**Pediatric Physical Therapy in Infancy: From Nightmare to Dream? A Two-Arm Randomized Trial**

Cornill H. Blauw-Hospers, Tineke Dirks, Lily J. Hulshof, Arend F. Bos and Mijna Hadders-Algra

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# Pediatric Physical Therapy in Infancy: From Nightmare to Dream? A Two-Arm Randomized Trial

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**Background.** Systematic reviews have suggested that early intervention by means of specific motor training programs and general developmental programs in which parents learn how to promote infant development may be the most promising ways to promote infant motor and cognitive development of infants with or at high risk for developmental motor disorders.

**Objective.** The purpose of this study was to investigate the effects of a recently developed pediatric physical therapy intervention program ("Coping With and Caring for Infants With Special Needs" [COPCA]) on the development of infants at high risk for developmental disorders using a combined approach of a 2-arm randomized trial and process evaluation.

**Setting.** The study was conducted at the University Medical Center Groningen in the Netherlands.

**Participants and Intervention.** Forty-six infants at high risk for developmental disorders were randomly assigned to receive COPCA (a family-centered program) (n=21) or traditional infant physical therapy (TIP) (n=25) between 3 to 6 months corrected age (CA). Developmental outcome was assessed by blinded assessors at 3, 6, and 18 months CA with a neurological examination, the Alberta Infant Motor Scales, the Pediatric Evaluation of Disability Inventory, and the Mental Developmental Index (MDI) of the Bayley Scales of Infant Development. Contents of the intervention were analyzed by a quantitative video analysis of therapy sessions. Quantified physical therapy actions were correlated to evaluate associations between intervention and developmental outcome components.

**Results.** The trial revealed that developmental outcome in both groups was largely identical. Process evaluation showed that typical COPCA actions—(1) family involvement and educational actions, (2) application of a wide variation in challenging the infant to produce motor behavior by himself or herself and allowing the infant to continue this activity, and (3) stimulation of motor behavior at the limit of the infant's capabilities—had positive correlations with developmental outcome at 18 months CA. The use of handling techniques was negatively associated with the Pediatric Evaluation of Disability Inventory outcome at 18 months CA.

**Limitations.** Major limitations were the limited size of the groups studied and the differences between the groups in frequency and duration of physical therapy sessions.

**Conclusion.** Extending the randomized trial with process evaluation was needed to obtain insight into associations between the components of intervention and developmental outcome. Specific therapist behaviors of parent coaching are associated with improved developmental outcome measures. Further studies are needed to examine whether these associations are caused by therapist behavior or whether therapist behavior is modified by children's motor skills.

C.H. Blauw-Hospers, PhD, Department of Pediatrics–Developmental Neurology, Beatrix Children's Hospital, University Medical Center Groningen, Groningen, the Netherlands.

T. Dirks, PT, Department of Pediatrics–Developmental Neurology, Beatrix Children's Hospital, University Medical Center Groningen.

L.J. Hulshof, MD, Department of Pediatrics–Developmental Neurology, Beatrix Children's Hospital, University Medical Center Groningen.

A.F. Bos, MD, PhD, Department of Pediatrics–Developmental Neurology, Beatrix Children's Hospital, University Medical Center Groningen.

M. Hadders-Algra, MD, PhD, Department of Pediatrics–Developmental Neurology, Beatrix Children's Hospital, University Medical Center Groningen, Hanzeplein 1, 9713 GZ, Groningen, the Netherlands. Address all correspondence to Dr Hadders-Algra at: m.hadders-algra@med.umcg.nl.

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Research has shown that evidence for the effectiveness of pediatric physical therapy on motor and cognitive development of infants with or at high risk for developmental disorders is inconclusive.[1–4] However, early pediatric physical therapy is widely advocated and desired in the management of infants at high risk for developmental disorders. In addition, current interventions primarily promote cognitive development and have little effect[1,2] or no effect[3,4] on motor development. The inconclusiveness may be related to the specific difficulties inherent in studies on early pediatric physical therapy intervention. One important difficulty for these studies is the heterogeneity of the study group. Early detection of infants at risk for a developmental disorder implies that the clinical picture of the problems that an infant will eventually develop has not yet manifested itself. In addition, there are many variations in the conditions of families such as socioeconomic status and family routines.

Another, equally important factor that might explain the inconclusiveness of results is related to the intervention itself. Treatment application often is eclectic,[5,6] which would indicate that a broad heterogeneity in implementing a treatment exists, even within treatments that adhere to the same principles.[7] Pediatric physical therapists tend to include in their treatment those techniques that they perceive as helpful, while leaving other techniques out. Presumably, this heterogeneity in treatment practice has been brought about by an evolution in treatment techniques and theoretical assumptions. Finally, the outcome measures that are chosen to evaluate the effect of an intervention might not be the appropriate ones. Usually, instruments are chosen out of habit, as well as for practical reasons, and not on the basis of information regarding test accuracy, utility, and theoretical basis.[8,9]

The best method for controlling the impact of these factors is to evaluate the effect of intervention in a randomized controlled trial (RCT). Randomized controlled trials are offered as the most quantitative and unbiased design for evaluating intervention programs.[10] Random allocation of intervention among the participants ensures that differences in group characteristics that may affect outcome are minimized. The aim is to have the groups compared as similarly as possible except for the precisely defined interventions being examined. Although RCTs are the most straightforward method for measuring effectiveness, they do not explain the underlying mechanisms that might influence outcome.[11]

Systematic reviews indicated that early intervention by the application of specific motor training programs and general developmental programs in which parents learn how to promote infant development seem most promising to influence infant motor and cognitive development.[1,2] During the last decades, it has become clear that "family centered" is a crucial aspect of interventions applied in infants and young children.[12–18] These findings and novel insights into the biological and psychological principles governing motor development after a lesion of the brain at early age[19,20] led to the development of the "Coping With and Caring for Infants With Special Needs" (COPCA) intervention program.[18,21] The family-centered COPCA program is based on: (1) a focus on the family, including an educational component,[22,23] and (2) a motor component based on the neuronal group selection theory (NGST).[20] The COPCA program aims to promote family function and motor and cognitive development. Recently, Hielkema et al[24] reported that phys-

## The Bottom Line

### What do we already know about this topic?

The evidence for the effectiveness of pediatric physical therapy for infants with developmental disorders is inconclusive. Specific motor-training programs and general developmental programs seem to offer the most promise in influencing motor and cognitive development.

### What new information does this study offer?

Three components of the "Coping With and Caring for Infants With Special Needs" (COPCA) program—(1) parent coaching, (2) challenging infants to produce motor behavior by themselves and then allowing the infants to continue this activity, and (3) stimulation of motor behavior at the limit of the infant's capabilities—were associated with improved developmental outcome.

### If you're a caregiver, what might these findings mean for you?

The findings suggest that infant development may be best promoted by offering infants the opportunities to explore the world by means of trial and error.

ical therapy actions characteristic of COPCA are associated with better motor development.

The purpose of this study was twofold. The first aim of this study was to describe the results of a randomized trial on pediatric physical therapy in infancy. In an early intervention project, the Vroege Interventie Project (VIP), we evaluated the effects of early pediatric physical therapy intervention on the developmental outcome of infants with or at high risk for developmental disorders. The effects of COPCA were compared with the effects of traditional infant physical therapy (TIP). The VIP project was designed with a dual approach. It pairs the setup of the randomized trial with that of process evaluation. The latter approach was added, as it was anticipated that heterogeneity in the application of physical therapy[7] could result in a reduction of contrast between the 2 interventions.

The second aim of this study was to investigate correlations between specific physical therapy actions characteristic of COPCA and TIP and outcome. For the purpose of this process evaluation, 2 intervention sessions per infant were video recorded and physical therapy actions observed during the interventions were quantified with the help of a standardized observation protocol.[7] The primary outcome parameter of the VIP project was the Infant Motor Profile (IMP), a new instrument developed to document motor development during infancy.[25] We recently reported that IMP scores of infants in the COPCA group and those in the TIP group did not differ. The process evaluation, however, revealed positive associations between physical therapy actions characteristic of COPCA and outcome at 18 months and negative associations between physical therapy actions characteristic of TIP and outcome.[24]

## Method

### Participants

The study groups of the VIP project consisted of infants who had been admitted to the neonatal intensive care unit of the University Medical Center Groningen between March 2003 and May 2005. At 10 weeks corrected age, a video recording was made of the infants' general movements (GMs). Infants and their families were selected to participate in the project when the quality of the infants' GMs was classified as definitely abnormal. The presence of definitely abnormal GMs at fidgety GM age (ie, at 2–4 months postterm) indicates a high risk for developmental disabilities, such as cerebral palsy (CP).[26,27] Infants with severe congenital anomalies and infants whose caregivers had an inadequate understanding of the Dutch language were excluded from the study (see flow diagram in Fig. 1). Informed consent was obtained from the infants' caregivers.

Forty-six infants participated in the VIP project. Through block randomization (full-term infants, blocks of n=2; preterm infants, blocks of n=12) the infants were assigned to receive the COPCA program (n=21) or traditional infant physical therapy (TIP) (n=25). Traditional infant physical therapy is the standard care for infants at high risk for developmental motor disorders in the Netherlands and is largely based on neurodevelopmental treatment (NDT) (see article by Dirks et al[18] in this issue). The groups were comparable on baseline characteristics, such as sex, gestational age, birth weight, and presence and severity of brain lesions (Tab. 1), but they differed on maternal education, which was significantly higher in the TIP group (Tab. 1). The randomized intervention was provided between 3 and 6 months corrected age (CA). After the intervention period, pediatric physical therapy was continued only when the pediatrician in charge of the infant considered it necessary.

### Intervention

The intervention period was between 3 and 6 months CA. The COPCA program was applied twice a week for 1 hour in the home situation by 1 of 4 specially trained pediatric physical therapists. Frequency and location of TIP intervention depended on the pediatrician's advice. In the TIP group, intervention was applied at a median frequency of once a week, mainly in the home environment by the pediatric physical therapist working in the area. Three control infants did not receive physical therapy. The pediatrician decided about continuation and type of intervention in both groups after the intervention period. As a result, 36 infants received physical therapy between 6 and 18 months CA. In the COPCA group, 15 infants continued with physical therapy (12 with COPCA [mean number of sessions=6] and 3 with TIP [mean number of sessions=33], as no COPCA coach was available), 4 infants stopped physical therapy, and data were missing for 2 infants. In the TIP group, 21 infants continued with physical therapy (mean number of sessions=14), 2 infants did not receive physical therapy between 6 and 18 months CA, and data were missing for 2 infants.

### TIP

Traditional infant physical therapy consisted of infant physical therapy as it currently is applied in the Netherlands. It is the standard care infants at high risk for developmental motor disorders receive. For the most part, TIP consists of the implementation of the "living concept" of NDT principles, which primarily focuses on the sensorimotor functional problems of the infant.[18,28] More recently,

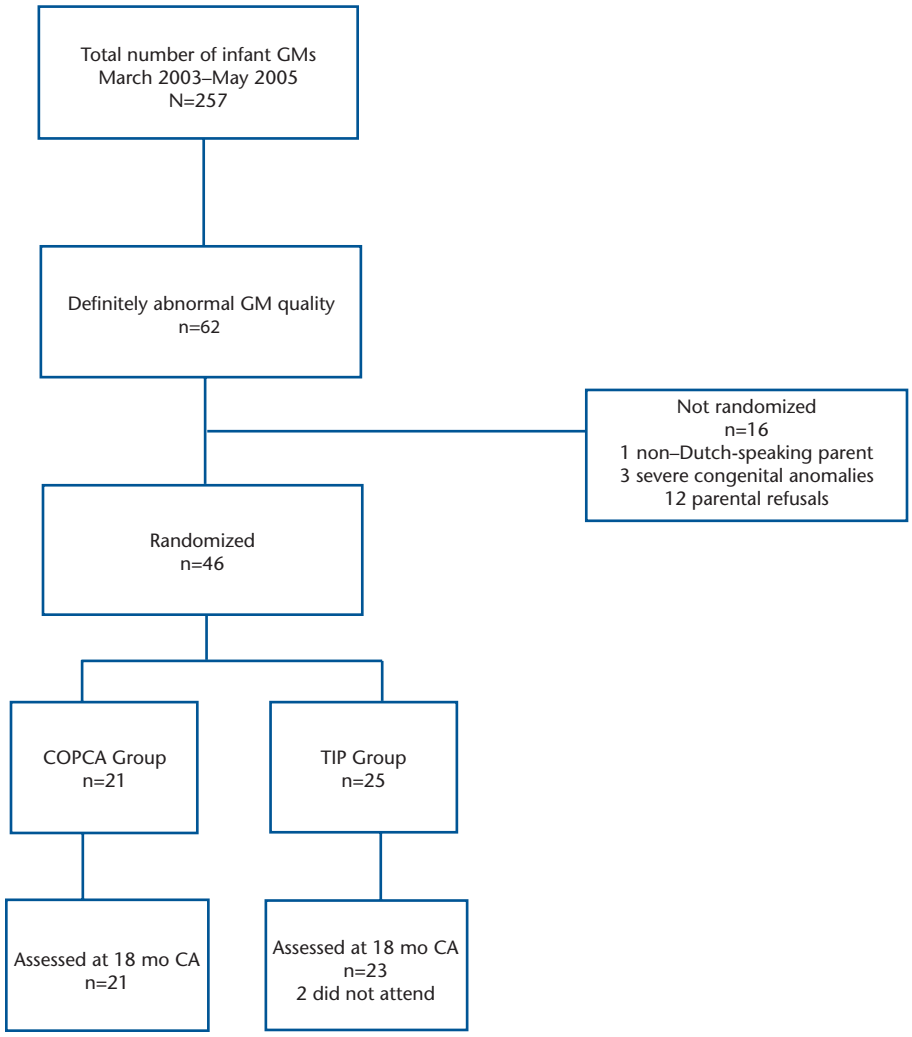


**Figure 1.**
Flow chart of recruitment of participants. COPCA=Coping With and Caring for Infants With Special Needs program, TIP=traditional infant physical therapy, CA=corrected age, GM=general movement.

influences from a more functional approach, such as the encouragement of self-produced motor behavior, have been incorporated into the treatment. The functional approach emphasizes that critical parts of motor learning are finding solutions for new task demands and adapting to changes in the environmental context.[29,30] For details on TIP, see article by Dirks et al[18] in this issue.

We recently demonstrated that TIP is applied in a very heterogeneous way in the Netherlands.[7] The spectrum varies from "classic" NDT to treatment entirely based on a functional approach. The classic NDT approach is a hands-on approach in which the therapist treats the infant by means of handling and pressure techniques, sensory experience, and motor experience followed by handling techniques. Parents have to continue the treatment techniques at home. Through guiding and training of caregivers, the therapist tries to establish carryover from treatment into activities of daily life.[31] In the functional approach, the child acts as an active participant in the therapy. The child gets the opportunity to actively explore his or her possibilities and to find the best strategies and solutions for a functional task. The treatment is composed of actions that focus on the improvement of functional tasks that are problematic in daily life. In this approach, caregivers are involved in all stages of the program (from goal setting and implementation in daily life to evaluation).[14,29]

## COPCA

The COPCA program[18,21] differs from existing approaches, both in theoretical background and in imple-

mentation.[18] It consists of 2 theoretical components. The first theoretical component is formed by a family-involvement component and an educational-parenting component. A fundamental idea of COPCA is the transactional perspective on family function, in other words, on patterns of reciprocal contingent interactions between caregiver and infant, with the notion that changing patterns of behavior are a characteristic of early development.[32,33] Thus, development is seen as a result of a continuous dynamic interplay between child behavior and caregiver responses to the child's behavior, along with environmental variables that may influence both child and caregiver.

**Table 1.**
Baseline Characteristics[a]

| Variable | COPCA Group (n=21) | TIP Group (n=25) |
|---|---|---|
| Sex, n (%) | | |
| Male | 9 (43) | 11 (44) |
| Female | 12 (57) | 14 (56) |
| Gestational age (wk), median (range) | 29 (27–40) | 30 (25–39) |
| Birth weight (g), median (range) | 1,210 (585–4,750) | 1,143 (635–3,460) |
| Maternal age (y), $\bar{X}$ (SD) | 30.5 (6.2) | 31.8 (4.3) |
| Firstborn child, n (%) | 12 (57) | 13 (52) |
| Twin pairs, n (%) | 9 (43) | 7 (28) |
| Abnormal cerebral ultrasound,[b] n (%) | | |
| IVH grade 4 or PVL grade 3–4 | 3 (14) | 3 (12) |
| Maternal education,[c] n (%) | | |
| Low | 3 (14) | 3 (12) |
| Middle | 16 (76) | 11 (44) |
| High | 2 (10) | 11 (44) |

[a] COPCA=Coping With and Caring for Infants With Special Needs program, TIP=traditional infant physical therapy.
[b] IVH=intraventricular hemorrhage (grading according to Volpe[66]); PVL=periventricular leukomalacia (grading according to de Vries et al[67]).
[c] Levels of education: low=primary education/junior vocational training, middle=secondary education/senior vocational training, high=university education/vocational colleges ($P<.05$).

Caregivers are coached to recognize the infant's signals and to respond appropriately to the actual needs of the infant.[18] Coaching implies that the pediatric physical therapist—in the COPCA program, the coach—supports all family members, including the infant with special needs, in order to reveal their competencies, goals, desires, and hopes. On the basis of an ongoing, equal partnership in which the family defines the priorities for intervention,[34] the coach supports the family members in developing their own ways of caring for the infant and in improving personal coping skills. Specific attention is paid to educational actions, such as spending brief amounts of time playing in child-preferred activities, in which the motor principles of NGST are taken into account, as well as educational actions promoting appropriate behavior.[18] For instance, family members receive suggestions for incorporating variation and trial and error in daily activities, as these factors might enhance the infant's motor repertoire and promote the ability to select the best strategy for different conditions. Some examples of variation in daily activities are those where the infant is challenged to produce self-initiated motor behavior during playing or sitting.[18]

The second, and equally important, theoretical component of COPCA is a neurodevelopmental component based on the principles of NGST.[20] Neuronal group selection theory emphasizes that development is the consequence of a complex interaction between genetic information and environmental influences. According to NGST, development is characterized by 2 phases of variability: primary and secondary. During primary variability, the child explores all of the variations of motor possibilities that are available in the nervous system. In this phase, the child is not yet able to adjust his or her behavior to external conditions. In infants who are developing typically, this phase is characterized by abundant variation. At function-specific ages, the infant reaches the phase of secondary variability, that is, the child gradually learns to select the most efficient solution for a given task out of his or her motor repertoire. This selection is based on self-produced trial-and-error experiences.[35] Infants with a prenatally, perinatally, or early postnatally acquired lesion or malformation of the brain have a reduced repertoire of motor strategies available for exploration, which is already expressed during the initial postnatal months by a limited repertoire of general movements and continues when goal-directed motility emerges.[36,37] In addition, these infants have problems with the selection of the most appropriate solution for a certain task out of the repertoire due to deficits in the processing of sensory information.[36,37]

The aim of the COPCA program, therefore, is to promote self-produced motor behavior (hands-off), variation, and trial-and-error experiences by means of play, all

with the ultimate goal of providing an infant with a wider diversity in terms of neuronal networks that will help him or her find an appropriate solution for any given motor task.

## Developmental Outcome

Apart from the primary outcome, the IMP,[24] development was assessed with a set of instruments, ranging from instruments measuring at the impairment level (neurological examination) to instruments measuring at the level of activity and participation (Pediatric Evaluation of Disability Inventory [PEDI]). The assessments were carried out by 2 people who were blinded to group allocation and well trained in the various assessment techniques. The infants were assessed at baseline (3 months CA) and at 6 and 18 months CA.

Neurological condition at 3 and 6 months was measured with the Touwen Infant Neurological Examination (TINE).[38] The neurological condition was summarized as normal, normal-suboptimal, minor neurological dysfunction (MND), or abnormal. The classification of abnormal during early infancy implies the presence of a distinct neurological syndrome such as a clear hypotonia or hypertonia, a hemi syndrome, or a hyperexcitability syndrome. To distinguish between MND, normal-suboptimal, and normal neurological conditions, the findings of the TINE were classified according to age-specific norms into 5 clusters of dysfunction: dysfunctional reaching and grasping, dysfunctional gross motor function, brain-stem dysfunction, visuomotor dysfunction, and sensorimotor dysfunction. Two forms of normal neurological development could be distinguished: neurologically normal, when none of the clusters met the criteria for dysfunction, and normal-suboptimal, when 1 or 2 clusters fulfilled the criteria for dysfunction. When more than 2 clusters fulfilled the criteria for dysfunction, infants were classified as having MND. A recent study has shown that MND can be assessed reliably with the TINE.[38]

At 18 months CA, a neurological assessment was carried out according to Hempel.[39] The findings of the Hempel assessment were classified as neurologically normal, simple MND, complex MND, or CP. The distinction between simple and complex MND also was based on the number of clusters of dysfunction. Note that the clusters of dysfunction of the Hempel assessment are similar but not identical to those of the TINE. The criteria for classification also differed for both assessments. Simple MND at 18 months denotes the presence of one cluster of dysfunction, and complex MND at 18 months denotes the presence of more than one cluster of dysfunction. The classification CP implies the presence of a "classical" configuration of neurological signs.[40] The Hempel assessment has good construct validity and satisfactory interrater reliability. No data are available on predictive validity.[41]

Additionally, we used the Neurological Optimality Score (NOS)[42] to summarize neurological condition at 18 months CA. The NOS is the sum of 57 items representing the neurological examination that meets predefined criteria for optimality. It is important to realize that the definition of *optimal* is narrower than that of *normal* or *typical* and that reduced optimality does not always mean abnormal.[43] The NOS has been proven to be an excellent instrument for evaluating subtle differences in neurodevelopmental outcome.[44]

Gross motor development was assessed with the Alberta Infant Motor Scales (AIMS).[45] The AIMS consists of 58 items that evaluate gross motor function in supine, prone, sitting, and standing positions. Through observation of spontaneous motor behavior, each item can be scored on 3 aspects of motor performance: weight bearing, posture, and antigravity movements. The AIMS has very good reliability coefficients.[8,45] In addition, the validity of the AIMS has been thoroughly examined and proven to be satisfactory.[45–47]

As previous research indicated that early intervention studies most often show an effect on cognitive development,[2] we used the Dutch version of the Bayley Scales of Infant Development (BSID-II)[48,49] to assess the cognitive outcome of the infants at 6 and 18 months CA. The Mental Developmental Index (MDI) consists of items concerning problem solving, memory, discrimination, classification, language, and social skills. Raw scores were converted into age-equivalent scores, as derived from the Dutch norms.[48] The interrater reliability of the MDI was sufficient; the construct and concurrent validity were moderate.[8]

The PEDI[50] was used to measure the functional ability of each child. The PEDI was developed for young children from 6 months to 7.5 years of age and adapted to a Dutch version by Custers et al.[51] The PEDI is a discriminative measure that aims to detect whether a child has limitations in functional status and, if so, to determine the extent and content area of the limitations. With the PEDI, both the capability of the child (what a child can do) and the performance (what the child actually does) of routine daily childhood activities can be evaluated. Capability is measured by the functional skills scale, and the caregiver assistance scale and the modifications scale provide information on performance. Each scale consists of 3 domains: self-care, mobility, and social function. The PEDI can be considered a reliable and valid instrument.[51–53]

### Analysis of the Contents of COPCA and TIP

At 4 and 6 months CA, we made video recordings of an intervention session. The people who made the video recordings were not the same as those who carried out the assessments of infant development. For 43 infants, video recordings of infant physical therapy sessions were available. The remaining 3 infants (all in the TIP group) had too few intervention sessions to make a video recording. The contents of the sessions were analyzed with a standardized observation protocol that we recently developed for analysis of physical therapy intervention sessions in young infants.[7] The protocol is based on knowledge about infant physical therapy and analysis of directly observable physical therapy and caregiver actions. Interrater and intrarater agreement proved to be satisfactory.[7] The observation protocol classifies physical therapy actions into 8 main categories:

(A) Family involvement and educational actions;
(B) Communication;
(C) Handling techniques;
(D) Sensory experience;
(E) Passive motor experience;
(F) Self-produced motor behavior, no interference from physical therapist or caregiver;
(G) Challenge to self-produce motor behavior where the infant is allowed to continue activity; and
(H) Challenge to self-produce motor behavior that flows over into therapeutic handling.

We added a variable that was the amount of postural support provided during physical therapy actions.

The analysis was carried out with the help of a Noldus computer program (The Observer, version 5.0).* The Observer software is a tool for collecting and analyzing observational data in a descriptive and quantitative way. The outcome parameters of the analysis were the relative amounts of time spent on physical therapy actions. The category self-produced motor behavior without interference of the physical therapist or the caregiver that is present in the original protocol was left out of the current analyses because of a qualitative difference between the 2 groups during the periods of entirely spontaneous activity.[18] Dirks et al,[18] in their article in this issue, report that physical therapy actions at 4 months were largely comparable to those at 6 months. Assuming that the 2 measurements at 4 and 6 months represented the actions during the intervention period better than a single measurement, we used the average of the 4-month and 6-month values for physical therapy actions in the correlations with developmental outcome.

### *Post Hoc* Analysis

Because the video analysis showed that the treatment application was very heterogeneous[18] and because, based on the literature,[1–3] we expected to find correlations between functional physical therapy actions and developmental outcome, we decided to regroup the infants. Based on the contents of the video, we reallocated the infants into intervention subgroups. Infants who received COPCA were allocated to COPCA++ or COPCA+ subgroups, and intervention sessions of infants who received TIP were classified as TIP++ or TIP+. The ++ notation indicated that the intervention was performed fully according to the principles of COPCA or TIP. In the case of TIP, this meant that the principles of the original concept of classic NDT according to Bobath were used. The + notation indicated that the contents of the intervention were more diverse. For COPCA, this notation implied that COPCA principles were applied incompletely, and for TIP, it implied that treatment consisted of a mix of actions according to the original Bobath concepts along with current NDT principles involving a more functional approach.

The classification ++ versus + was based upon the amount of time that was spent on the typical COPCA or TIP actions. Typical COPCA actions were actions where the physical therapist coached the caregiver, stimulated motor behavior at the limit of an infant's capabilities, and the infant was challenged to self-produce motor behavior that was continued by the infant. Typical TIP actions were training the caregiver, handling and pressure techniques, sensory experience, a challenge to self-produce motor behavior followed by a handling technique, and the amount of time that actions were performed while the pelvis of the infant in a supine position was lifted slightly by the hands of the physical therapist. On the basis of the average time values of the typical COPCA or TIP actions observed during the 2 intervention sessions, each infant was given a score. When the time spent on a typical action was below the 33rd percentile of the range, 1 point was given; a time score between the 33rd and 67th percentile resulted in 2 points; and a time score over the 67th percentile was given 3 points. For instance, in the TIP group, the time spent on sensory experience ranged from 0% to 36% of the treatment time, indicating that the 33rd percentile was 5% and the 67th percentile was 9.8%. A TIP video recording in which 7% of the treatment time was spent on sensory experience received 2 points. In this way, a total COPCA score (maxi-

* Noldus Information Technology, PO Box 268, 6700 AG, Wageningen, the Netherlands.

mum: 3 actions × 3 points=9) and a total TIP score (maximum: 5 actions × 3 points=15) were calculated. The cutoff for the distinction between the ++ and + classifications was the 67th percentile of the total score.

In the *post hoc* analysis, we tested whether the developmental outcome of infants who received treatment fully adherent to the principles of COPCA or TIP differed from that of infants who received intervention consisting of a mixture of techniques.

### Data Analysis

Statistical analyses were performed using the SPSS computer package (version 17.0).[†] To evaluate the effect of type of intervention (COPCA or TIP; group classification on the basis of the video contents of the physical therapy session) on developmental outcome at 6 and 18 months CA, the nonparametric Mann-Whitney *U* test was used because the data were not normally distributed. Differences having a *P* value of $<.05$ were considered statistically significant.

Physical therapy actions were correlated with developmental outcome at 6 and 18 months CA using bivariate correlations. To minimize the possibility that associations could be explained by the influence of potential confounders, partial correlations were carried out using the control variables baseline condition (neurological outcome and AIMS score at 3 months, the presence of a severe brain lesion), social factors (maternal education, being the first child or not), and factors related to the intensity of physical therapy treatment (frequency and duration of sessions). In this way, the contribution of the relative duration of physical therapy actions to outcomes on the NOS, AIMS, BSID-II, and PEDI were assessed. Because of the probability of chance capitalization, correlations with a *P* value of $\leq.01$ were considered statistically significant.

[†] SPSS Inc, 233 S Wacker Dr, Chicago, IL 60606.

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## Results

### Developmental Outcome According to Randomized Group Allocation

The developmental outcome of the 3 infants in the TIP group who had too few intervention sessions to make a video recording was similar to the other 22 infants who received TIP. Therefore, we decided to include them in the analysis of the randomized trial.

The neurological condition at 3, 6, and 18 months CA in the COPCA and TIP groups was similar (Tab. 2). At 3 months, 1 infant in the COPCA group had a normal-suboptimal neurological condition, 16 were classified as MND, and 4 showed an abnormal neurological condition. In the TIP group, 1 infant had a normal-suboptimal neurological condition, 16 were classified as MND, and 8 had an abnormal neurological condition. At 6 months, 1 infant in the COPCA group had a normal-suboptimal neurological condition, 16 were classified as MND, and 4 showed an abnormal neurological condition. In the TIP group, 20 infants were classified as MND and 5 had an abnormal neurological condition. At 18 months CA, 10 infants, 5 in each group, had developed CP. Three infants in the COPCA group and 2 infants in the TIP group were neurologically normal. The remaining infants (12 in the COPCA group, 16 in the TIP group) had complex MND. Two infants in the TIP group did not return to the follow-up at 18 months. The NOS of the COPCA group at 18 months tended to be a bit better than that of the TIP group (COPCA group, median value=31; TIP group, median value=27; Tab. 2), but the difference did not reach statistical significance.

Performance on the AIMS at 3, 6, and 18 months CA was identical for the groups. This finding was true for the total AIMS scores and the scores on the subscales (Tab. 2). The data revealed that at the age of 18 months, the AIMS suffered from a ceiling effect.[45,46] It could only differentiate between children with and without CP.

The MDI scores at 6 and 18 months CA did not differ for the COPCA and TIP groups. At 6 months CA, the median value of the MDI was 106.5 in the COPCA group and 115.5 in the TIP group; at 18 months CA, the median values of the MDI were 100 and 98, respectively. The data also indicated that in both groups the MDI decreased between 6 and 18 months CA. The decrease in MDI score from 6 to 18 months CA was statistically significant in the TIP group ($P=.001$; Fig. 2) but nonsignificant in the COPCA group ($P=.07$). The mean decrease between groups reached statistical significance when the level of maternal education was included ($P=.03$). The data indicated that infants in the COPCA group whose mother had a lower level of education showed the smallest drop in MDI score (Fig. 3). At 18 months, there were no differences between the COPCA and TIP groups on the PEDI (Tab. 2).

## Associations Between Treatment Principles and Developmental Outcome

The results of the RCT showed only minimal differences between the COPCA and TIP groups. However, we did observe changes in developmental outcome within both groups. To examine whether these changes could be associated with treatment principles used by the physical therapist or caregiver during intervention or with confounding factors, we applied process evaluation to the data. First, we analyzed the contents of the intervention sessions. The details of the analysis are described in the article by Dirks et al.[18] Typical COPCA components were: (1) physical therapist coaches the parent (coaching model), (2) to stimulate self-produced motor behavior at the limit of an infant's capabilities, and (3) infant is challenged to produce motor behavior by himself or herself and is allowed to continue activity. Typical TIP components were: (1) physical therapist teaches the infant and trains the parent (teacher-learner model), (2) in handling techniques, (3) in sensory stimulation, and (4) to challenge for self-produced motor behavior that is followed by a handling technique.

Preliminary analyses indicated that correlations between physical therapy actions and developmental outcome measurements differed for infants who developed CP (n=10) and those who did not develop CP (n=33). An overview of the associations between treatment principles and developmental outcome is presented in Table 3.

In infants who developed CP, no statistically significant associations were found between specific physical therapy actions and developmental outcome at 6 months CA. Some physical therapy actions were correlated with outcome at 18 months in the infants with CP. The COPCA-related action "infant was challenged in a widely varying way to produce motor behavior and was allowed to continue this activity" was associated with a positive outcome on the domain of mobility of the functional skills scale ($r$=.684, $P$=.004) and the domain of mobility in the caregiver assistance scale ($r$=.664, $P$=.005) of the PEDI at 18 months CA. More time spent with passive experience was associated with a lower NOS at 18 months CA ($r$=−.642, $P$=.007).

In the children without CP, the amount of time spent on coaching the caregiver showed a positive correlation with the total functional ability score of the PEDI at 18 months ($r$=.377, $P$=.007). The amount of

**Table 2.**
Developmental Outcome on the Group Level (Randomized Groups)[a]

| Variable | COPCA Group (n=21) | TIP Group (n=25) |
|---|---|---|
| 3 mo CA (baseline) | | |
| TINE (n=46) | | |
| Normal-suboptimal | 1 | 1 |
| MND | 16 | 16 |
| Abnormal | 4 | 8 |
| AIMS, median (range) | 8 (6–9) | 8 (3–11) |
| 6 mo CA | | |
| TINE (n=46) | | |
| Normal-suboptimal | 1 | 0 |
| MND | 16 | 20 |
| Abnormal | 4 | 5 |
| AIMS, median (range) | 18 (6–22) | 17 (9–22) |
| BSID-MDI, median (range) | 106.5 (50–135) | 115.5 (84–145) |
| PEDI functional skills scale, median (range) | | |
| Total score | 5 (2–7) | 6 (2–9) |
| 18 mo CA[b] | | |
| Hempel assessment | | |
| Normal | 3 | 2 |
| Complex MND | 12 | 16 |
| Abnormal/CP | 5 | 5 |
| NOS, median (range) | 31 (9–51) | 27 (10–47) |
| AIMS, median (range) | 57 (10–58) | 58 (16–58) |
| BSID-MDI, median (range) | 100 (50–119) | 98 (72–135) |
| PEDI functional skills scale, median (range) | | |
| Self-care | 24 (13–38) | 24 (11–27) |
| Mobility | 35 (6–44) | 29 (6–37) |
| Social function | 21 (11–36) | 22 (11–31) |
| Total score | 79 (36–106) | 75.5 (28–94) |

[a] COPCA=Coping With and Caring for Infants With Special Needs program, TIP=traditional infant physical therapy, AIMS=Alberta Infant Motor Scale, BSID-MDI=Bayley Scales of Infant Development Mental Developmental Index, CA=corrected age, CP=cerebral palsy, MND=minor neurological dysfunction, NOS=Neurological Optimality Score, PEDI=Pediatric Evaluation of Disability Inventory, TINE=Touwen Infant Neurological Examination.
[b] TIP group, n=23.

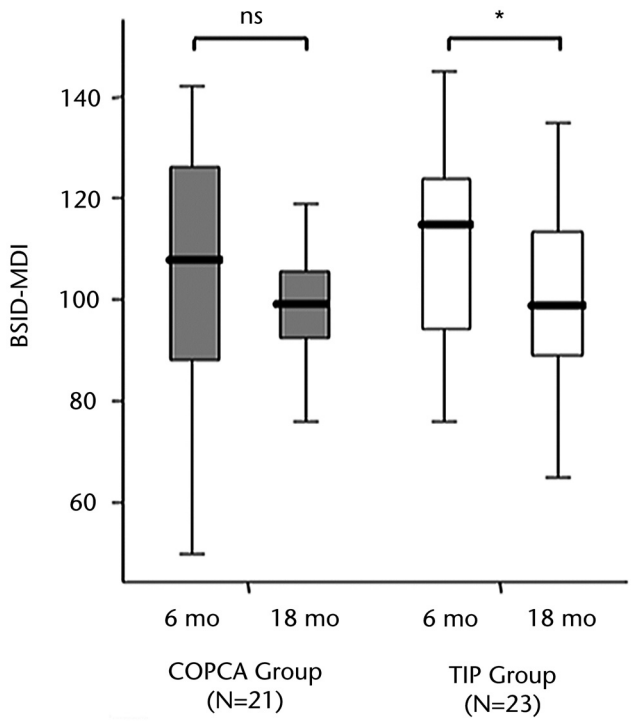


**Figure 2.**
Bayley Scales of Infant Development Mental Developmental Index scores at 6 and 18 months in the Coping With and Caring for Infants With Special Needs program (COPCA) and traditional infant physical therapy (TIP) groups. Vertical bars represent range of values, horizontal lines represent median values, boxes represent interquartile range, ns=not significant. *$P$=.001 (Wilcoxon signed ranks test).

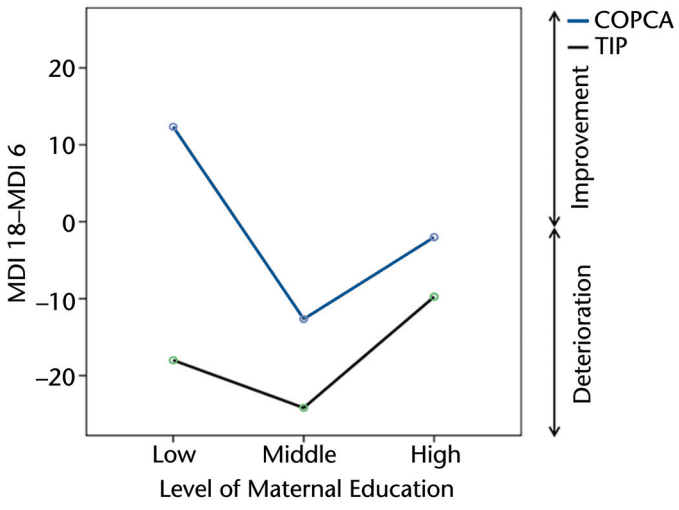


**Figure 3.**
Relative deterioration in Mental Developmental Index (MDI) score between 6 and 18 months and level of maternal education. The graphs illustrate that the difference in MDI score between 6 and 18 months was affected by the type of intervention ($P$=.03) when the level of maternal education is taken into account. COPCA=Coping With and Caring for Infants With Special Needs program, TIP=traditional infant physical therapy.

time spent on communication was positively associated with the domain self-care of the caregiver assistance scale of the PEDI at 18 months. The amount of time spent on sensory and passive experience showed a positive correlation with the MDI at 6 months ($r$=.404, $P$=.004 and $r$=.387, $P$=.005, respectively), but these associations did not persist to the age of 18 months. In children without CP, more time spent on challenging the infant to produce motor behavior that was followed by a handling technique was associated with a lower score on the total functional ability and caregiver assistance score of the PEDI at 18 months and a lower score on the domain social of the caregiver assistance scale (all $P$<.01).

### *Post Hoc* Analysis

Because the treatment application was very heterogeneous, we decided to regroup the infants into intervention subgroups on the basis of the contents of the video. This regrouping resulted in a new group allocation that is presented in Table 4. Fourteen infants were assigned to the TIP++ group and 8 infants were assigned to the TIP+ group. Seven infants were reallocated to the COPCA+ group, and 14 infants were reallocated to the COPCA++ group. The allocation of the groups based on the time spent on physical therapy actions matched the classification of the second author (T.D.) on the basis of Gestalt perception of the video recording.

Based on the new group allocation, we reanalyzed the outcome measurements. The groups did not differ in neurological classification or AIMS and MDI scores at 6 and 18 months (Tab. 5). For the domain of mobility of the functional skills scale of the PEDI at 18 months, the infants who received COPCA or TIP+ performed significantly better than the infants in the TIP++ group (Mann-Whitney

*U* test, $P<.01$; Fig. 4A). They also needed less caregiver assistance in the mobility domain at 18 months ($P=.03$; Fig. 4B). The groups did not differ in scores of the remaining PEDI scale outcomes.

## Discussion

The randomized trial revealed that COPCA and TIP were associated with similar effects for developmental outcome. The process evaluation, however, indicated that the virtual absence of difference in group effect may partially have been caused by the extensive heterogeneity in intervention strategies within the groups, especially within the TIP group. The process analysis indicated that there were some indications that important components of the COPCA intervention were associated with improved developmental outcome. The therapeutic components of intervention during early infancy, which were associated with a better developmental outcome at 18 months, were parent coaching and the application of broad variations in challenging the infant to produce motor behavior by him/herself and allowing the infant to continue this activity.

### Methodological Considerations

The major strength of this study was its double approach. The combination of the randomized trial with a process evaluation made it possible to determine the influence of the intervention on developmental outcome. Another strength of this study was that all of the infants received intervention during the same age period (ie, from 3 to 6 months postterm), which made the COPCA and TIP groups more comparable. There was hardly any attrition during the study. Only 2 infants did not return to the follow-up at 18 months CA. The final strength was that we used a set of instruments to document outcome, ranging from instruments measuring at impairment level (neurological examination) to instruments measuring the level of activity and participation (PEDI).

**Table 3.**
Overview of Associations Between Physical Therapy Actions and Developmental Outcome at 6 and 18 Months[a]

| Variable | Outcome Measure | *r* | *P* |
|---|---|---|---|
| Infants who developed CP (n=10) | | | |
| Passive motor experience | NOS 18 mo | −.642 | .007 |
| Infant challenged to produce motor behavior and allowed to continue activity (wide variation offered) | PEDI functional skills scale, mobility, 18 mo | .684 | .004 |
| | PEDI caregiver assistance scale, mobility, 18 mo | .664 | .005 |
| Infants without CP (n=33) | | | |
| Sensory experience | MDI 6 mo | .404 | .004 |
| Passive motor experience | MDI 6 mo | .387 | .005 |
| Infant challenged to produce motor behavior followed by a handling technique | PEDI caregiver assistance scale, social function, 18 mo | −.441 | .001 |
| | PEDI functional skills scale, total score, 18 mo | −.371 | .008 |
| | PEDI caregiver assistance scale, total score, 18 mo | −.379 | .007 |
| Parent coaching | PEDI functional skills scale, total score, 18 mo | .377 | .007 |
| Communication | PEDI caregiver assistance scale, self-care, 18 mo | .366 | .009 |

[a] MDI=Mental Developmental Index, NOS=Neurological Optimality Score, PEDI=Pediatric Evaluation of Disability Inventory, CP=cerebral palsy.

As mentioned in the introduction, RCTs in pediatric physical therapy have limitations. Randomized controlled trials are offered as the most quantitative and unbiased design to determine the effect of intervention by measuring the change in developmental outcome previous to and after the intervention period,[10] but they do not explain the underlying mechanisms that might influence outcome.[11] The contents of pediatric physical therapy programs rarely are analyzed, despite the fact that such analysis might serve as an eye-opener in interpreting the results of effectiveness studies. Lettinga et al[54] emphasized the importance of an in-depth understanding of the characteristics of interventions. They

**Table 4.**
Reallocation Into Intervention Groups[a]

| Classification | Total Group (n=43) | Infants With CP (n=10) | Infants Without CP (n=32)[b] |
|---|---|---|---|
| TIP++ | 14 | 3 | 11 |
| TIP+ | 8 | 2 | 5[b] |
| COPCA+ | 7 | 1 | 6 |
| COPCA++ | 14 | 4 | 10 |

[a] COPCA=Coping With and Caring for Infants With Special Needs program, TIP=traditional infant physical therapy, CP=cerebral palsy, TIP++=original Bobath approach, TIP+=mix of original Bobath and a more functional approach, COPCA+=COPCA principles applied incompletely, COPCA++=COPCA principles fully applied.
[b] One infant did not return for follow-up.

**Table 5.**
Developmental Outcome on the Group Level (After Reallocation)[a]

| Variable | TIP++ (n=14) | TIP+ (n=8) | COPCA+ (n=7) | COPCA++ (n=14) |
|---|---|---|---|---|
| 3 mo CA (baseline) | | | | |
| TINE (N=46) | | | | |
| Normal-suboptimal | 1 | 0 | 0 | 1 |
| MND | 8 | 7 | 3 | 11 |
| Abnormal | 5 | 1 | 4 | 2 |
| AIMS, median (range) | 7 (3–9) | 9 (7–11) | 8 (6–9) | 7.5 (6–9) |
| 6 mo CA | | | | |
| TINE (N=46) | | | | |
| Normal-suboptimal | 0 | 0 | 0 | 1 |
| MND | 12 | 7 | 6 | 8 |
| Abnormal | 2 | 1 | 1 | 5 |
| AIMS, median (range) | 14 (9–21) | 17 (14–22) | 18 (6–19) | 16.5 (11–22) |
| BSID-MDI, median (range) | 128 (76–145) | 117 (92–135) | 92 (50–139) | 117.5 (75–142) |
| PEDI functional skills scale, median (range) | | | | |
| Total score | 6 (2–9) | 7.5 (5–8) | 5 (2–7) | 5 (3–7) |
| 18 mo CA | | | | |
| Hempel assessment (n=44) | | | | |
| Normal | 0 | 2 | 0 | 1 |
| Complex MND | 11 | 3 | 6 | 9 |
| Abnormal/CP | 3 | 2 | 1 | 4 |
| NOS, median (range) | 26 (10–41) | 31 (13–47) | 27 (9–37) | 31.5 (16–51) |
| AIMS, median (range) | 53 (36–58) | 58 (36–58) | 57 (10–58) | 57 (15–58) |
| BSID-MDI, median (range) | 98 (65–130) | 109 (78–128) | 98 (50–109) | 101.5 (76–119) |
| PEDI functional skills scale, median (range) | | | | |
| Self-care | 24 (11–27) | 26 (14–27) | 21 (19–26) | 25 (13–38) |
| Mobility | 22 (6–37) | 35 (16–37) | 33 (6–38) | 35 (16–40) |
| Social function | 19 (11–31) | 24 (19–27) | 21 (11–24) | 22.5 (14–36) |
| Total score | 65 (28–89) | 80 (57–89) | 76 (36–83) | 82.5 (47–103) |

[a] COPCA=Coping With and Caring for Infants With Special Needs program, TIP=traditional infant physical therapy, CA=corrected age, TIP++=original Bobath approach, TIP+=mix of original Bobath and a more functional approach, COPCA+=COPCA principles applied incompletely, COPCA++=COPCA principles fully applied, TINE=Touwen Infant Neurological Examination, AIMS=Alberta Infant Motor Scale, BSID-MDI=Bayley Scales of Infant Development Mental Developmental Index, CP=cerebral palsy, MND=minor neurological dysfunction, NOS=Neurological Optimality Score, PEDI=Pediatric Evaluation of Disability Inventory.

stated that every trial that compares the effects of different types of intervention should start with a detailed analysis of the similarities and differences in the content of the interventions under study. This analysis will serve as an addition to discovering the effective and ineffective elements in the interventions and will consequently result in knowledge about the implementation of the intervention by different pediatric physical therapists in different settings. Another limitation of RCTs is related to the validity of using experimental methods in research addressing human activity, which is, for example, the case in early intervention programs. Watson et al[11] argued that changes in behavior and psychosocial issues are better evaluated with qualitative approaches, even though these approaches may be less robust. In the present study, it turned out that the qualitative aspect, the process evaluation, offered more insight into the associations between the intervention and developmental outcome than the randomized trial part.

It may be considered a limitation of the study that we studied a relatively

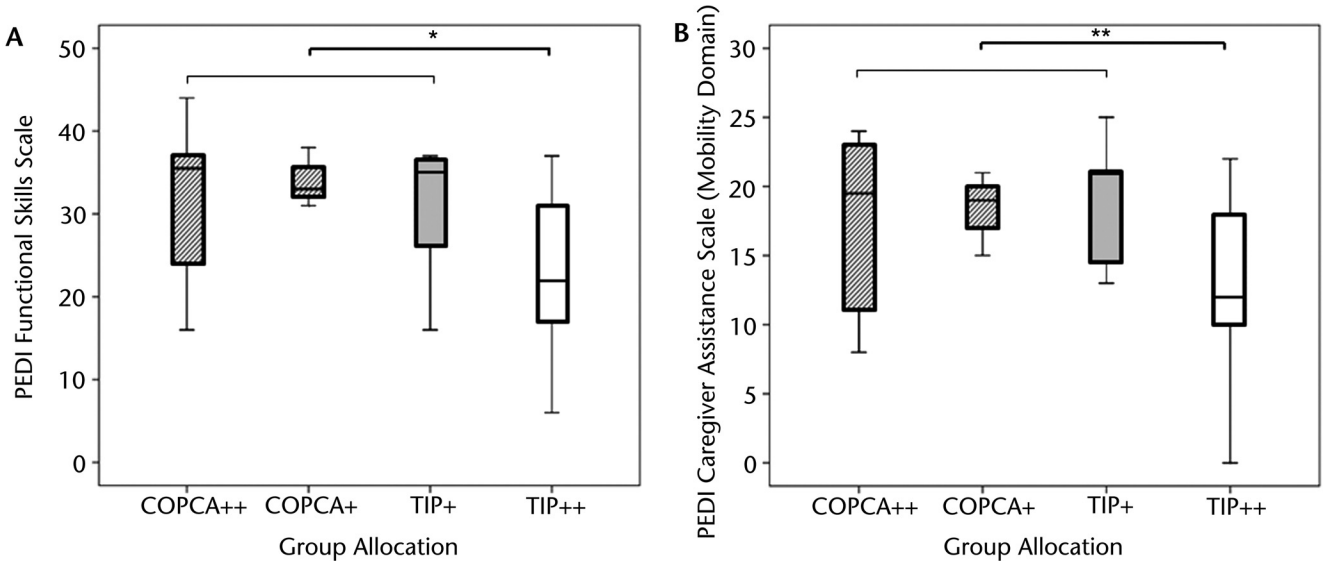


**Figure 4.**
(A) Scores on the mobility domain of the functional skills scale of the Pediatric Evaluation of Disability Inventory (PEDI) at 18 months corrected age in the COPCA+, COPCA++, TIP+, and TIP++ groups. Vertical bars represent range of values, horizontal lines represent median values, and boxes represent interquartile range. *Difference between TIP++ group and other 3 groups; $P<.01$. (B) Scores on the caregiver assistance scale in the mobility domain of the PEDI at 18 months corrected age in the COPCA+, COPCA++, TIP+, and TIP++ groups. Vertical bars represent range of values, horizontal lines represent median values, and boxes represent interquartile range. **Difference between TIP++ group and other 3 groups; $P=.03$. COPCA=Coping With and Caring for Infants With Special Needs program, TIP=traditional infant physical therapy, TIP++=original Bobath approach, TIP+=mix of original Bobath and a more functional approach, COPCA+=COPCA principles applied incompletely, COPCA++=COPCA principles fully applied.

small group of infants (N=46). Although the infants were selected because they all showed definitely abnormal GMs at 10 weeks CA, they had a heterogeneous developmental outcome. Some studies have indicated that the presence of definitely abnormal GM is associated with a high risk for developmental motor disorders such as CP.[26,27] In this study, only a minority of the infants were diagnosed with CP at 18 months. This limitation is inherent to developmental changes in the central nervous system. Developmental outcome at 18 months CA was relatively good because the median values of the MDI were 98 to 100. It should be noted that the majority of infants showed complex MND at 18 months, which puts the infant at risk for learning and behavioral disorders at school age.[40,41]

A second limitation of this study was that the treatment frequency and duration were different for both groups. Evidence suggests that higher-intensity programs are more likely to result in improved developmental outcome.[55–58] However, in the high-intensity programs in these studies, infants received treatment once a week. A recent study of Weindling and colleagues[59] showed no relationship between intensity and outcome. To account for the differences in frequency and duration between the groups, we included both factors as control variables in the process evaluation.

Another limitation is that we used 18 months CA in this study to evaluate the long-term outcome of the intervention. As mentioned previously, some developmental problems do not emerge before school age. Therefore, we recommend that future research should re-examine these children at school age. Finally, the major limitation of this study was the heterogeneity of the composition of treatment in the TIP group. We anticipated this problem by including a process analysis, thereby turning a major limitation into a major strength.

## Physical Therapy Considerations

The randomized trial revealed only minor differences between the COPCA group and the TIP group. One possible explanation for the small size of the effect is that intervention can affect developmental outcome in children with brain dysfunction to a limited extent only.[60–63] Animal and human studies indicate that intervention after a lesion of the brain at early age affects motor development considerably less than cognitive development.[3,64] Another explanation for the lack of effect could be the heterogeneity of the TIP treatment. For research purposes, it is quite nightmarish that treatment application, although

based on the same theoretical background, can be so diverse. In our opinion, this heterogeneity in infant physical therapy interferes with studies using an RCT design.

The randomized trial had 2 interesting results. First, there was a significant difference between the COPCA and TIP groups in the relative drop in MDI score between 6 and 18 months CA when the level of maternal education was taken into account. Infants whose mothers had a lower level of education showed less decline in MDI score over time than infants whose mothers had completed higher education. This effect was especially present in the COPCA group. This finding suggests that mothers with lower education benefit more from coaching by a therapist who uses COPCA principles, whereas mothers with higher education are less affected by coaching as well as training performed by a therapist. Second, the finding of a similar neurological outcome in the COPCA and TIP groups is intriguing considering the diametrically opposed view of TIP and COPCA on the importance of the neurological parameters of muscle tone (velocity-dependent resistance to stretch) and atypical movements. In the TIP treatment, especially when applied to the original concepts of Bobath or NDT, influencing tone by means of handling techniques plays an important role in the activities of the therapist during intervention sessions. In COPCA, no attention is paid to these impairments. In other words, handling techniques aimed at influencing muscle tone and facilitating movement sequences to improve function do not seem to affect neurological outcome.

Process evaluation indicated that specific components of the interventions in the study were associated with an improvement in developmental outcome. We would like to stress that observed associations are not causations. Associations between physical therapy actions and outcome are unavoidably contaminated by the child's initial degree of impairment. An infant with a more serious impairment most likely elicits different physical therapy actions than an infant with milder impairments where the degree of initial impairment to a substantial extent determines later outcome. Our data indeed revealed clear interactions between the infant's condition and therapist actions. We, therefore, studied associations separately for infants with and without CP. In addition, we used partial correlations in order to be able to take into account the infant's initial degree of impairment. Nevertheless, it also is conceivable that other infant-specific factors that we did not include in the analyses did affect the choice of physical therapy actions and the child's developmental outcome. Yet, the results of the analysis may guide our thinking about the effectiveness of specific physical therapy actions.

Two components of COPCA were associated with a higher score on the functional skills scale of the PEDI. The first component was parent coaching. In COPCA, this component implies coaching of family members to develop their own ways to care for the infant and to cope with the problems of the infant with special needs. During the intervention, 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. Second, wide variation in self-produced motor activities (hands-off), trial-and-error experiences, and, if necessary, the provision of minimal postural support creates a challenging environment in which the infant may explore and practice his or her motor possibilities.[18]

Some typical TIP actions also were associated with developmental outcome. The use of passive motor experience was correlated to a worse performance on the NOS, and challenging the infant to produce motor behavior that was followed by a handling technique was associated with a lower total score on the functional ability and caregiver assistance scale. On the other hand, sensory and passive experiences were associated with a higher MDI immediately after the intervention period. Perhaps sensory and passive experiences reflect situations of increased infant attention that may promote cognitive development.[65] Our data indicated that this beneficial effect disappeared over time.

Because we expected the treatment application to be heterogeneous, we *a priori* included video recordings. The results showed that our expectation was correct (for details, see the article by Dirks et al[18] in this issue) and that functional aspects of intervention were associated with improved developmental outcome. Eventually, the quantification of the intervention sessions gave us the opportunity to perform a *post hoc* analysis. Infants were regrouped on the basis of the contents of the video into intervention subgroups. Although this approach lacks the advantages of an RCT, it was interesting to see that infants in the COPCA group and in the functional TIP group scored better on the domain mobility on the functional skills scale and needed less caregiver assistance for domain of mobility on the PEDI than infants who received TIP treatment according to the original Bobath approach. It was interesting to observe that the effects of intervention were clearer at 18 months CA than immediately after the intervention at 6 months CA.

This finding could imply that coaching influences infant development. On the other hand, it also is possible that the inherent mobility of the infant facilitates a greater tendency for coaching and less "handling" from the therapist. Further studies will have to explore these associations to an extent that can inform about causality. Our findings were in accordance with the findings of Hielkema et al,[24] who also found positive correlations between physical therapy actions characteristic for COPCA and developmental outcome at 18 months CA measured with the IMP. The findings perhaps are related to the COPCA approach, which aims at supporting family members on the basis of an ongoing, equal partnership in order to uncover their own specific problem-solving strategies for caring and coping with the infant with special needs.

## Conclusions

The study showed that our nightmare had a good outcome. Extending the randomized trial with process evaluation was necessary in order to answer the question about what components of intervention are associated with developmental outcome. The study showed that 3 components of COPCA—(1) parent coaching, (2) challenging the infant with a wide variation to produce motor behavior by himself or herself and then to allow the infant to continue this activity, and (3) stimulation of motor behavior at the limit of the infant's capabilities—were associated with improved developmental outcome. Further studies are needed to explore the direction of the associations.

Dr Blauw-Hospers, Ms Dirks, and Dr Hadders-Algra provided concept/idea/research design. Dr Blauw-Hospers, Ms Dirks, Dr Bos, and Dr Hadders-Algra provided writing. Dr Blauw-Hospers, Dr Hulshof, and Dr Hadders-Algra provided data analysis. Dr Hadders-Algra provided project management, fund procurement, facilities/equipment, and institutional liaisons. Dr Bos provided participants and consultation (including review of manuscript before submission).

The research project was approved by the Medical Ethics Committee of University Medical Center Groningen.

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Cornill H. Blauw-Hospers, Tineke Dirks, Lily J. Hulshof, Arend F. Bos and Mijna Hadders-Algra

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