The effectiveness of instrumented gait analysis for interdisciplinary interventions in young children with cerebral palsy
A randomised controlled trial


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O 047 - The effectiveness of instrumented gait analysis for interdisciplinary interventions in young children with cerebral palsy – a randomised controlled trial

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Introduction

In the Nordic countries the Cerebral Palsy follow-Up Program (CPUP) is used to ensure timely and consistent examinations of ambulatory children with cerebral palsy. However, the specific gait function or ‘how’ the child is walking is not evaluated within CPUP, which can be done by 3-dimensional instrumented gait analysis. Nonetheless, the potential added benefits of the use of instrumented gait analysis on gait function in the decision-making of interdisciplinary interventions towards impairments in gait have not been investigated.

Research Question

To test the hypothesis that improvements in gait and patient reported outcomes following interdisciplinary interventions consisting of orthopaedic surgery, spasticity management, physical therapy and/or orthotics using instrumented gait analysis in the decision-making are superior to those following ‘care as usual’ without gait analysis in young children with cerebral palsy.

Methods

A pragmatic single-centre, single blind, randomised (1:1) controlled trial. Primary outcome was gait function evaluated by Gait Deviation Index (GDI) and secondary outcomes were: walking (1-min walk test) and patient-reported outcome measures of function, disability and health-related quality of life. Follow-ups were done at 26 weeks (only questionnaires) and at 52 weeks (primary endpoint). The sample size was based on group-mean GDI of 79.3 (SD 12.0) using a minimum clinically important difference of 7.9 GDI-points, which is equivalent to an improvement of 10%. With alpha = 0.05, 80% power, and anticipating a dropout rate of 5% a total of 60 children were included. Main comparative analyses on between-groups change scores were performed by a multiple regression model with group and baseline values of the relevant variables as covariates. The statistical analysis plan was
registered at ClinicalTrials.gov (NCT02160457) and a detailed trial protocol paper was published ahead.

**Results**

Sixty children (median age 6y11m) with cerebral palsy (unilateral: n = 43, bilateral: n = 17) at Gross Motor Function Classification System levels I (n = 42) and II (n = 18), were randomised to interventions with or without gait analysis (Table 1) and complete assessment were available from 55 children at 52 weeks follow-up. The recommended categories of interventions were dominated by non-surgical interventions that were applied in 36 to 86% of the participants. No significant or clinically relevant between-group differences in change scores of the primary or secondary outcomes were found (Figure 1).

**Discussion**

Interdisciplinary interventions using gait analysis did not improve gait function or patient-reported outcomes in the present sample of relatively young and independently walking children with cerebral palsy. The present results on relatively well functioning children may not be generalizable and instrumented gait analysis may still be relevant in many situations, for example in children with higher levels of disability, at older age, and/or if a functional diagnosis or documentation of changes are needed.
**Figure caption:**

Figure 1 – Between-group change scores from baseline to 52 weeks follow-up.

Values: Between-group changes scores expressed as mean and 95% confidence intervals.

Abbreviations: Pediatric Evaluation of Disability Inventory (PEDI), The Pediatric Quality of Life Inventory (PedsQL), The Pediatric Outcomes Data Collection Instrument (PODCI)

Figure 1 – Between-group change scores from baseline to 52 weeks follow-up

- Gait Deviation Index (GDI)
- 1-minute walk test (metre)
- PEDI, Functional skills
- PEDI, Caregiver assistance
- PedsQL, Daily Activities
- PedsQL, School Activities
- PedsQL, Movement and Balance
- PedsQL, Pain and Hurt
- PedsQL, Fatigue
- PedsQL, Eating Activities
- PedsQL, Speech and Communication
- PODCI, Global functioning scale
- PODCI, Upper extremity function
- PODCI, Transfer and basic mobility
- PODCI, Sports and physical functioning
- PODCI, Pain/Comfort Scale
- PODCI, Happiness Scale

Values: Between-group change scores expressed as mean and 95% confidence intervals.

Abbreviations: Pediatric Evaluation of Disability Inventory (PEDI), The Pediatric Quality of Life Inventory (PedsQL), The Pediatric Outcomes Data Collection Instrument (PODCI)
Table 1 – Baseline characteristics

<table>
<thead>
<tr>
<th>Gender and classification</th>
<th>Experimental (n=30)</th>
<th>Control (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Girls / boys, n</td>
<td>9/21</td>
<td>12/18</td>
</tr>
<tr>
<td>CP spastic subtype, Unilateral / bilateral, n</td>
<td>21/9</td>
<td>22/8</td>
</tr>
<tr>
<td>GMFCS level I/II, n</td>
<td>20/10</td>
<td>22/8</td>
</tr>
</tbody>
</table>

**Age and body mass index**

<table>
<thead>
<tr>
<th>Age (Years, months), median (iqr)</th>
<th>6 y 6 m (2 y 8 m)</th>
<th>6 y 11 m (1y 10m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body Mass Index, median (iqr)</td>
<td>15.40</td>
<td>14.88</td>
</tr>
</tbody>
</table>

**Outcome measures**

| Gait Deviation Index              | 78.20            | 75.45             |
| Gait speed (meters / sec)         | 1.13             | 1.17              |
| 1-min walk test, (meters / min)a  | 79.39 (13.87)    | 78.77 (15.21)     |

**Pediatric Evaluation of Disability Inventory**

| Functional skills                | 79.65 (11.35)    | 82.81 (12.25)     |
| Caregiver assistance             | 80.67 (14.00)    | 82.65 (15.55)     |

**The Pediatric Quality of Life Inventory**

| Daily Activities                 | 62.27 (23.29)    | 63.68 (23.43)     |
| School Activities, median (iqr)  | 75.00 (31.25)    | 62.50 (31.25)     |
| Movement and Balance             | 78.17 (16.27)    | 71.13 (21.80)     |
| Pain and Hurtb                   | 67.50 (23.06)    | 64.22 (21.77)     |
| Fatigue                          | 58.75 (21.12)    | 57.08 (25.47)     |
| Eating Activities, median (iqr)  | 80.00 (15.00)    | 82.50 (25.00)     |
| Speech and Communication, median (iqr) | 87.50 (27.08) | 81.25 (18.75)     |

**The Pediatric Outcomes Data Collection Instrument**

| Global Functioning Scale         | 76.48 (11.90)    | 76.88 (12.84)     |
| Upper Extremity and Physical Function, median (iqr) | 79.17 (20.83) | 80.95 (25.00)     |
| Transfer and Basic Mobility, median (iqr) | 91.67 (13.64) | 93.94 (15.15)     |
| Sports and Physical Functioning, median (iqr) | 70.14 (36.11) | 71.34 (27.95)     |
| Pain/Comfort Scale               | 75.89 (20.97)    | 75.83 (20.04)     |
| Happiness Scale, median (iqr)c   | 77.50 (35.00)    | 80.00 (35.00)     |

Values are presented as mean ± SD if not otherwise stated

\( a \) EXP group, n=28, CON group: n=29, \( c \) CON group, n= 29, and \( d \) EXP group, n=29.

Abbreviations: Cerebral palsy (CP), Gross Motor Function Classification System (GMFCS).