DR HELLE MÄTZKE RASMUSSEN (Orcid ID : 0000-0002-7522-8144)

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Gait analysis for individually tailored interdisciplinary interventions in children with cerebral palsy: a randomized controlled trial

HELLE M RASMUSSEN[1,2]
NIELS W PEDERSEN[1,2]
SØREN OVERGAARD[1,2]
LARS K HANSEN[3]
ULRIKE DUNKHASE-HEINL[4]
YANKO PETKOV[5]
VILHELM ENGELL[1,2]
ANDERS HOLSGAARD-LARSEN[1,2]

1 The Orthopaedic Research Unit, Department of Orthopaedic Surgery and Traumatology, Odense University Hospital, Odense; **2** Department of Clinical Research, University of Southern Denmark, Odense; **3** H.C. Andersen Children's Hospital, Odense University Hospital, Odense; **4** Department of Paediatrics, Lillebaelt Hospital, Kolding; **5** Department of Paediatrics, Hospital of Western Jutland, Esbjerg, Denmark.

Correspondence to Helle M Rasmussen, The Orthopaedic Research Unit, Department of Orthopaedic Surgery and Traumatology, Odense University Hospital, Sdr. Boulevard 29, DK-5000 Odense, Denmark. E-mail: helrasmussen@health.sdu.dk

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ABBREVIATIONS

CPUP Cerebral Palsy Follow-up Programme

GDI Gait Deviation Index

AIM To test the hypothesis that improvements in gait and function following individualized interdisciplinary interventions consisting of physical therapy, orthotics, spasticity management, and orthopaedic surgery using instrumented gait analysis are superior to 'usual care' in children with cerebral palsy (CP).

METHOD This was a prospective, single blind, parallel-group, randomized controlled trial investigating the effectiveness of interventions based on the use of gait analysis. Primary outcome was gait (Gait Deviation Index) and secondary outcomes were walking and patient-reported outcome measures of function, disability, and health-related quality of life. Follow-ups were done at 26 weeks (questionnaires) and at the primary end point of 52 weeks (all outcomes).

RESULTS Sixty participants with CP (39 males, 21 females, mean age 6y 10mo, standard deviation 1y 3mo, range 5y 0mo– 9y 1mo) in Gross Motor Function Classification System levels I or II, were randomized to interventions with or without gait analysis. No significant or clinically relevant between-group differences in change scores of the primary or secondary outcomes were found. The recommended categories of interventions were dominated by non-surgical interventions and were applied in 36% to 86% of the participants.

INTERPRETATION Interventions using gait analysis were not superior to 'usual care' on gait, walking, or patient-reported outcomes in a sample of relatively young and independently walking children with CP not expected to need surgery.

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What this paper adds

- Gait analysis in children in Gross Motor Function Classification System levels I or II recommends interdisciplinary interventions.
- Compliance to interventions recommended after gait analysis was low.
- No statistically significant advantages were identified for the intervention group versus the control group.

[Main text]

Cerebral palsy (CP) is caused by a non-progressive brain injury in the developing brain, which influences neuromusculoskeletal functions,[1] including gait,[2] walking, and functional mobility;[3] as a consequence it might affect overall health, participation in daily activities,[4] and health-related quality of life.[5] The majority of children with CP walk independently and exhibit altered gait such as stiff knee gait or equinus.[2] Gait pathology has been identified by children with CP and their parents as an important factor that adversely affects health-related quality of life and as a domain they would like to see improved via interventions.[6,7] The interdisciplinary interventions addressing impairments that affect gait can be classified into four categories: (1) physical therapy, (2) orthotics, (3) spasticity management, and (4) orthopaedic surgery. These interventions aim to restore or support the joints to improve muscle function and functional capabilities of the child.[8]

In Denmark, impairments that affect the patient's gait are addressed by a local health care team, which consists of a paediatrician, a paediatric orthopaedic surgeon, a physiotherapist, and/or an orthotist.[9,10] Interventions are planned on the basis of a clinical examination and the standardized examination performed as part of the Cerebral Palsy Follow-up Programme (CPUP), which is offered to all children with CP by the public Danish health care system ('usual care').[10] In the CPUP, the child is classified according to the Gross Motor Function Classification System (GMFCS) and some children are tested with the Gross Motor Function Measure. However, objective features in the gait that reflect underlying neuromusculoskeletal impairments are not

described. This can be done with three-dimensional instrumented gait analysis that provides objective measures of gait in three planes, identification of features, and the underlying impairments. This may be of relevance in the planning of interdisciplinary interventions.[11] Studies have shown that gait analysis affects the decisions regarding orthopaedic surgical interventions, and that good agreement can be obtained between recommendations based on gait analysis and the surgery performed.[12–14]

The effects of orthopaedic surgery and physiotherapy with and without gait analysis, to specify impairments in gait have been investigated in monodisciplinary settings with varying results; the use of gait analysis in planning physiotherapy has been reported to be superior to clinical examinations alone,[15] which is not always the case in orthopaedic surgery owing to lack of compliance with the recommended interventions.[14] Nonetheless, the effects of interdisciplinary interventions with and without gait analysis have not been investigated in children with CP.

The current study aimed to test the hypothesis that improvement in overall gait pathology, walking performance, and patient-reported outcome measures of function, disability, and health-related quality of life following individually tailored interventions when gait analysis is used are superior to those following 'usual care'. Thus, the study was designed to provide evidence for the use of gait analysis as part of the CPUP.

METHOD

A single-centre, prospective, single-blind, parallel-group, balanced randomization (1:1) superiority trial approved by the Committee for Medical Research Ethics in the Region of Southern Denmark (S-20120162), the Danish Data Protection Agency (2008-58-0035), and compliance with the Declaration of Helsinki was conducted. A study protocol has been published previously,[9] and the trial and the statistical analysis plan have been registered at ClinicalTrails.gov (NCT02160457). The reporting follows the recommendations from the Consolidated Standards of Reporting Trials (CONSORT) statement. After commencement of the trial, minor changes in data collection and the number of secondary analyses were made and described in the published statistical analysis plan (NCT02160457).

Participants

All children aged 5 to 8 years, diagnosed with spastic CP in GMFCS levels I or II followed in the Danish version of the CPUP in the region of Southern Denmark and the North Denmark region were invited to participate via written information sent to their parents and physiotherapists. The decision not to include older children and children in GMFCS level III or IV was based on ethical considerations and clinical equipoise concerning removal of gait analysis (for those allocated to the control group) as a standard examination for patients in need of surgery. Patients interested in participation in the study were screened by telephone for eligibility. Eligibility criteria have been described in detail previously.[9] In brief, eligible participants were children aged 5 to 8 years, diagnosed with spastic CP in GMFCS levels I or II. Exclusion criteria were orthopaedic surgery up to 52 weeks before baseline assessment or injection with botulinum neurotoxin A 12 weeks before baseline assessment. Furthermore, the children were excluded if they were unable to participate in the examination or their parents could not speak and understand Danish. The participants (children and parents) were invited to the baseline assessment at the Motion Analysis Laboratory at Odense University Hospital, where the parents signed an informed consent form.[9]

Randomization

After baseline assessment, participants were randomized to either the experimental or the control group. The randomization was stratified according to the specific physiotherapist to whom the participant was appointed (i.e. the first participant randomized determined how potential following participant(s) was/were allocated). The allocation sequence was computer-generated by a researcher with no other involvement in the study. The allocation sequence (0=experimental group/1=control group) was concealed in sequentially numbered opaque, sealed envelopes. When the participants had completed the baseline assessment, the principal investigator (HMR) opened the envelope and informed the parents and the local team about the allocation. The assessors were blinded to the assigned interventions throughout the study. Furthermore, data were masked for group allocation during statistical analysis and interpretation of results.

Interventions

The interventions were offered by the public health care system in Denmark and described in detail elsewhere.[9] In brief they were divided into the following four categories: (1) physical therapy to

impact body function and structures (i.e. fitness training and strength training), activities (i.e. functional training, goal-directed training, hippotherapy, home programmes, hydrotherapy, and neurodevelopmental therapy) or participation (i.e. with use of assistive technology); (2) orthotics, most often ankle–foot orthoses that provide stability and/or mobility of the joints and/or support muscle function; (3) spasticity management, most often injection of botulinum neurotoxin A in the gastro-soleus muscles to reduce muscle tone; (4) orthopaedic surgery, such as tendon transfer, muscle tendon lengthening, rotational osteotomy, and stabilization of joints that aim to restore joint mobility, muscle function, stability, and lever arm dysfunction.

The study did not involve standardization of the interdisciplinary interventions and did not provide training of the participating health care professionals. Both study groups received individually tailored interdisciplinary interventions based on information from clinical examinations and standardized measurements and the experimental group was provided with an additional gait analysis report. The gait analysis report was prepared via a four-step process by an experienced team, comprised of health care professionals with 2 to 10 years of clinical experience in gait analysis.

Step 1

Gait analysis was carried out as part of the baseline assessment, including clinical examination, video recording, and three-dimensional kinematics and kinetics by an eight-camera Vicon T40 system (Vicon, Oxford, UK) operating at 100Hz and two force-plates (OR6-7-1000; AMTI, Watertown, MA, USA), sampling at 1000Hz. The Plug-in Gait model, Vicon Nexus Software (version 1.7.1 or later) and Vicon Polygon software (version 3.5.2 or later) were used for data processing. The children walked barefoot and, if relevant, also with orthotics and shoes, at a self-selected speed along a 10m walkway until at least five acceptable trials were collected.

Step 2

Impairment-focused interpretation and reporting were performed according to Baker.[16] This involves identification of features that reflect the impairments affecting the child's gait.

Step 3

The recommendations for interventions were based on consensus and given by the gait analysis team, which consisted of a neuropaediatrician (LKH), a paediatric orthopaedic surgeon (NWP or VE), a physiotherapist (HMR), and a biomechanist (AHL).

Step 4

The report from the gait analysis (step 2) and the recommendations for interdisciplinary interventions (step 3) were, to reflect daily clinical practice, mailed to the participant and members of their local health care team, who were responsible for implementing the recommendations.

The time point 'start of intervention' was defined as the week in which the report was sent. Data collection in the control group was adjusted according to the planned time points in the experimental group.

The local health care teams provided the interventions in both study groups addressing impairments that affected the child's gait, which included physical therapy, orthotics, spasticity management, and/or orthopaedic surgery. The study did not involve standardization of the intervention and adherence to the recommended interventions was not a prerequisite for this pragmatic study.

Outcome measures

At baseline, weight, height, and leg length were measured. In addition, classification according to the GMFCS and Functional Mobility Scale were performed,[17,18] and distribution of spastic CP subtype (unilateral or bilateral) was collected from the local health care teams.

All outcomes were assessed at baseline and 52 weeks (primary end point) after the start of the intervention. In addition, patient-reported outcome measures were also conducted at 26 weeks. Six assessors who remained blinded to group allocation performed data collection with gait analysis and 1-minute walk test. The patient-reported outcome questionnaires were mailed to the participants and collected on the visit to the hospital or returned by mail.

The primary outcome was the between-group difference in change scores of Gait Deviation Index (GDI).[19] GDI is based upon kinematic data from the gait analysis (step 1) and summarizes the overall gait pathology into a single score when compared with non-pathological gait.[19] GDI was calculated according to the methods provided by Schwartz and Rozumalski,[19] using our own reference data set of 30 typically developing children.[20] The median of five trials for each leg was used to calculate the average of both legs to provide a single index for each child. We have

previously demonstrated excellent reliability (intraclass correlation coefficient 0.81–0.88) and acceptable agreement for GDI in a similar patient group.[20]

The between-group differences in change scores were evaluated for all secondary outcome measures. Walking performance was evaluated using the 1-minute walk test,[21] and functional mobility in everyday activities with regard to functional skills and amount of caregiver assistance was evaluated with the Danish version of the Mobility Scale of the original Pediatric Evaluation of Disability Inventory.[22] The Pediatric Quality of Life Inventory Cerebral Palsy Module was used to evaluate health-related quality of life,[5] and the Pediatric Outcomes Data Collection Instrument was used to evaluate overall health, pain, and participation in normal daily activities.[23]

Information about the recommended and applied interventions was used to explore adherence to the recommended interventions and to compare the interventions used in the study groups.

Furthermore, the parents were asked about their perception of the interventions with three anchor questions with a five-point Likert scale as response categories.

Statistics

The statistical analysis plan was published at ClinicalTrails.gov (NCT02160457) before analysis and unblinding of group allocation. The sample size was based on data from a previous study performed in our laboratory demonstrating a group mean GDI of 79.3 (standard deviation 12.0).[20] Furthermore, a minimum clinically important difference in GDI was a priori defined as 7.9, which is equivalent to an improvement of 10%, as suggested by Schwartz et al.[24] Therefore, a minimum of 29 participants in each group (n=58) was required with alpha of 0.05 and 80% power. We anticipated a dropout rate of 5% and aimed to include 60 children (randomization 1:1).

Baseline characteristics data were checked for completeness and distribution was investigated using normal probability plots and the Shapiro–Wilk test. Descriptive statistics were calculated with median and 25th and 75th centiles or number of patients. Main comparative analyses between groups were performed on the full analysis set with missing data imputed using last observation carried forward. A multiple regression model with group and baseline values of the relevant variable as covariates was used to analyse between-group mean changes. The model assumptions were checked for relationship, homoscedasticity, outliers, and normality of residuals. As minor violations of the assumptions were present, the analysis was performed with robust

estimation. Between-group changes from baseline to 52 weeks (primary time point) are presented with the effect size, using η^2.

Differences between the interventions applied and participant-perceived responses to the interventions were investigated with descriptive statistics, Pearson's χ^2 and Mann–Whitney *U* test.

Statistical analyses were performed using Stata/IC 14.2 or later for Mac (StataCorp, College Station, TX, USA). Statistical results where the *p*-values were less than 0.05 (two tailed) were considered statistically significant.

RESULTS

In total, 160 children were invited to participate in the study. Of these, 83 children were screened for eligibility and 60 participants were randomized to either the experimental intervention (*n*=30) or the control (*n*=30) groups (Fig. S1, online supporting information). Recruitment of participants and data collection were carried out between June 2014 and July 2017. Complete assessments were available from 57 participants at baseline, 48 participants at the 26-week follow-up, and 55 participants at the primary end point (52 weeks).

The 60 participating children had a median age of 6 years and 11 months. The full list of patient characteristics is given in Table SI (online supporting information). There were 43 children with unilateral CP, 17 with bilateral spastic CP, 42 children in GMFCS level I, and 18 in GMFCS level II.

Primary outcome

At the 52-week follow-up, the mean change scores of GDI at self-selected walking speed did not differ significantly between the groups (GDI: –0.59 [95% confidence interval {CI} –3.9 to 2.6], η^2<0.01) (Table I). In total, 11 participants improved more than the a priori-defined minimum clinically important difference in GDI of 7.9 (experimental group *n*=5; control group *n*=6), resulting in a non-significant risk difference of –0.03 (95% CI –0.23 to 0.16 [*Z*=0.33; *p*=0.738]).

Secondary outcomes

No significant between-group differences in change scores were observed in the 1-minute walk test (3.02m [95% CI –2.9 to 8.9], η^2=0.02) at 52 weeks or in the patient-reported outcome measures at

26 weeks or 52 weeks. Significant and potential clinically relevant within-group improvements were seen in some of the secondary outcome measures at 26 weeks and 52 weeks (Table I).

Additional/tertiary outcomes

No significant difference was observed between the groups in participant-perceived responses to the interventions (p=0.19) or changes in walking (p=0.38). However, a difference between the groups was seen at 52 weeks in the anchor-based question 'overall health' in favour of the experimental group (p=0.03) (Table SII, online supporting information).

Interventions

The compliance with the recommended types of interventions were 24 of 28 participants for physiotherapy (86%), six of 10 participants for orthotics (60%), five of 14 for spasticity management (36%), and zero of one for orthopaedic surgery (0%) (Table SII).

Post hoc analysis

Based on the observed lack of difference in the GDI (representing overall gait function) and the relatively high proportion of children with unilateral CP, a post hoc analysis was performed with the aim of investigating potential specific effects on GDI of the 'most' affected side, defined as the affected leg in children with unilateral CP and the leg with the lowest GDI score in children with bilateral CP (Table SIII, online supporting information). As for the primary analysis, the present post hoc analysis on the 'most' affected side demonstrated no statistical superiority on mean change scores (GDI: 1.20 [95% CI –2.8 to 5.2], η^2<0.01) and the within-group mean improvements did not exceed statistical significance between baseline and 52 weeks (experimental group, GDI: 1.84 [95% CI –3.9 to 2.6]; control group, GDI: 1.01 [95% CI –3.9 to 2.6]).

Lack of compliance to the recommended interventions was not described as a part of our a priori planned per-protocol analysis. However, to investigate potential effects on gait in the subgroup of 12 children, where the recommendations were fully complied for all categories (physiotherapy [n=12], orthotics [n=3], and spasticity management [n=4]), a post hoc analysis was performed. As for the intention-to-treat analysis, the post hoc analysis demonstrated no superiority for the primary outcome measure in favour of the experimental group and no within-group improvements were observed.

Adverse events

The participants (children and parents) did not report any serious adverse events during the study period. However, during the testing, the assessors experienced one child who did not want to wear the adhesive reflective markers at the follow-up examination, and five different children (three at baseline and two at follow-up) were too exhausted to complete the 1-minute walk test.

DISCUSSION

In this randomized controlled trial, we found that implementing gait analysis in the interdisciplinary interventions in young, independently walking children with CP did not have a significant impact on change scores between groups on gait, walking, or patient-reported outcome with only a few, non-serious adverse events reported. Our findings are not in line with previous studies investigating the effectiveness of the use of gait analysis in individualized physiotherapy for children with CP.[15,25] However, our findings are equal to the results of a previous randomized controlled trial on the outcome of lower extremity orthopaedic surgery with and without gait analysis.[14] The lack of documented between-group differences in change scores may be attributed to our study population of relatively young and well-functioning children (GMFCS levels I and II), most of whom did not need or receive surgery. Furthermore, a possible crossover of applied interventions between the two study arms, the pragmatic implementation of the applied interventions, a lack of compliance with the recommended interventions, the timing of follow-up, and the selected outcome measures may have biased the negative findings.

The relatively young and well-functioning study population was chosen for several reasons: (1) to investigate an extended use of gait analysis beyond children undergoing surgical interventions; and (2) to ensure good data quality (walking without mobility device) from the gait analysis. In Denmark, gait analysis is primarily done before planning surgery. Therefore, from an ethical point of view, including older and more severely affected children would have restrained children in the control group from gait analysis before planned surgical interventions or resulted in a high number of children crossing over from the control group to the experimental group. Also, it should be noted that we have not investigated the effects of gait analysis on gait problems reported by the participants or following a specific intervention, but rather as an integral part of the interdisciplinary interventions.

Minimum clinically important improvements have been proposed for the subscales of the Pediatric Outcomes Data Collection Instrument,[26] and also for the primary outcome of the current study (GDI: ≥10% improvements).[24] However, anchor-based questions about the patient's perception of the minimum clinically important improvements are not available for the present outcome measures and thus it is difficult to interpret whether the observed within-group improvements in 1-minute walk test (both groups at 52wks); Pediatric Evaluation of Disability Inventory Mobility Scale, Functional Skills (experimental group at 26wks and 52wks), and Caregiver Assistance (both groups at 26wks and 52wks); The Pediatric Quality of Life Inventory Daily Activities (experimental group at 26wks and both groups at 52wks), Fatigue (control at 26wks), Eating activities (control group at 26wks), and Speech and Communication (experimental group at 26wks); The Pediatric Outcomes Data Collection Instrument Global Functioning Scale (both groups at 26wks), Transfer and Basic Mobility (both groups at 52wks), and Sports and Physical Functioning (experimental groups at 26wks and 52wks), are of clinical importance. In addition, one must keep in mind that although not documented by normative data, improvements, as observed in the present study, can be expected over a period of 52 weeks, as part of the natural clinical course and/or biological maturation.

Despite initiatives to increase internal validity, recommendations of orthoses and spasticity management were only followed in 60% and 36% of the participants respectively, and the recommendation for orthopaedic surgery was not followed in the one case where it was recommended. However, this is comparable to the compliance rate of 42% to 97% in studies investigating outcomes of surgery with or without gait analysis.[14,27] The following reasons for non-compliance have previously been proposed: inconsistent results from different examinations, lack of knowledge about gait analysis, and preferences of the participants.[14,27] The current pragmatic study was not designed to reveal reasons for not following the recommendations, but the issue merits further investigation.

In this study, we used objective and patient-reported outcome measures. Furthermore, we asked the participants about their perceived effects from the intervention. The assessments were chosen to make it possible to detect changes on a wide range of constructs, including changes important to the participants. For the primary outcome, we used GDI, an objective measure of deviation in gait. GDI is not a direct measure of muscle function or functional capabilities of the child, but it provides a valid, reliable, and comprehensive outcome measure to investigate overall gait deviations. There is growing evidence that GDI is a useful objective outcome measure to

quantify the degree of deviation from normality in children with CP.[20,28] However, the measure has been criticized for not being responsive in detecting changes in gait, when the movements are close to normal gait (i.e. ceiling effect) and that responsiveness has only been documented in the context of orthopaedic surgery.[28,29] The study did not reveal any statistical superiority in favour of the experimental group or significant within-group improvements at follow-up based on GDI measures as the average of both legs, GDI on the 'most' affected side, or when comparing the 12 children where recommendations were fully complied for all categories of intervention.

Strengths and limitations

We conducted a pragmatic randomized controlled trial following the CONSORT statement on a representative sample of patients with spastic CP in GMFCS level I and II recruited from a population based follow-up programme for children with CP, the CPUP. A limitation of the study is the fact that the participants (parents and children) and the local health care teams were unblinded and thus aware of their allocation. Nonetheless, data collection and the statistical analysis were performed blinded. A predefined single imputation (last observation carried forward) was used to handle missing data, which may be a biased method. A 'per-protocol' and best-worst and worst-best case sensitivity analyses did not change the results and the overall conclusion.

The pragmatic approach used to reflect daily clinical practice and to optimize external validity may, on the other hand, have introduced a limitation because of potential inconsistency in the delivery of the interventions. Furthermore, the study did not aim at or was not designed to ensure a standardized implementation of the applied interventions and reasons for not offering or applying interventions. In spite of the fact that the participants demonstrated movement and posture disorders, which influenced walking (GDI mean 76.82, range 51.7–98.3) we did not examine to what extent the participants and their parents considered this as a major functional impairment. This can be considered a limitation in the applicability of the study results. Finally, a rather cautious approach to the identified impairments and recommended interventions was used as both were based on consensus given by the gait analysis team. It is possible that other gait analysis teams would have recommended more/less/different interventions than the present. A more explanatory approach involving controlled interventions could have counteracted some of the issues described above, with the risk of a conclusion of less external validity and generalizability.

Generalizability

The participants were recruited from the CPUP, a population-based follow-up programme for children with CP. The study population was limited to children aged 5 to 8 years with spastic CP who walked independently (GMFCS level I or II), meaning that the results may not be generalizable to older children, children with other subtypes of CP, or children with more limited function, where orthopaedic surgery will be a more frequent intervention.

Interpretation

This study could not confirm the hypothesis that improvement in the overall gait pathology, walking performance, and patient-reported outcomes following individually tailored interventions when gait analysis is used are superior to those following 'usual care' to a sample of children with CP in GMFCS levels I and II, at an early age. Gait analysis may still be relevant in many situations, for example if a functional diagnosis or documentation of changes is needed.

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Supporting information

The following additional material may be found online:

Figure S1: Flow diagram of participants in the study.

Table SI: Baseline characteristics

Table SII: The recommended interventions, applied interventions, compliance, and distribution of answers for the anchor questions

Table SIII: Post hoc analysis: mean difference within groups and difference between groups at 52-week follow-up

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Table I: Mean difference within groups and difference between groups at 26 and 52 weeks' follow-up (95% confidence interval)

	Within-group mean improvements				Between-group change (mean and 95% CI)			
	Baseline to 26wks		Baseline to 52wks		Baseline to 26wks	Baseline to 52wks		
	Experimental (*n*=30)	Control (*n*=30)	Experimental (*n*=30)	Control (*n*=30)			*p*	η^2
GDI	–	–	0.19	1.68	–	–0.59 (–3.8 to 2.6)	0.72	<0.01
1-minute walk test[a]	–	–	8.29	5.38	–	3.02 (–2.9 to 8.9)	0.31	0.02
PEDI, Mobility Scale								
Functional Skills	2.53	2.09	4.17	2.19	0.15 (–3.0 to 3.3)	1.37 (–2.4 to 5.1)	0.47	<0.01
Caregiver Assistance	3.12	3.27	3.92	4.34	–0.57 (–3.8 to 2.7)	–0.93 (–5.5 to 3.6)	0.68	<0.01
PedsQL, Cerebral Palsy Module								
Daily Activities	6.68	2.75	11.12	7.52	3.72 (–0.8 to 8.2)	3.26 (–1.9 to 8.4)	0.21	0.03
School Activities	–1.81	3.13	1.88	1.45	–4.41 (–14.3 to 5.5)	1.12 (–8.7 to 10.9)	0.82	0.06
Movement and Balance	–1.50	1.71	2.25	7.00	–1.05 (–9.9 to 7.8)	–1.19 (–9.4 to 7.0)	0.77	<0.01
Pain and Hurt[b]	4.58	–0.64	–4.17	3.88	5.69 (–0.22 to 11.6)	–7.13 (–15.6 to 1.3)	0.10	0.05
Fatigue	4.58	7.29	1.67	5.42	–2.47 (–10.6 to 5.7)	–3.41 (–12.5 to 5.7)	0.46	<0.01
Eating Activities	1.17	3.67	1.50	–0.17	–1.81 (–6.9 to 3.3)	2.73 (–4.5 to 9.9)	0.44	0.01
Speech and Communication	3.61	3.54	2.15	3.96	–0.28 (–4.8 to 4.2)	–2.64 (–8.8 to 3.5)	0.40	0.01
PODCI								
Global Functioning Scale	3.31	1.14	2.91	2.27	2.15 (–1.2 to 5.5)	0.58 (–3.1 to 4.2)	0.75	<0.01
Upper Extremity Function	2.36	0.83	4.09	–0.50	1.25 (–3.7 to 6.2)	4.31 (–0.6 to 9.2)	0.08	0.05
Transfer and Basic Mobility	2.47	1.06	4.34	2.52	1.31 (–1.9 to 4.6)	1.63 (–0.6 to 3.9)	0.15	0.04
Sports and Physical Functioning	4.14	2.36	–	4.30	1.78 (–3.1 to 6.7)	1.52 (–4.7 to 7.7)	0.62	<0.01
Pain/Comfort Scale	4.22	1.02	–2.63	2.69	3.22 (–4.8 to 11.2)	–5.3 (–14.0 to 3.4)	0.23	0.03

Happiness Scale[c]	4.48	2.50	0.17	4.17	2.11 (–5.7 to 9.9)	–3.89 (–13.0 to 5.2)	0.40	0.01

[a]Experimental group, *n*=28; control group, *n*=29. [b]Control group, *n*=29. [c]Experimental group, *n*=29. GDI, Gait Deviation Index; PEDI, Pediatric Evaluation of Disability Inventory; PedsQL, Pediatric Quality of Life Inventory; PODCI, Pediatric Outcomes Data Collection Instrument (PODCI).