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Infants at very high risk of cerebral palsy

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CHANGES OVER TIME IN CONTENTS OF INFANT PHYSICAL THERAPY: A QUANTITATIVE, OBSERVATIONAL STUDY

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ABSTRACT

Aims: Pediatric physical therapy (PPT) gradually implements novel concepts on family and development. Aim of our observational longitudinal study is to evaluate changes over time in standard PPT for infants at risk for neurodevelopmental disorders.

Methods: PPT-sessions in two time periods (2003-2005 (n=22) and 2008-2014 (n=16)) were video-recorded and analyzed quantitatively in five categories: neuromotor, educational and communication actions, position and situation. Differences in percentages of time spent on therapeutic actions between periods were tested with Mann Whitney U- and Hodges Lehmann's-tests.

Results: No significant changes appeared in main categories of neuromotor actions. Time spent on not-specified educational actions towards caregivers (median from 99% to 81%, $p=0.04$) and not-specified communication (median from 72% to 52%, $p=0.002$) decreased. Consequently, time spent on specific educational actions (caregiver training and coaching; median from 1% to 19%, $p=0.04$) and specific communication (information exchange, instruct, provide feedback; median from 21% to 38%, $p=0.007$) increased. Position changed only minimally: time spent on transitions – i.e. change of position – decreased slightly over time (median from 7% to 6%, $p=0.04$). Situation did not change significantly over time.

Conclusions: Neuromotor actions in PPT remained largely stable over time. Specific educational actions and communication increased, indicating larger family involvement.

INTRODUCTION

Pediatric physical therapy (PPT) is developing. Over the years, novel concepts and theories have been implemented. Traditionally, concepts of motor development were mainly based on maturational theories, in which the central nervous system is supposed to control motor development in a predetermined way.¹ Gradually, more environmental influences were acknowledged and incorporated in theories and practice. A theory in which environment plays a major role is the Dynamic Systems Theory.² This theory explains development by a process in which different components interact with each other resulting in changes, which are the starting point for future changes. Another neuromotor theory, the Neuronal Group Selection Theory^{3,4}, incorporates both influences from the central nervous system and the environment. According to this theory infants first develop a varied motor repertoire by creating networks between the billions of available neurons in the brain; subsequently infants learn to select strategies from the motor repertoire that are adaptive to the specifics of the condition. Based on animal studies, encouraging enriched environments are incorporated in several early intervention programs, to optimize use of the neuroplasticity of the brain.^{5,6}

Concurrent with changes in the concepts of motor development, the application of the International Classification of Function for Children and Youth (ICF-CY)⁷ encouraged two shifts over time: one from a focus on body functions and structures towards activities and participation, the other from a child centred approach to a more context focused and family centred approach.^{8,9} Family centred care involves partnerships between professionals and families, in which caregivers are recognized as the decision makers for their child.¹⁰

Developments in theories about neuromotor development and the increasing focus on family and function, induced changes in intervention over the years. This may be illustrated by the changes that occurred in the widely used approach of NeuroDevelopmental Treatment (NDT).^{11,12} Originally – in the second half of last century – it was based on maturational theories and aimed to optimize and normalize movements and muscle tone. But during the years and due to the fact that the approach was developed as a living concept, new neuroscience insights were incorporated and led to a more functional approach, aiming to transfer motor activities into daily life activities.¹³ Others created context therapy on the basis of dynamic systems theory in combination with a family centered approach.¹⁴ During the last two decades also novel types of early intervention have been developed that discarded the maturational developmental theories. Cases in point of novel early intervention programs are the COPCA-intervention (COPing with and CAring for infants with special needs – a family centered approach¹⁵ and the GAME-program (Goals, Activity and Motor Enrichment).¹⁶ The COPCA-program is based on the theoretical framework of the NGST combined with a family centred approach.¹⁵ The GAME-program uses principles of environmental enrichment together with frequent, goal-oriented task practice in the

critical early period of brain development.¹⁶ The described conceptual changes in theory and practice, imply that contents of PPT nowadays differ from that in the past. However, the contents of PPT largely remains a 'black box'¹⁷ and little is known about possible changes across time.

In the last decades, we have been involved in two early intervention studies, which compared the effect of the COPCA-program with that of standard – or typical - physical therapy (typical infant physical therapy – TIP).^{18,19,20} In order to understand the actual contents of the interventions we videotaped the intervention sessions. As the studies occurred in different time periods (2003-2005 and 2008-2013), the video material allowed us to study changes over time in typical infant physical therapy. Therefore, the aim of the current observational study is to explore changes across time in PPT by comparing quantitatively the contents of TIP in both intervention studies. Knowledge on changes in standard PPT will improve our interpretation of intervention studies, in which recently developed interventions are often compared with standard care. We hypothesize that developmental changes in PPT over time would be associated with 1) a decrease in the use of hands-on neuromotor actions (NDT-techniques), in line with developments with more focus on environment and context, together with the shift from a focus on body functions and structures towards activities and participation; and 2) an increase in family centeredness, fitting into the development from child centred towards more family centred care.

METHODS

Participants

Participants are infants enrolled in the Vroegtijdige Interventie (Early Intervention) Project (VIP; 2003-2005)^{18,19} or the LEARN2MOVE 0-2 years project (L2M; 2008-2014).²⁰ Both projects were approved by the medical ethic committee of the University Medical Center Groningen (UMCG) and registered in the Dutch trial register, under NTR361 and NTR1428 respectively. In the VIP-project, infants admitted to the neonatal intensive care unit of the UMCG between March 2003 and May 2005 presenting with definitely abnormal general movements at 10 weeks corrected age (CA) (indicating a high risk for developmental disorder) were included after informed consent of the caregivers. The L2M-project included between November 2008 and December 2013 infants between 0 and 9 months CA at very high risk for cerebral palsy (CP), based on imaging of the brain (cystic periventricular leukomalacia, preterm or term parenchymal lesion), asphyxia with abnormalities on brain imaging or clear neurological dysfunction suspect for the development of CP. Caregivers gave informed consent. Infants were recruited from 12 hospitals in the Northern part of the Netherlands and around Amsterdam.

Exclusion criteria for both intervention projects were the presence of a severe congenital disorder or an insufficient understanding of the Dutch language of the caregivers. Infants were randomly assigned to either TIP or COPCA after informed consent of the caregivers. In the present study, we focus only on the infants who received TIP, i.e. the infants who received standard physical therapy care (VIP-project: n=25; L2M-project: n=20).

Characteristics of the infants are presented in Table 1. Inherent to the difference in design of the studies, significantly more infants presented with a severe brain lesion in the L2M-project than in the VIP-project ($p < 0.001$) and consequently, more CP was diagnosed in the children of the L2M-project ($p = 0.033$).

Table 1: Characteristics of the infants

| | VIP-project (n=22) | L2M-project (n=16) |
|--|-----------------------|-----------------------|
| Sex | | |
| ▪ Male: n (%) | 10 (45) | 10 (62) |
| ▪ Female: n (%) | 12 (55) | 6 (38) |
| Gestational age | | |
| ▪ Median (weeks) | 30 | 30 |
| ▪ Range | 25-39 | 26-41 |
| Birthweight | | |
| ▪ Median (grams) | 1243 | 1440 |
| ▪ Range | 635-3460 | 820-5400 |
| Brain lesion | | |
| ▪ No severe brain lesion: n (%) | 19 (86) | 2 (12) |
| ▪ Severe brain lesion*: n (%) | 3 (14) ^a | 15 (88) ^a |
| Maternal education | | |
| ▪ Low or middle: n (%) | 12 (55) | 10 (63) |
| ▪ High: n (%) | 10 (45) | 6 (37) |
| Paternal education | | |
| ▪ Low or middle: n (%) | 16 (80) | 5 (44) |
| ▪ High: n (%) | 4 (20) | 8 (50) |
| ▪ Missing: n (%) | 0 (0) | 1 (6) |
| Maternal age at birth | | |
| ▪ Median (years) | 33 | 34 |
| ▪ Range | 22-39 | 17-41 |
| Age infant at PT-video | | |
| ▪ Median (months) | 5.1 | 5.2 |
| ▪ Range | 3.3-7.5 | 2.8-8.0 |
| Infants diagnosed with CP at 18 or 21 months CA | | |
| ▪ CP: n (%) | 5 (23) | 7 (44) |
| ▪ No CP: n (%) | 17 (77) | 7 (44) |
| ▪ Unknown (%) | 0 (0) | 2 (12) |

CA = Corrected Age; CP = Cerebral Palsy; L2M = LEARN 2 MOVE; n = Number; PT = Physiotherapy; TIP = Traditional Infant Physiotherapy; VIP = Vroegtijdig Interventie Project (Early Intervention Project); *Periventricular leukomalacia (PVL) grade 3 or 4, parenchymal hemorrhage/infarction or ischaemic cerebral lesions; a = difference between VIP and L2M: Chi-square test, $p < 0.001$

Intervention in the VIP-project was provided between 3 and 6 months CA; in the L2M-project intervention was applied for one year, starting after inclusion. In both projects, physical therapy was usually provided at home (90%); the frequency depended on the pediatrician's advice and the physiotherapist's findings. Median duration of PPT-sessions in both projects was 32 minutes (ranges: VIP 12-51; L2M 17-63).

Measures and procedure

Both projects are follow-up studies in which infants underwent regular neuromotor tests. The last measurement (in VIP: 18 months CA; in L2M: 21 months CA) included assessment of the presence or absence of CP, based on the Touwen Infant Neurological Examination.²¹ In the VIP-project, PPT-sessions were videotaped at 4 and 6 months CA (median age 4.9 months, range 3.3-7.5). Three infants did not receive physical therapy on pediatrician's advice; therefore PPT-sessions had been recorded in 22 infants. In L2M, PPT-sessions were videotaped at 1, 6 and 12 months after inclusion. In order to exclude an effect of the infant's age on the comparison of VIP with L2M, we selected from the L2M videotapes only the sessions occurring between 2.5 and 8.0 months CA, resulting in a group of 16 infants (median age 5.2 months; range 2.8-8.0). Contents of the data of PPT-sessions of infants who had two videotaped PPT-sessions was largely comparable (tested with the Wilcoxon signed rank test). Therefore, data of both sessions were averaged, in order to have one set of data per infant for further analyses.

PPT-sessions of both VIP- and L2M-project were analyzed with a detailed observation protocol, the Groningen Observer Protocol version 2 (GOP 2.0; see appendix for a detailed description). GOP 2.0 differs slightly from the first version of GOP¹⁵: a) two additional therapeutic approaches were included, i.e., Vojta²² and constrained induced movement therapy^{23,24}, to allow for an up to date and international application of the protocol; b) the category Self-Produced Motor Behavior was better specified and c) categories were reorganized, especially by lumping most neuromotor actions into the main category of 'neuromotor actions' resulting in five instead of eight main categories. Two observers (RFT and SJH) performed the analyses of the PPT-actions with help of The Observer version 11.5.²⁵ Time spent on specific PPT-actions was expressed by the percentage of time in relation to the total duration of the PPT-session. PPT-actions were scored as continuous variables in five main categories: neuromotor actions, educational actions, communication, position and situation. Within each category, actions were scored mutually exclusive. Actions which do not fulfill the criteria of one of these categories are scored as 'not specified' behavior within that category. Some PPT-actions are further specified by 'modifiers', specific sub-behaviors within a category.

Interobserver agreement for GOP 2.0 was determined by calculating intraclass correlation coefficients (ICC) of 10 independently assessed videos. Interobserver reliability

was good to excellent for all main categories (median ICC 0.945 (0.677-0.998)) and most of the modifiers (ICC 0.620-0.999). ICCs were moderate for three modifiers: sitting with minimal support (0.582); challenged to self-produced motor behavior (CSPMB) with large variation (0.480) and instructing with strict instructions (0.551); and poor for CSPMB with little variation (0.159) and CSPMB without challenge (-0.186). We did not include the two items with poor ICCs into the analyses.

Data analyses

We compared prevalence of PPT-actions in the two periods. PPT-actions that were observed in less than five infants or observed in less than 2% of time in each of the infants studied were excluded from the analyses.

SPSS version 20 was used for statistical analyses. Non-parametrical Mann Whitney U Tests and Chi-square tests were used to test differences in distribution and between baseline characteristics respectively, as the data were not normally distributed. A p-value of 0.05 was used as cut-off for statistical significance, as the study aimed to explore possible changes across time. In view of the number of tested variables, the relatively high p-value as cut-off score was chosen because we were also interested in tendencies and trends. Hodge's Lehmann estimates of the difference of the medians are provided with 95% confidence intervals to estimate the size of the differences.

RESULTS

Two infants were lost to follow-up in the L2M-project due to family overload. In the VIP-project, none of the 22 infants receiving therapy were lost to follow-up.

Table 2 shows developments across time in contents of physical therapy. As we observed various changes over time in the modifiers (i.e. the details) of the communication items, we added these modifiers in the table. In the other main categories changes in modifiers were restricted to single behaviors; these are summarized in the text.

Each paragraph describes the developments across time in physical therapy contents, in which we compare contents of the VIP-project with that of the L2M-project. Numbers in brackets represent p-values and, when not provided in the tables, also information about median percentages and ranges. First differences in the main categories (e.g., neuromotor actions: facilitation) are reported, followed by a report on differences in modifiers (e.g., neuromotor actions: facilitation, with handling techniques). When it was conceivable that presence or absence of a difference in PPT-actions over time was partly explained by a higher number of children diagnosed with CP in the L2M-project, we added information on the association between that PPT-actions and CP.

Table 2: Changes over time in contents of infant physical therapy

| PT-situation or action | VIP-project (2003-2005) | L2M-project (2008-2013) | MWU | Hodge's Lehmann diff between medians | | |
|---|----------------------------|----------------------------|------------------|---|--------|-------|
| | Median (range) | Median (range) | p-value | Estimate | 95% CI | |
| | | | | | Lower | Upper |
| Neuromotor action | | | | | | |
| Facilitation | 18.2 (2.5-37.4) | 10.1 (0.0-29.2) | 0.122 | -4.0 | -11.4 | 0.9 |
| Sensory experience | 2.4 (0.0-20.1) | 4.1 (0.0-20.3) | 0.549 | 0.7 | -1.7 | 4.9 |
| Passive motor experience | 1.2 (0.0-21.7) | 2.1 (0.0-18.7) | 0.326 | 0.7 | -0.6 | 2.2 |
| SPMB | 36.2 (17.5-64.4) | 36.8 (15.1-69.7) | 0.965 | 0.2 | -9.4 | 9.7 |
| CSPMB, infant is allowed to continue activity | 26.7 (11.2-40.1) | 22.8 (0.0-57.0) | 0.804 | 1.0 | -11.8 | 9.0 |
| CSPMB, flows over into hands-on techniques* | 8.5 (0.4-23.0) | 10.3 (0.0-21.9) | 0.737 | 1.0 | -4.0 | 6.3 |
| NS neuromotor action | 3.6 (1.6-18.9) | 7.0 (1.9-15.3) | 0.069 | 2.3 | -0.1 | 5.2 |
| Educational actions toward caregiver | | | | | | |
| Caregiver training | 0.7 (0.0-47.5) | 16.5 (0.0-60.1) | 0.258 | 8.5 | -0.1 | 18.8 |
| Caregiver coaching | 0.0 (0.0-11.7) | 0.0 (0.0-41.7) | 0.404 | 0.0 | 0.0 | 0.0 |
| NS educational actions | 99.0 (51.31-100) | 81.3 (10.2-100) | 0.042 | -14.2 | -24.4 | 0.0 |
| Communication | | | | | | |
| Information exchange | 2.1 (0.0-8.4) | 7.5 (2.3-18.0) | 0.001 | 4.0 | 1.8 | 7.8 |
| ▪ About NDT | ▪ 0.0 (0.0-1.3) | ▪ 0.9 (0.0-5.1) | 0.002 | 0.7 | 0.0 | 1.6 |
| ▪ About family issues | ▪ 2.0 (0.0-7.6) | ▪ 7.5 (1.3-14.0) | 0.002 | 2.9 | 0.0 | 6.3 |
| Instruct | 1.5 (0.0-14.5) | 6.3 (0.2-17.3) | 0.056 | 3.1 | -0.4 | 6.4 |
| ▪ Strict instruction | ▪ 0.6 (0.0-12.5) | ▪ 1.4 (0.0-14.9) | 0.625 | 0.3 | -1.5 | 1.7 |
| ▪ Multiple options | ▪ 0.8 (0.0-5.0) | ▪ 0.4 (0.0-8.2) | 0.784 | 0.0 | -0.6 | 0.7 |
| ▪ Giving hints | ▪ 0.0 (0.0-2.3) | ▪ 1.1 (0.0-15.1) | 0.009 | 0.7 | 0.0 | 1.6 |
| ▪ Not specified | ▪ 0.0 (0.0-0.3) | ▪ 0.0 (0.0-0.0) | 0.222 | 0.0 | 0.0 | 0.0 |
| Provide feedback | 13.7 (0.8-46.0) | 22.0 (6.8-35.9) | 0.045 | 6.8 | 0.3 | 14.2 |
| ▪ Share information | ▪ 1.8 (0.0-7.3) | ▪ 7.9 (1.0-23.4) | <0.001 | 5.6 | 1.9 | 11.7 |
| ▪ Asks & listens to opinion of caregiver | ▪ 0.1 (0.0-16.7) | ▪ 0.6 (0.0-9.3) | 0.192 | 0.4 | 0.0 | 0.9 |
| ▪ Evaluating the procedure | ▪ 11.3 (0.8-24.0) | ▪ 8.8 (2.4-26.0) | 0.605 | -1.2 | -7.4 | 3.5 |
| ▪ Right/wrong | ▪ 0.0 (0.0-1.6) | ▪ 0.0 (0.0-1.5) | 0.590 | 0.0 | 0.0 | 0.0 |
| No communication | 5.9 (0.74-18.4) | 4.7 (0.0-27.3) | 0.767 | -1.0 | -3.9 | 6.8 |
| Not specified communication | 72.2 (35.0-92.9) | 52.0 (41.0-73.3) | 0.002 | -17.1 | -28.1 | -7.4 |
| Position | | | | | | |
| Supine | 48.5 (23.5-87.7) | 54.0 (2.9-79.6) | 0.298 | 6.0 | -6.1 | 15.7 |
| Prone | 20.1 (4.3-29.5) | 13.9 (1.7-31.7) | 0.089 | -5.2 | -10.7 | 0.5 |
| Sitting | 18.2 (0.0-30.7) | 14.2 (0.2-57.8) | 0.872 | -1.5 | -4.2 | 0.5 |
| Transition | 7.1 (3.6-19.5) | 5.6 (1.1-16.1) | 0.042 | -1.9 | -4.2 | -0.1 |

Table 2: Changes over time in contents of infant physical therapy (Continued)

| PT-situation or action | VIP-project (2003-2005) | L2M-project (2008-2013) | MWU | Hodge's Lehmann diff between medians | | |
|------------------------|----------------------------|----------------------------|--------------|---|-----------------------|-----|
| | Median (range) | Median (range) | p-value | Estimate | 95% CI Lower Upper | |
| Situation | | | | | | |
| Motor activity/play | 97.6 (81.2-100) | 94.3 (65.8-100) | 0.312 | -2.2 | -12.2 | 0.9 |
| Feeding | 0.0 (0.0-1.5) | 0.0 (0.0-32.7) | 0.438 | 0.0 | 0.0 | 0.0 |
| Bathing | 0.0 (0.0-0.0) | 0.0 (0.0-0.0) | 1.000 | 0.0 | 0.0 | 0.0 |
| Dressing | 1.1 (0.0-18.9) | 0.6 (0.0-29.7) | 0.672 | 0.0 | -1.6 | 0.8 |
| Carrying | 0.3 (0.0-2.3) | 0.8 (0.0-9.3) | 0.042 | 0.4 | 0.0 | 1.4 |
| Changing diapers | 0.0 (0.0-0.76) | 0.0 (0.0-2.2) | 0.988 | 0.0 | 0.0 | 0.0 |

P-values in bold represent significant differences. CI= Confidence interval; CSPMB = Challenged to self-produced motor behavior; diff = difference; L2M = LEARN2MOVE; MWU = Mann Whitney U test; NDT = neurodevelopmental treatment; NS=not specified; PT = Physical therapy; SPMB = Self-produced motor behavior; TIP = Typical Infant Physical Therapy; VIP = Vroegtijdig Interventie (Early Intervention) Project.

* For readability we abbreviated 'flows over into or is combined with facilitation, sensory or passive experience' into: 'flows over into hands-on techniques'

Neuromotor actions

Time spent with the main categories of neuromotor actions did not change over time. Neuromotor actions that occurred most frequently were self-produced motor behaviors of the infant, either as spontaneous actions of the infant, or elicited by a challenge of an adult person. The analyses of the modifiers yielded one change: in case of 'CSPMB with an overflow into or is combined with facilitation, sensory or passive experience, sensory experience techniques' were less often applied over time (in VIP 1.0% (0.0-15.1), in L2M 0.0% (0.0-4.8); $p=0.048$).

Educational actions towards caregiver

The most frequently occurring educational actions were not specified actions. These not specified educational actions towards caregivers decreased across time (Table 2, $p=0.042$); i.e., specified educational actions (the amount of caregiver training and caregiver coaching together; median from 1.0% to 18.7% , $p=0.042$) increased.

Communication

Not specified communication was the most frequent type of communication. Time spent on not specified communication decreased across time ($p=0.002$). Consequently, total time spent on specified communication (i.e. the sum of information exchange, feedback and instruction) increased significantly over time (from 20.9% to 37.5%, $p=0.007$). The

increases in the amount of information exchange and in the provision of feedback were also individually statistically significant ($p=0.001$ and $p=0.045$, resp.), the amount of instructing was more stable over time ($p=0.056$). The modifier analyses on the type of information exchange indicated that over the years more time was spent both on explanation about NDT ($p=0.002$) and on family issues ($p=0.002$). Also the type of instruction changed: in the second period more time was spent on giving hints ($p=0.009$). In addition, the modifier analyses on the type of feedback showed that in the second period more time was spent on sharing information ($p<0.001$).

Position

During the therapy sessions the infants were mostly in supine position. Treatment position remained large stable across time, with the exception of a small but significant decrease in the percentage of time spent on transitions, i.e. time spent on changing from one position to another ($p=0.042$). The analysis of the modifiers indicated two changes across time: 1) an increase in the time spent in prone position on the upper part of the caregivers' body (from 0.0% (0.0-7.3) to 0.6% (0.0-6.1), $p=0.042$) and 2) a decrease in time spent in prone position across the leg of the caregiver or therapist (from 0.6% (0.0-5.8) to 0.0% (0.0-5.4), $p=0.042$).

Situation

Virtually all therapy time was spent on motor activity and play, this was true for both periods. The only minor change over time that occurred was a small increase in the therapy time spent with carrying ($p=0.042$).

DISCUSSION

Our study indicated changes in PPT during the last decade. Sharing of information increased, with more information exchange, provision of feedback and education by means of a combination of training and coaching. The observed changes fit into caregivers needs for sharing information with professionals.^{26,27} Interestingly, the type of neuromotor actions remained largely stable over time.

Both communication and educational actions towards the caregiver became more specific over time, i.e., not specified actions were partially replaced by caregiver training and coaching. It reflects more involvement of the caregivers and may indicate the intention to implement a family centred approach, with partnership with family members.¹⁰ Our findings suggest that family involvement increased, but probably did not yet reach a full level of equal relationship, as the educational actions showed that time spent on training was much higher than the time spent on coaching and that the type of instruction was

most often strict. However, time spent on giving hints increased indicating that the type of communication changed.

We expected a decrease in hands-on techniques - i.e., neuromotor actions in the form of facilitation, sensory experience or passive experience - over time. Yet, appliance of neuromotor actions remained largely stable over time. The absence of changes in neuromotor actions may be explained by the higher number of infants with severe brain lesions in the L2M-project than in the VIP-project. Theoretically, it is conceivable that infants who are neurologically more affected and whose motor repertoire and possibilities are more restricted trigger therapists to use more often hands-on techniques. This in turn may have occluded a decrease in the application of hands-on techniques. However, our data indicated that the amount of time spent on hands-on techniques was similar for children diagnosed with CP and those without this diagnosis, which does not support this idea. As hands-on techniques are mainly focused on body functions and structures, the absence of a change in those actions suggests that we did not find the expected shift in neuromotor actions from body functions and structures towards activities and participation. Nevertheless, a minor shift towards activities and participation may be observed in the increase in time spent on daily activities like carrying, and the decrease in time spent on transitions. Moreover, in prone position an increase in the time spent on the caregivers body was observed, and a decrease in the time spent in prone across the caregivers or therapist's leg. These two changes may suggest a more affective and less technical approach of applying neuromotor techniques.

A major strength of our study is the detailed quantification of PPT-contents. To our knowledge, our study is the first in comparing contents of PPT-interventions over time. Contents of interventions in non-pharmacological health care are in general poorly reported.²⁸ In pediatric rehabilitation, recently an instrument has been developed to evaluate whether interventions for children with physical disabilities provide what they are supposed to do, the Pediatric Rehabilitation Observational Measure of Fidelity, by scoring frequencies.²⁹ In our opinion, our analyses with durations of PPT-actions describe more precisely the contents of PPT. Subjective interpretation was ruled out as far as possible, by providing a detailed protocol. Analyses were performed by two independent blinded observers, who had a good to excellent interobserver reliability, enlarging opportunities for replicability. Unfortunately, the videos were not assessed in random order, but sequentially. Yet, the fact that we did not find the motor action trend that we expected suggests that the analyses were relatively free from bias. Another limitation of the study is the small size of the samples, which may have resulted in underreporting of significant changes in less frequently occurring PPT-actions. Our study deliberately explored differences in many variables to pick up current trends, with the probability of chance capitalization. This implies that our results should be interpreted with caution; they call for reproduction in other studies. The different

inclusion criteria of both projects is another limitation: infants in the L2M-project had more often brain lesions and CP than those in the VIP-project. The higher proportion of CP in the L2M-project did however not explain the changes in PPT-actions over time. Because both intervention programs have been studied in the Netherlands, generalizability to other countries may be limited.

CONCLUSIONS

Our study sheds light on the contents and implementation of PPT, which is a prerequisite for the understanding of effective working components.³⁰ Moreover, insight in current interventions may help to develop and implement new interventions. The PPT community is aware that PPT is changing, probably as the result of developing insights in pediatric and rehabilitation care. Our study indicated that family involvement increased over time, signaling advances in the implementation of family centred care. However, we did not find a decrease over time in hands-on techniques, i.e., the neuromotor actions applied did not reflect a change in therapy focus from body functions and structures towards activities and participation. This means that the observed changes in our study sometimes corresponded to novel insights and theories, sometimes they did not. Thus, our findings disclose a gap between theory and daily practice. Awareness of this gap will facilitate the process of gap closure, so that in future interventions practice will match theory. Concordance between theory and practice is a cornerstone of the house of evidence based PPT interventions.

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APPENDIX

THE GRONINGEN OBSERVER PROTOCOL (GOP 2.0)

A standardized observation protocol for the classification of pediatric physical therapy actions

A. DEPENDENT VARIABLES

A.1 NEUROMOTOR ACTIONS

1.1 Behaviors

1.1.1 Facilitation techniques

All therapeutic hands-on actions of the physical therapist or caregiver aimed at guidance of movement or maintenance of the infant's posture by gently placing the hands on specific parts of the infant's body, thus providing the infant with sensorimotor experience and controlling movement output. Note that if the therapists also applies constraint of the best arm during facilitation, scoring of facilitation continues (i.e., it is not interrupted by 'constraint').

Modifier group:

Type of facilitation

1.1.2 Reflex locomotion

According to Vojta holding and pressure point techniques aim to provoke reflex locomotion. These techniques may be observed in two major forms: a) 'pure' Vojta like, i.e., consisting of actions that aim to fixate the infant in a defined starting position (holding) which may be followed by application of pressure on defined points of the body (pressure points). b) Vojta pressure point techniques which are applied in combination with handling.

Examples of holding:

- o Supine, side lying, prone.
- o Head turned with an arm and/or leg in a seemingly unnatural position.

Examples of pressure points:

- o Points on the head, around the mouth, around the shoulder, elbow or wrist.
- o Points on the thorax or pelvis.
- o Points around the hip, knee and ankle.

Modifier group:

Type of reflex locomotion

1.1.3 & 1.1.4 Sensory experience; point & state event

All tactile and vestibular stimulation given to the infant during treatment – *without* the aim of facilitation, tapping, or passive motor experience. Sensory events are only scored when they are explicitly provided as a sensory stimulus. This implies that other activities involving sensory experience, such as spontaneous motility, being dressed or undressed, or being repositioned a few centimeters in order to obtain a better camera view, are not scored as sensory experience.

Examples of concrete PT/caregiver actions:

- o Touching skin with toy.
- o Touching to comfort or praise the infant.

Modifier group:

Aim of sensory experience

1.1.5 Passive motor experience

All handling techniques induced by the PT or the caregiver in which no activity of the infant is required in the performance of the actions.

Examples of concrete PT/caregiver actions:

- o Passive movements of arms and/or legs.
- o Repetitive movements of the upper arm towards (frontal) support surface.

1.1.6 Self-produced motor Behavior (SPMB), no interference with PT/CG

All actions during which the infant is given ample opportunities to explore toys or other aspects of the environment or his body, without interference from PT or caregiver.

Examples of concrete PT/caregiver actions:

- o Placing an infant activity play center over the infant and letting the infant explore the effect of movements of arms, hands, legs, and feet. Note that this implies that the infant plays by itself and that nobody interferes or joins in, e.g., by shaking one of the rattles of the activity center. If the latter occurs CSPMB is scored.
- o Infant is given opportunity for spontaneous exploration with or without toy.
- o Postural challenges, infant spontaneously explores postural capacities.

1.1.7 SPMB in combination with constraint of one upper limb

All actions during with the infant is given ample opportunities to explore toys or other aspects of the environment or his body while one upper limb, i.e., the best performing limb, is being restrained to participate by a caregiver, PT or by a device such as a sling, towel or mitten.

When SPMB in combination with a constraint (SPMB+) is combined with a facilitation-technique, SPMB+ will change into facilitation when the constraint lasts for more than 10 seconds.

Modifier-group:

Type of constraint

1.1.8 Challenged to SPMB (CSPMB), infant is allowed to continue activity by him/herself

All actions in which the infant is challenged by toys or the face of the PT or caregiver to experience a variety of motor activity that is continued by the infant her/himself. Note that the neuromotor action CSPMB changes into 'Self-produced motor Behavior' if PT/CG has not renewed the challenge within an interval of 20 seconds. However, if in the latter case 'SPMB' lasts less than 10 seconds before it changes into challenging again, CSPMB is not interrupted by SPMB but continued.

Modifier-groups:

1. Variation
2. Extent of challenge

1.1.9 CSPMB in combination with constraint of upper limb, infant is allowed to continue by him/herself

All actions in which the infant is challenged by toys or the face of the caregiver to experience a variety of motor activity that is continued by the infant her/himself while one upper limb, i.e., the best performing limb, is being restrained to participate by a caregiver or by a device such as a sling, towel or mitten.

Modifier-groups:

1. Variation
2. Type of constraint upper limb
3. Extent of challenge

1.1.10 CSPMB, activity flows over into or is combined with facilitation, sensory or passive experience

All actions in which the infant is challenged by toys or the face of the PT or caregiver to experience a variety of motor activity that is followed by or combined with handling techniques, facilitation (with or without the help of support devices; pressure; tapping), sensory or passive experiences. The interval between the challenge and the handling techniques may be very short (starting virtually simultaneously) and may last maximally 20 seconds. If the time interval between challenging and therapeutic handling is longer than 20 seconds, 'CSPMB; infant is allowed to continue activity by her/himself' is scored. Note that the activity that is being challenged (for instance grasping Behavior) does not have to be directly related to the main aim of handling (for instance facilitation of rolling into prone). To indicate that a 'facilitation technique' starts while the challenge continues, in the category 'Educational actions towards the infant' an 'interference by PT/CG during treatment session' is scored as 'PT/CG corrects when infant fails'.

Modifier-groups:

1. Variation
2. Type of facilitation techniques, sensory, passive motor experience
3. Extent of challenge

1.1.11 Craniosacral therapy

Applying a gentle manual force to address somatic dysfunctions of the head and spinal cord, in particular aiming to mobilize the cranial structures. Craniosacral therapy is a hands on technique focusing on mobility in neck and spine. This aim is clear from the hand movements of the therapist.

1.1.12 Not specified neuromotor action

All therapeutic actions during the treatment session that cannot be classified into the ten defined categories.

Example:

- o Changing the treatment situation.

1.2 Modifier groups

1.2.1 Type of facilitation

- *Handling*: Specific hands-on techniques to give the infant sensorimotor experience to improve the quality and repertoire of the infant's movements.

Examples of concrete PT/caregiver actions:

- o In supine position or sitting: Shoulders function as key point: handling hands guide shoulders of the infant in protraction to control tone and to facilitate hand-hand contact and symmetry.
 - o In supine position: Proximal or distal leg functions as key point: the infant's hip is passively brought in semi-flexion while adducting the leg across the midline to facilitate head righting and rolling.
 - o In supine position: Pelvis functions as key point: the infant's pelvis is slightly lifted to elongate the extensor muscles of the trunk and to control tone; in this way hand-foot contact and symmetry are facilitated.
 - o In prone position: Shoulder functions as key point, the arms are placed in puppy position to facilitate head righting, midline orientation, and body-alignment.
 - o Sitting: Shoulder functions as key point: the shoulders are moved alternately forwards and backwards to dissociate and facilitate independent arm movements.
- *Pressure techniques:* All handling techniques that produce intermittent pressure to stimulate and gain control over muscle tone, posture, and movement. Pressure is scored when the observer is able to see that the hand which rests on the child exerts pressure. The presence of pressure should not be concluded on the basis of the Behavioral reaction of the child.

Examples of concrete PT/caregiver actions:

- o Sitting: intermittent downward pressure on shoulders in the direction of the pelvis to facilitate extension of the trunk.
 - o Sitting: slight intermittent pressure movements on abdominal region in direction of the sacrum to facilitate contraction of the ventral muscles.
- *Tapping techniques, intermittent and sweep tapping*

1.2.2 Type of reflex locomotion

- Holding with pressure points
- Pressure points with handling
- Holding without pressure points
- Other

1.2.3 Aim of sensory experience

- Affective sensory experience
- Mixed affective and body awareness
- With the aim of body awareness

1.2.4 Type of constraint

- Caregiver/ PT
- Towel, mitten, etc.

1.2.5. Type of variation

During one activity variation is scored once; it represents the overall degree of variation during that activity. If the child during a specific activity is challenged to explore more than two strategies, the modifier of variation is scored as 'large' as long as 'CSPMB' continues.

- Little variation: All actions in which the infant is challenged by toys or the face of the PT or caregiver to explore one or two strategies to reach and grasp, to control posture, to roll, etc. This may also imply that the PT or caregiver presents objects in various directions, but does not provide the infant with ample opportunity to deal with the challenge.
- Large variation: All actions in which the infant is challenged by toys or the face of the PT or caregiver; the infant is challenged to explore more than two strategies to reach and grasp, to control posture, to roll, etc. This implies that the infant is offered ample time to deal with the various challenges, and that some challenges are offered multiple times.

1.2.6 Extent of challenge

- Minimal challenge (easy/too easy)
- Just at the verge of the infant's abilities (has to put some effort)

A.2 EDUCATIONAL ACTION

2. A Educational actions towards infant; Interference by PT/CG during treatment session

2.1.A Behaviors

2.1.A.1 PT/CG interferes with activities of infant

2.1.A.2 Not specified educational actions towards infant

2.2.A Modifier-groups

2.2.A.1 Type of interference

- PT/CG interrupts activities of infant after having given ample time
- PT/Caregiver interrupts activities of the infant, does not allow the infant time
- PT/Caregiver provokes reflex activity
- PT/CG corrects when infant fails

2.B EDUCATIONAL ACTION TOWARD CAREGIVER

2.1.B Behaviors

2.1.B.1 Caregiver training

All actions during which the PT instructs caregivers on how to handle the infant or how to use specific Vojta techniques with the aim being that caregivers can continue treatment strategies during daily-life activities and/or in the home environment. The PT (teacher) provides parents with references about what the therapist is doing or what a parent could do while the therapist treats the infant (hands-on).

Examples of concrete actions:

- o PT demonstrates therapeutic handling actions to caregiver.
- o PT demonstrates Vojta techniques to caregiver
- o PT demonstrates action to caregiver, variable options provided.
- o PT practices with caregivers teaching them how to continue some of the handling techniques in daily life at home.
- o PT practices with caregivers; he/she teaches caregivers how to continue some of the handling techniques in combination with some of the Vojta techniques in daily life at home
- o PT practices with caregivers; he/she teaches the caregivers how to perform reflex rolling and crawling in the home situation

2.1.B.2 Caregiver coaching

All actions during which the PT coaches the caregiver. Coaching aims to empower caregivers so that they can make their own educational decisions during daily-care activities in the home environment. The coach listens, informs, and observes (hands-off), while the caregiver is involved in daily routines with the child, including play, thereby creating a situation in which caregivers feel free to explore and discuss alternative strategies.

Examples of concrete actions:

- o PT patiently observes the parent and infant behavior.
- o PT provides a suggestion how the caregiver may challenge motor performances just at the limit of the infant's abilities.
- o PT provides a suggestion how the caregiver may provide as little postural support as possible – in order to challenge postural behavior of the infant.
- o PT observes while the caregiver tries to evoke pleasure in the infant.

2.1.B.3 Not specified educational action toward caregiver

A.3 COMMUNICATION

3.1 Behaviors

3.1.1 Information exchange

All communication between the PT and the caregiver that is related to the guidance of infant and family (includes imparting knowledge) and that is not directly related to the child's development. Impart knowledge implies communication that provides the caregiver with knowledge about the therapeutic actions that are performed.

Examples of concrete actions:

- o PT asks about the performance of an action.
- o PT explains the ins and outs of an action.
- o PT asks about understanding.
- o PT asks about ability of caregiver to perform an action; PT listens to caregiver's comments on actions.

Modifier group:

Type of exchange

3.1.2 Instruct

All communication in which the caregiver is given assignments, hints or strict directions regarding treatment strategies.

Examples of concrete actions:

- o PT assigns, gives advice what to do.
- o PT gives hints, provides a suggestion or clue in a very indirect way so that caregivers feel free to explore ample variable opportunities.
- o PT gives strict directions what to do.

Modifier group:

Type of instructing

3.1.3 Provide Feedback

All communication in which the treatment or the performances of infant and caregiver are evaluated.

Examples of concrete actions:

- o PT tells the caregiver what went right/wrong.
- o PT evaluates the procedure.
- o PT asks and listens to the opinion of the caregiver.
- o Caregiver and PT share information on infant development.

Modifier group:

Type of feedback

3.1.4 Not specified communication, e.g. communication with infant

3.1.5 No communication

No communication is scored if there is a silence for more than 5 seconds.

3.2 Modifier-groups

3.2.1 Type of exchange

- Regarding family history, NICU experiences, current situation or daily business
- Regarding principles of NDT: All communication that explains the background of the treatment strategies, including developmental education and family related items (includes imparting knowledge).

Examples of concrete actions:

- o Information on role of parents as member of the team, as co-therapist; PT informs the parent what they should or may do (extension of therapy).
- o PT explains handling in terms of typical movement patterns, typical development, posture, muscle tone, asymmetry/symmetry, and hand placing.
- o PT discusses the application of intervention strategies to daily routines in terms of handling.
- Regarding principles of VOJTA: All communication that explains the background of the treatment strategies, including developmental education and family related items (includes imparting knowledge).

Examples of concrete actions:

- o Information on role of parents as therapist in treatment according to Vojta: therapist as teacher, the PT informs the parent what to do during daytime (frequency and duration).
- o PT explains Vojta test and reflex locomotion in terms of holding the infant in a specific position, pressure on specific parts of the body, reflex rolling, reflex crawling.
- o PT discusses the frequency of application of Vojta techniques at home (e.g., number of times/day and duration).

- Regarding principles of COPCA: All communication that explains the background of the treatment strategies, including developmental education and family related items (includes imparting knowledge).

Examples of concrete actions:

- o Information on family function, individual lifestyle, family autonomy, raising children, coping with problems, role of siblings, and daily care.
- o Information on role of the coach: observing, listening, partners.
- o PT explains the need for variation, minimal support, exploration, trial and error, challenge, and patience.
- o PT explains the infant's need to explore.
- o PT explains means to stimulate speech and language development [communication].
- o PT discusses the application of the intervention to daily routines in terms of variation, exploration, motor challenge.

3.2.2 Type of instructing

Different types of instruction or rather in the way ideas are communicated can be distinguished. The distinction is based on the space of freedom created by the PT allowing the CG to discover and/or formulate own ideas and actions. Note that the way the information is provided does not determine the type of instruction. For example strict instructions may be phrased as a polite question.

- PT gives strict instruction on the best way to perform: only a single, explicitly formulated option is provided, e.g. "While bathing, the child should be sitting" or "Could you, please, have the child in sitting position during bathing?".
- Instruction about multiple ways to achieve best performance: more than one explicitly formulated option is provided, e.g. "While bathing, the child can either sit or lay in supine position".
- PT gives hints, provides a suggestion/clue (indirect): no explicitly formulated options are provided, the subject to be discussed is presented in an open way, encouraging the CG to generate options and ideas, e.g. "Could you think of different positions while bathing your child?".
- Not specified.

3.2.3 Type of feedback

- PT tells the caregiver what went right/wrong: only short comments without details, e.g. 'well done', 'good job'.
- PT evaluates the procedure: includes all communication on therapeutic actions and caregiving strategies which have been addressed during PT-sessions. E.g. how well the

child performs during treatment, how implementation in daily life works out or how the child reacts to different actions.

- PT asks and listens to the opinion of the caregiver: scored when the PT is interested in the CG's opinion, is interested to obtain more insight in the CG's point of view.
- Caregiver and PT share information on infant development: all information exchange involving the child's development that is not directly related to therapeutic actions or CG coaching.

A.4 POSITION

The position of the child is always scored except for situations in which the child is not visible. A new position (after a transition) starts when the child stays in the position for at least three seconds.

For exceptions and specific scorings of postures see Appendix I.

4.1 Behaviors

4.1.1. *Supine*

Modifier groups:

1. *Surface*
2. *Lifting of the pelvis*
3. *Adaptations*

4.1.2. *Prone*

4.1.3. *Side*

4.1.4. *Sitting*

4.1.5. *Standing*

4.1.6. *Walking*

4.1.7. *Transition*

4.1.8: *Not specified position*

Modifier groups:

1. *Surface*
2. *Postural support*
3. *Adaptations*

Modifier group: *With or without handling*

4.2 Modifier-groups

4.2.1. *Lifting of the pelvis:*

- With imposed pelvis lift
- Pelvis not lifted
- Pelvis lift not observable

4.2.2. *Surface*

- On flat surface
- On lap PT /CG
- On Bobath ball

- On Bobath roll
- Across leg/arm of PT/CG
- Saddle
- Maxicosi/buggy
- Baby chair
- Baby walker
- On dressing mattress
- Against upper part of CG/PT's body
- Other surface

4.2.3 Postural support:

Postural support can be offered by the CG/PT or the environment, e.g., a baby chair. Other examples of postural support by the environment are holding onto the table, leaning against the wall or leaning with one or two hand(s) on the ground.

- No postural support: PT or caregiver leaves it to the infant to adjust posture independently. "Hands-off"
- Minimal postural support: PT or caregiver provides as little support as possible in order to challenge postural Behavior of the infant performance just at the verge of the infant's abilities, The child has to "work" hard to maintain balance, which is for example visible in wobbling or swaying back and forth. The amount of support that is considered minimal is depending on the abilities of the child and varies between infants and situations. Note that if the infant is able to maintain the position itself, e.g., is able to sit independently on a flat surface, it is not possible to allude the score 'minimal' to the support provided. The latter support has to be classified as either clear or full support depending on the situation.
- Clear postural support: PT or caregiver provides support to such that minimal active involvement of the infant is required to adjust posture.
- Full postural support: PT or caregiver supports all parts of the body of the infant that play a role in postural adjustments. No active involvement of the infant is required.

4.2.4 Adaptive equipment, e.g., lying, seating, standing or walking devices

- No adaptive equipment
- Adaptive equipment

4.2.5 With or without handling

- With a handling technique: when the PT/CG changes the position of the child by using a specific handling technique ('Handling' has to be scored at the same time for 'Neuromotor action')
- Without a handling technique: when the PT/CG changes the position without using a specific technique ('Not specified neuromotor action' has to be scored at the same time for 'Neuromotor action')

A.5 SITUATION OF TREATMENT SESSION

The situation of the treatment is always scored except for situations in which the child is not visible.

5.1 Behaviors

- 5.1.1. Motor activity/play
- 5.1.2. Feeding
- 5.1.3. Bathing
- 5.1.4. Dressing/Undressing
- 5.1.5. Changing Diapers
- 5.1.6. Carrying
- 5.1.7. Not specified situation

A.6 ADDITIONAL CATEGORIES

A. Comforting

Comforting of the infant is scored when the therapeutic actions stop in order to comfort the child. When applicable the variables 'Situation of the treatment session', 'Position' and 'Neuromotor action' are scored / continue to be scored during comforting. When the child is held and cuddled to be comforted, the 'Neuromotor action' in general will be 'Sensory state event – Affective'. When the 'Neuromotor action' is not clear, 'not specified neuromotor action' is scored.

A.1 BEHAVIORS

- a.1.1 No comforting
- a.1.2 Comforting of the infant when infant is upset/crying/tired.

B. Interruption by operator

B.1 Behaviors

b.1.1 No interruption

b.1.2 Interruption

C. LOCOMOTION

C.1 BEHAVIORS

c.1.1. Crawling

c.1.2. Creeping

c.1.3. Bottom shuffling

c.1.4. Walking

c.1.5. Other

c.1.6. No locomotion

B. INDEPENDENT VARIABLES

Independent variables: the value of this variable is supposed not to change during the course of an observation. It gives the observer the opportunity to summarize briefly the important characteristics of the observation. Independent variables are to be scored after finishing the Observer XT in a dropdown menu.

B.1 TYPE OF SESSION (CLINICAL IMPRESSION)

Categories:

1. COPCA
2. TIP (based on NDT)
3. VOJTA
4. TIP (based on NDT) in combination with VOJTA
5. Cranio-sacral therapy
6. TIP (based on NDT) in combination with Cranio-sacral therapy
7. Constraint Induced Movement Therapy (CIMT)
8. COPCA in combination with CIMT

B.2 DRESSING

The way in which the infant is dressed during the treatment session. If the dressing situation changes during the session, score the predominant dressing situation.

Categories:

1. Dressed
2. Infant is partially dressed, wears more clothes than underwear only
3. Infant is wearing underwear only
4. Infant is undressed

B.3. FAMILY MEMBERS INVOLVED IN THE TREATMENT SESSION

The description of the family members that have an active role in the treatment session are included in scoring. This also implies that e.g. the presence of an infant twin sister of brother who does not play an active role in the session, is not scored as 'other family member present'.

Categories:

1. Mother present only
2. Father present only
3. Other adult relatives only, e.g. grandparents, aunt
4. Both caregivers but no other family members present
5. In addition to parent(s) also other family members present
6. Caregiver or caregivers present but no active role in the treatment session

B.4 ROLE OF THE CAREGIVER

The way in which the caregiver of family members are involved in the treatment session.

Categories:

1. Physical therapist performs treatment by means of handling techniques
2. PT performs treatment by means of specific Vojta techniques (holding the infant in specific 'Vojta positions' provoking reflex locomotion by pressure stimulation on specific defined points on the head, trunk or limbs).
3. PT performs treatment by means of handling in combination with Vojta techniques
4. Caregiver and physical therapist act together in handling techniques, physical therapist performs the treatment (hands on) while the caregiver guides the attention of the infant
5. Caregiver performs handling techniques. The PT instructs the caregiver how to handle.
6. PT and caregiver act together; PT trains caregiver how to perform the Vojta techniques
7. Caregiver performs the treatment by means of specific Vojta techniques
8. Caregiver performs the treatment by means of handling in combination with Vojta techniques
9. Caregiver and PT act together (hands off), caregiver is playing with the child and may provide the infant with minimal support but leaves the infant always with ample

opportunities for exploration. PT observes the caregiver-infant relationship and may give hints.

10. Caregiver is playing with the infant (hands off) and leaves the infant with ample opportunities for exploration.
11. PT is playing with infant (hands off) and leaves the infant with ample opportunities for exploration – caregiver observes
12. PT is playing with infant (hands off) and leaves the infant with ample opportunities for exploration – no specific role of caregiver

B.5. PRESENCE OF TWINS

Categories:

1. no = singleton infant
2. yes = twins

EARLY INTERVENTION IN INFANTS
AT VERY HIGH RISK OF CEREBRAL
PALSY

PART



