



Effect of early intervention on functional outcome at school age: Follow-up and process evaluation of a randomised controlled trial in infants at risk



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ABSTRACT

Background: The long-term effect of early intervention in infants at risk for developmental disorders is unclear. The VIP project ($n = 46$, originally) evaluated by means of a randomised controlled trial the effect of the family centred early intervention programme COPCA (Coping with and Caring for infants with special needs) in comparison to that of traditional infant physiotherapy (TIP).

Aims: To evaluate the effect of early intervention on functional outcome at school age.

Methods and procedures: Parents of 40 children (median age 8.3 years) participated in this follow-up study. Outcome was assessed with a standardised parental interview (Vineland Adaptive Behaviour Scale) and questionnaires (Developmental Coordination Disorder Questionnaire, Child Behaviour Checklist, Utrechtse Coping List, and questions on educational approach). Quantified video information on physiotherapeutic actions during infancy was available.

Outcomes and results: Child functional outcome in the two randomised groups was similar. Process evaluation revealed that some physiotherapeutic actions were associated with child mobility and parental educational approach at follow-up: e.g., training and instructing were associated with worse mobility.

Conclusions and implications: Functional outcome at school age after early intervention with COPCA is similar to that after TIP. However, some specific physiotherapeutic actions, in particular the physiotherapist's approach, are associated with outcome.

What this paper adds: Early intervention is generally applied in infants at risk for developing disorders, with the aim of improving overall functional outcome. However, little is known on the long-term effect.

The VIP project evaluated by means of a randomised controlled trial the effect of the family centred early intervention programme COPCA (Coping with and Caring for infants with special needs) in comparison to that of traditional infant physical therapy (TIP). Outcome at 18 months corrected age was virtually similar. Process evaluation of the physiotherapy actions revealed that some characteristics of COPCA were associated with improved developmental outcome at 18 months.

This paper presents data on functional outcome at school age (median 8.3 years) in 87% of the original participants. Outcome of infants who received three months of COPCA and that of infants who received three months of TIP was similar. Yet, parents of families who had received the COPCA intervention still more often used a trial and error approach when the child learned a new skill than parents of children who had received TIP. Process evaluation showed that more time spent on caregiver training and strict instructions during early intervention was associated with worse mobility. Four other physiotherapeutic actions were associated with parental educational approach. None of the neuromotor actions were associated with child outcome at school age.

We conclude that long-term outcome after three months of COPCA or TIP is similar. However, our study does suggest that the professional approach of the physiotherapist can make a difference.

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1. Introduction

The long-term effect of early intervention in infants at risk for developmental disorders remains unclear. A recent Cochrane meta-analysis on early intervention in preterm born children demonstrated a small positive effect of early intervention on motor and cognitive outcome in infancy, with the cognitive effect persisting into preschool age [1]. Only a few studies evaluated developmental outcome after pre-school age [1]. The data available suggest no or inconclusive effects of early intervention. The present study aims to contribute to the limited knowledge on the effect of early intervention on developmental outcome at school age.

One of the factors that might explain the small effect of early intervention on developmental outcome is our limited understanding of which elements of intervention are effective in promoting better outcome [1–3]. It has been assumed that general developmental programmes and parental coaching are most effective [2,4]. In line with these suggestions of the literature, the family centred COPCA (COPing with and Caring for infants with special needs) programme had been developed [5,6]. Strengthening of family autonomy and participation, and promotion of infant mobility are the major goals of the COPCA programme. COPCA focuses on the family and includes educational components. The neurodevelopmental component of COPCA is based on the neuronal group selection theory (NGST) [7,8].

The VIP project (Dutch: Vroegtijdig Interventie Project) evaluated, by means of a two arm randomised controlled trial (RCT), the effect of 3 months of COPCA in early infancy in comparison to that of 3 months of traditional infant physiotherapy (TIP) in infants at risk for developmental disorders. The at risk infants had been admitted to the neonatal intensive care unit (NICU) of the University Medical Centre Groningen and showed definitely abnormal general movements at 10 weeks corrected age (CA), indicating that they had a high risk for developmental disorders like cerebral palsy (CP). As paediatric physiotherapy is characterized by heterogeneity, we presumed that the contents of the two intervention programmes would overlap. We therefore had expected that the difference in outcome of the two randomised groups might be minimal. Indeed, at 18 months CA we only found a minor advantage of COPCA for cognitive development, when the level of maternal education was taken into account [9]. In anticipation, we therefore had video recorded physiotherapy sessions, as quantification of the contents of the physiotherapy sessions would allow for process evaluation. The process evaluation of the physiotherapy actions revealed that some characteristics of COPCA were associated with improved developmental outcome. For example, in children at 18 months diagnosed with CP, i) the time spent on the physiotherapy action “challenging the infant to self-produced motor behaviour, continued by the infant with little variation”, had a positive association with the quality of the child's motor behaviour, and ii) the time spent on caregiver coaching had a positive correlation with the child's ability to adapt motor behaviour at 18 months CA. Other physiotherapy actions that were positively associated with the child's functional mobility were “family involvement and educational actions”, “postural support at the verge of the infant's abilities” and “challenging the infant to self-produced motor behaviour, continued by the infant with large variation”. In addition, the analyses indicated that spending more time on some TIP actions, such as handling techniques, was associated with worse developmental outcome [9,10]. In children with CP, the time spent on sensory experiences showed a negative correlation with the quality of the child's motor behaviour, and passive motor experiences were negatively associated with a neurological optimality score. In children without CP, more time spent on facilitation was associated with a lower functional mobility, and the time spent on “instructing the caregiver by means of assigning” showed a negative correlation with movement fluency at 18 months CA.

The aim of the present VIP follow-up study was to evaluate the effect of COPCA and TIP on outcome at school age. Long-term evaluation of early intervention is needed, as a) new associations between

physiotherapy actions during early intervention and outcome may emerge, as i) parents may continue to apply throughout childhood the physiotherapy principles they learned during early intervention, and ii) the child develops new functions that may depend on early life experiences; b) previously present associations between physiotherapy actions and outcome during infancy may fade and disappear. In line with the framework of the International Classification of Functioning Disability and Health, Child and Youth version (ICF-CY) and in accordance with the current focus of paediatric rehabilitation on activities and participation [11–13], we evaluated the children's functional outcome with assessment tools addressing the activity and participation domain. To this end, we used parental interviews and questionnaires to obtain information on the children's functional performance in daily life activities. Therefore, our primary outcome measurement was the Vineland Adaptive Behaviour Scale (VABS) [14]. Secondary outcome measurements included 1) the children's mobility and behaviour, and 2) parental coping strategies and educational approach. Next to the analyses of outcome at RCT level – and in line with the analyses performed for outcomes in infancy – we performed process evaluation in order to gain more insight into the possible working mechanisms of early intervention. We hypothesised that if families had incorporated the early intervention strategies into daily life, the earlier found associations between physiotherapy actions and developmental outcome might still be present.

2. Methods

2.1. Design overview

The present study is the follow-up of the VIP project, in which we compare functional outcome at school age of children who received either COPCA or TIP as early intervention. We sent an invitation letter to the parents of the VIP-children who participated in the final assessment of the original VIP-study at 18 months CA ($n = 44$, Fig. 1). The Medical Ethics Committee of the University Medical Centre Groningen approved the follow-up study (trial number NL39954.042.12).

2.2. Setting and participants

Inclusion in the VIP project was based on the presence of definitely abnormal general movements around 10 weeks CA (for details see references [9,10]). Infants with congenital anomalies and infants whose caregivers had an inappropriate understanding of the Dutch language were excluded. The infants had been admitted to the Neonatal Intensive Care Unit of the University Medical Centre Groningen between March 2003 and May 2005.

2.3. Randomization and interventions

Off-site participants had been randomly assigned with a random sequence generator to COPCA ($n = 21$) or TIP ($n = 25$). Intervention was applied between 3 and 6 months CA. The COPCA intervention took place in the home situation twice a week for 1 h. The frequency and location of the TIP intervention depended on the paediatrician's advice – it was mostly provided at home. Three infants assigned to TIP intervention did not receive physiotherapy. After the age of 6 months CA, the child's paediatrician decided whether to continue intervention [10]. Both COPCA and TIP interventions were provided by paediatric physiotherapists with over five years of experience in treating infants and children with special needs. A short description of the intervention in the two arms is provided below, for detailed information on the content of the interventions, see Dirks et al. and Blauw-Hospers et al. [5,9].

2.3.1. COPCA

COPCA is a family relationship oriented programme that theoretically consists of two main components. The first component includes

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