	12	10	7/7	14	8	21		1		I, II, III	?	?
Johnston et al. (2011) ³³	14	12	9/6	14	12	12	12		2	II, III, IV	?	?
McGibbon et al. (2009) ³⁴	25	22	8/6	27	20	25	9	7	6 ^e	I, II, III, IV	?	+
Smith et al. (2009) ³⁵ [^]	—	—	7/6	—	—	15				I	?	?
Al-Abdulwahab et al. (2009) ³⁶	21	10	7/8	—	—	31				<i>f</i>	?	?
Seniorou et al. (2007) ³⁷	11	9	12/6	10	10	20				I, II, III	?	?
McNee et al. (2007) ³⁸ [^]	5	4	7/1	4	5	6		3		I, II, III	+	?
Engsberg et al. (2006) ³⁹	3/4/2 ^c	3	9/11	3	9	12				I, II, III	?	?
Patikas et al. (2006) ⁴⁰	19	20	9/8	—	—	39				<i>f</i>	?	?
Kay et al. (2004) ⁴¹	11	12	7/1	12	11	13	1	9		<i>f</i>	+	?
Bottos et al. (2003) ⁴²	5	5	6/4	7	3	10				<i>d</i>	?	?
Desloovere et al. (2001) ⁴³	17	17	6/10	—	—	22		12		<i>d</i>	-	-
Graubert et al. (2000) ⁴⁴	18	11	6/10	—	—	29				<i>g</i>	+	+

GMFCS = Gross motor function classification scale, n = Number of children, yr = Year, mo = Month, E = Experimental group, C = Control group, M = Male, F = Female, SD = Spastic diplegia, SQ = Spastic quadriplegia, SH = Spastic hemiplegia, ST = Spastic triplegia, RSG = Random sequence generation, AC = Allocation concealment. [^] = Cross-over design, — = Not reported, ^a = Median of age, *b* = Diagnosis: SD or SQ, *c* = More than one experimental group, *d* = Independent walking, *e* = Diagnosis: Mixed, *f* = Independent or aided walking, *g* = Nonambulator, assisted ambulatory or independent ambulatory. + = Low risk of bias, ? = unclear risk of bias, - = High risk of bias.

Table 2. Characteristics of the studies included in the review.

Table 2

Characteristics of the studies included in the review

Study	Intervention		Assessment timing	IGA		Gait parameters' selection risk of bias
	E	C		Measurement tool	Data type	
Neto et al. (2014) ²⁴	PI	Placebo	Barefoot/Shoes/+Insoles	3DGA	Spatiotemporal	-
Abd El-Kafy et al. (2014) ²⁵	BT+CT	CT	Pre/Post	3DGA+Video	Spatiotemporal	-
Franki et al. (2014) ²⁶ ^	ITP	GTP	Pre/Post	3DGA+FP+sEMG	Spatiotemporal, kinematics, summary indexes	+
Abd El-Kafy (2014) ²⁷	CT+SS/+SAFO ^c	CT	Pre/Post	3DGA+Video	Spatiotemporal, kinematics	+
Grecco et al. (2014) ²⁸	TT+tDCS	TT+Placebo	Pre/Post/1month	3DGA+Video	Spatiotemporal, kinematics, summary indexes	+
Lee et al. (2013) ²⁹	WBVT+CT	CT	Pre/Post	3DGA	Spatiotemporal, kinematics	-
Dreher et al. (2012) ³⁰	SEMLS+CT	SEMLS+DRFT+CT	Pre/1year	3DGA+FP	Spatiotemporal, kinematics, summary indexes	-
Smania et al. (2011) ³¹	GT	CT	Pre/Post/1month	3DGA	Spatiotemporal, kinematics	-
Van der Houwen et al. (2011) ³²	BTX-A+CR	CT	Pre/6weeks	Video+sEMG	sEMG	+
Johnston et al. (2011) ³³	PBWSTT	CT	Pre/Post/1month	3DGA	Spatiotemporal	-
McGibbon et al. (2009) ³⁴	HT	BS	Pre/Post	Video+sEMG	sEMG	+
Smith et al. (2009) ³⁵ ^	DAFO	HAFO	Barefoot/DAFO/HAFO	3DGA+Video+FP	Spatiotemporal, kinematics, kinetics	-
Al-Abdulwahab et al. (2009) ³⁶	NMES		Pre/NMES/Post	3DGA	Spatiotemporal	-
Seniorou et al. (2007) ³⁷	SEMLS+CT+RS	SEMLS+CT+AE	Pre/Post/1year	3DGA	Spatiotemporal, kinematics	-
McNee et al. (2007) ³⁸ ^	CAST		Pre/Post	3DGA+FP	Spatiotemporal, kinematics, summary indexes	-
Engsberg et al. (2006) ³⁹	D-ST/P-ST/DP-ST ^c		Pre/Post	3DGA+Video+FP	Spatiotemporal, kinematics, kinetics	-
Patikas et al. (2006) ⁴⁰	SEMLS+CT+ST	SEMLS+CT	Pre/1year/2years	3DGA+FP	Spatiotemporal, kinematics, kinetics, summary indexes	-
Kay et al. (2004) ⁴¹	BTX-A+CAST	CAST	Pre/3months/1year	3DGA	Kinematics	-
Bottos et al. (2003) ⁴²	BTX-A+CAST+CT	BTX-A+CT	Pre/1month/4months	3DGA+FP+sEMG	Spatiotemporal, kinematics, kinetics, sEMG	-
Desloovere et al. (2001) ⁴³	CAST post BTX-A+CT	CAST pre BTX-A+CT	Pre/2months	3DGA+Video+FP+sEMG	Spatiotemporal, kinematics, kinetics, sEMG	-
Graubert et al. (2000) ⁴⁴	SDR+CT	CT	Pre/1year	3DGA	Spatiotemporal, kinematics	-

E = Experimental group, C = Control group, IGA = Instrumented gait analysis. ^ = Cross-over design, c = More than one experimental group. PI = Postural insole, BT = Balance training, CT = Conventional therapy, ITP = Individualized therapy program, GTP = General therapy program, SS = Strapping system, SAFO = Static ankle foot orthosis, TT = Treatmill training, tDCS = Transcranial direct current stimulation, WBVT = Whole body vibration training, SEMLS = Single event multilevel surgery, DRFT = Distal rectus femoris transfer, GT = Gait trainer, BTX-A = Botulinum toxin A, CR = Comprehensive rehabilitation, PBWSTT = Partial body-weight-supported treadmill training, HT = Hippotherapy, BS = Barrel-sitting, DAFO = Dynamic ankle foot orthosis, HAFO = Hinged ankle foot orthosis, NMES = Neuromuscular electrical stimulation, RS = Resistance strengthening, AE = Active exercise, CAST = Casting, D-ST = Dorsiflexion strength training, P-ST = Plantarflexion strength training, DP-ST = Dorsi-and plantarflexion strength training, ST = Strength training, SDR = Selective dorsal rhizotomy. Pre = Pre-intervention assessment, Post = Post-intervention assessment. 3DGA = Three dimensional gait analysis, FP = Force plate, sEMG = Surface electromyography. + = Low risk of bias, ? = unclear risk of bias, - = High risk of bias.

Table 3. Gait parameters definitions

Type	Nomenclature	Definition
Table 3		
Gait parameters definitions		
SPATIOTEMPORAL		
	Gait speed	Mean velocity of progression in longitudinal direction. In meters/second. ²⁸
	Cadence	Number of steps in a time unit. In steps/minute. ²⁸
	Stride length	Longitudinal distance between successive points of heel contact of the same foot. In meters. ²⁸
	Step width	Distance between the rear end of the right and left heel centerlines along the mediolateral axis. In meters. ²⁸
	Time of toe off	Instant in the gait cycle in which toe off occurs. It also refers to the duration of stance phase. In percentage of gait cycle.
	Single support	Percentage of the gait cycle in which one foot is in contact with the floor. ¹⁴ It includes MSt and TSt.
	Double support	Percentage of the gait cycle in which both feet are in contact with the floor. There are two double support periods during a gait cycle (LR and PSw). ¹⁴
KINEMATIC AND KINETIC		
	Value	
	MAX	Maximum value. ²⁰ In degrees (angle), N-m (moment) and W (power).
	MIN	Minimum value. ²⁰ In degrees (angle), N-m (moment) and W (power).
	MAPO	Temporal position of the maximum value. ²⁰ In percentage of gait cycle.
	MIPO	Temporal position of the minimum value. ²⁰ In percentage of gait cycle.
	ROM	Range of motion (MAX-MIN). ²⁰ In degrees (angle), N-m (moment) and W (power).
	MEAN	Mean value ²⁰ , in degrees (angle), N-m (moment) and W (power), calculated as: $MEAN_i = \frac{1}{T} \sum_{t=1}^T x_{i,t}$ where $x_{i,t}$ is the value of a gait variable i at a specific instant t in the gait cycle, and T is the number of instants into which the gait cycle was divided.
	GVS	The Gait Variable Score is the root mean square (RMS) difference between a normalized temporal kinematic variable (joint or segment angle) and the average kinematic variable from a reference group, calculated point-by-point across the gait cycle ^{26,28,53} : $GVS_i = \sqrt{\frac{1}{T} \sum_{t=1}^T (x_{i,t} - \bar{x}_{i,t}^{ref})^2}$ where $x_{i,t}$ is the value of a gait variable i at a specific instant t in the gait cycle, $\bar{x}_{i,t}^{ref}$ is the mean value of that variable at the same instant for the reference population, and T is the number of instants into which the gait cycle was divided. In degrees.
Time-series		
Foot kinematics		
	FootPro	Foot progression orientation in the frontal plane.
	FootInExRot	Foot rotation orientation in the transverse plane.
Ankle kinematics		
	DorsPlantFlex	Ankle dorsi-plantar flexion angle in the sagittal plane.
Knee kinematics		
	KneeFlexExt	Knee flexion-extension angle in the sagittal plane.
	KneeFlexExtVe	Knee flexion-extension velocity in the sagittal plane. It can be calculated as the temporal gradient (slope) of the KneeFlexExt angle: $v_{i,t} = \frac{1}{2} (x_{i,t+1} - x_{i,t-1})$ where $x_{i,t}$ is the value of a gait variable i at a specific instant t in the gait cycle. ²⁰
Hip kinematics		
	HipFlexExt	Hip flexion-extension angle in the sagittal plane.
	HipAddAbd	Hip adduction-abduction angle in the frontal plane.
	HipInExRot	Hip internal-external rotation angle in the transverse plane.
Pelvis kinematics		
	PelvicTilt	Pelvic tilt orientation in the sagittal plane.
	PelvicObl	Pelvic obliquity orientation in the frontal plane.
	PelvicRot	Pelvic rotation orientation in the transverse plane.
Ankle kinetics		
	PlantDorsFlexMo	Internal ankle moment in the sagittal plane. It indicates muscle activity of plantar-flexors (positive values) and dorsi-flexors (negative values). ⁵⁴
	AnkleGenAbsPo	Ankle power in the sagittal plane. Generation power indicates concentric contraction and absorption power indicates eccentric contraction. ⁵⁵
Knee kinetics		
	KneeGenAbsPo	Knee power in the sagittal plane. Generation power indicates concentric contraction and absorption power indicates eccentric contraction. ⁵⁵
Hip Kinetics		
	HipGenAbsPo	Hip power in the sagittal plane. Generation power indicates concentric contraction and absorption power indicates eccentric contraction. ⁵⁵
Gait phase		
Events		
	IC	Initial contact is the instant in which the initial foot strike occurs (0% of gait cycle). ⁵⁴
	ForeAftShear	Instant in which reversal of fore to aft shear occurs. ⁵⁴
	TOff	Instant in which toe off occurs ($\approx 62\%$ of gait cycle). ⁵⁴
Subphases		
	LR	Loading response or initial double-limb support goes from IC (0% of gait cycle) to opposite toe-off ($\approx 12\%$ of gait cycle). ⁵⁴
	MSt	Midstance refers to initial single-limb stance and goes from opposite toe-off ($\approx 12\%$ of gait cycle) to ForeAftShear ⁵⁴ (or heel off if it occurs).
	TSt	Terminal stance refers to terminal single-limb stance and goes from ForeAftShear (or heel off if it occurs) to opposite foot strike ($\approx 50\%$ of gait cycle). ⁵⁴
	PSw	Preswing or second double-limb support goes from opposite foot strike ($\approx 50\%$ of gait cycle) to TOff. ⁵⁴
	ISw	Initial swing goes from TOff to foot clearance ($\approx 75\%$ of gait cycle). ⁵⁴
	Msw	Midswing goes from foot clearance ($\approx 75\%$ of gait cycle) to tibia vertical ($\approx 85\%$ of gait cycle). ⁵⁴
	Tsw	Terminal swing goes from tibia vertical ($\approx 85\%$ of gait cycle) to second foot strike (100% of gait cycle). ⁵⁴
Phases		
	St	Stance is the phase in which the foot is in contact with the floor. It is from IC to TOff. It lasts for about 62% of gait cycle. ⁵⁴
	POff	Push off goes from ForeAftShear (or heel off if it occurs) to TOff. ⁵⁶ It includes TSt and PSw and it is part of the Stance phase.
	Sw	Swing is the phase in which the foot is not in contact with the floor. It is from TOff to second foot strike. It lasts for about 38% of gait cycle. ⁵⁴
Gait cycle		
	Stri	Stride is the movement from one foot strike (initial) to the successive foot strike (second) on the same side. ⁵⁴
SUMMARY INDEXES		
	GGI	The Gillette Gait Index, also called the Normalcy Index, uses multivariate statistical methods to quantify the deviation of a subject's gait from an unimpaired control group. It is calculated from three spatiotemporal parameters (timing of toe off, gait speed normalized by leg length and cadence) and 13 kinematic parameters (MEAN_PelvicTilt_Stri, ROM_PelvicTilt_Stri, MEAN_PelvicRot_Stri, MIN_HipFlexExt_Stri, ROM_HipFlexExt_Stri, MIN_HipAddAbd_Sw, MEAN_HipInExRot_Stri, KneeFlexExt_IC, MAPO_KneeFlexExt_Stri, ROM_KneeFlexExt_Stri, MAX_DorsPlantFlex_Stri, MAX_DorsPlantFlex_Sw and MEAN_FootPro_Stri). ¹⁸ Schutte et al ⁵⁷ described its calculation.
	GPS	Gait Profile Score is the RMS difference between a gait trial and averaged data from people with no gait pathology. It is calculated from 15 kinematic parameters (GVS_PelvicTilt_Stri, GVS_PelvicObl_Stri, GVS_PelvicRot_Stri, and GVS_HipFlexExt_Stri, GVS_HipAddAbd_Stri, GVS_HipInExRot_Stri, GVS_KneeFlexExt_Stri, GVS_DorsPlantFlex_Stri, GVS_FootPro_Stri for right and left sides). A GPS score can be determined for each side based on the nine GVS scores for that side ^{18,28} : $GPS = \sqrt{\frac{1}{N} \sum_{i=1}^N GVS_i^2}$. In degrees.

Table 6. Gait parameters responsiveness to different treatments.

Table 6
Gait parameters responsiveness to different treatments.

Interventions	Gait parameters										
	Spatiotemporal	Kinematic					SI	Kinetic			sEMG
		Foot	Ankle	Knee	Hip	Pelvis		Ankle	Knee	Hip	
Surgery ^{30,44}	o	ROM_FootInExRot_Stri	ROM_DorsPlantFlex_St, ROM_DorsPlantFlex_Sw	KneeFlexExt_IC, MIN_KneeFlexExt_St, MAX_KneeFlexExt_Sw, MAPO_KneeFlexExt_Sw, MEAN_KneeFlexExt_St, ROM_KneeFlexExt_Stri, ROM_KneeFlexExt_St, ROM_KneeFlexExt_Sw, MAX_KneeFlexExtVe_Stri	ROM_HipFlexExt_St	o	GGI	x	x	x	x
BTX-A + Casting ^{32,38,41-43}	Gait speed, Stride length, Single support	MEAN_FootPro_St, MEAN_FootInExRot_St	DorsPlantFlex_IC, MAX_DorsPlantFlex_LR-MSt, MAX_DorsPlantFlex_St, MAPO_DorsPlantFlex_St, MEAN_DorsPlantFlex_MSsw, MAX_DorsPlantFlex_Sw, ROM_DorsPlantFlex_Sw	MIN_KneeFlexExt_St, MIPO_KneeFlexExt_St, ROM_KneeFlexExt_St,	MIN_HipFlexExt_St	ROM_PelvicRot_Stri	o	MAX_PlantDorsFlexMo_LR, MAX_PlantDorsFlexMo_POFF, MIN_AnkleGenAbsPo_LR	x	MAX_HipGenAbsPo_St	Soleus, Tibialis anterior, Gastrocnemius, Rectus femoris, Lateral hamstrin Medial hamstrin
Orthopedic device ^{24,27,35}	Gait speed, Cadence, Stride length	x	DorsPlantFlex_IC, MAX_DorsPlantFlex_St, MIN_DorsPlantFlex_Sw, MAX_DorsPlantFlex_Sw	KneeFlexExt_ForeAftShear, MAX_KneeFlexExt_Sw	HipFlexExt_ForeAftShear, HipInExRot_ForeAftShear	x	x	MAX_PlantDorsFlexMo_POFF	x	x	x
Strength training ^{29,36,37,39,40}	Gait speed, Cadence, Stride length	x	MEAN_DorsPlantFlex_Stri	MIN_KneeFlexExt_St	o	o	o	o	o	o	x
Balance training ²⁵	Gait speed, Cadence, Stride length, Time of toe off	x	x	x	x	x	x	x	x	x	x
Gait training ^{28,31,33}	Gait speed, Cadence, Stride length	o	o	GVS_KneeFlexExt_Stri	HipFlexExt_IC, HipFlexExt_ForeAftShear, HipFlexExt_TOFF, MEAN_HipFlexExt_MSsw, GVS_HipAddAbd_Stri	GVS_PelvicTilt_Stri	GPS	x	x	x	x
ITP ²⁶	Stride length	o	o	GVS_KneeFlexExt_Stri	o	GVS_PelvicRot_Stri	o	x	x	x	x
Hippotherapy ³⁴	x	x	x	x	x	x	x	x	x	x	Adductor

BTX_A = Botulinum toxin A, ITP = Individualized therapy program, SI = Summary indexes. x = Not analyzed, o = No significant differences.