

Follow-up at school age after early intervention in infancy

Published: 03-05-2011

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To evaluate the long-term effects of early intervention in high-risk infants on the basis of the VIP-project.

Ethical review	Not approved
Status	Will not start
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational non invasive

Summary

ID

NL-OMON36287

Source

ToetsingOnline

Brief title

VIP follow-up

Condition

- Congenital and peripartum neurological conditions

Synonym

Cerebral Palsy, Developmental disorders

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W,ZONMW

Intervention

Keyword: COPCA, Developmental Disorders, Early intervention

Outcome measures

Primary outcome

Functioning in daily life (communication, daily living skills, socialization and motor skills) as measured by the Vineland Adaptive Behavior Scale (VABS).

Secondary outcome

Secondary measurements:

- Developmental Coordination Disorder Questionnaire (DCD-Q)
- Child Behavior Check List (CBCL)
- General Health Questionnaire; GHQ)
- Utrechtse Coping Lijst (UCL)
- Family Empowerment Scale (FES)
- Vragenlijst VIP fysiotherapie

Study description

Background summary

Between March 2003 and May 2006 high-risk infants were randomly assigned to study the effects of early paediatric physical therapeutical intervention on developmental outcome of infants with or at high risk for developmental disorders. The effects of a recently developed early intervention program COPCA (Coping with and Caring for infants with special needs * a family centered program) were compared to the effects of traditional infant physical therapy (TIP). The randomized intervention was applied between 3 and 6 months corrected age (CA). Outcome was monitored during the intervention, immediately after the intervention (at 6 months CA) and at 18 months CA with a large assessment battery including instruments to monitor neurological, motor, cognitive and functional development.

At the level of the RCT only a minimal advantage of COPCA intervention was found on cognitive development. The study showed that the contents of COPCA intervention partially overlaps with that of TIP, a situation which interferes with the RCT-design of the study. Additional process analyses of the contents

of the intervention revealed that some positive associations were found between characteristics of COPCA intervention and developmental outcome at 18 months. This suggests that it takes time before a beneficial effect of COPCA-approach emerges. Therefore we are interested in the long-term effects of early intervention.

Study objective

To evaluate the long-term effects of early intervention in high-risk infants on the basis of the VIP-project.

Study design

This study is a follow-up study of the VIP project (MEC 98/06/106).

Duration: data-collection July 2011 * November 2011; data-analysis November 2011 * April 2012.

Setting: VIP-project, n= 46 children. The infants had been recruited at the neonatal intensive care unit of the UMCG. Intervention was carried out in the infant*s home and coordinated by the UMCG-team. The current evaluation will be carried out by the UMCG-team. Caregivers will be interviewed by phone and questionnaires will be sent by mail.

Intervention

COPCA (Coping with and caring for infants with special needs - a family centered program) versus Traditional Infant Physiotherapy (TIP).

Study burden and risks

No risks is associated with participation in the follow-up study. The burden of the study: interviews will be carried out by phone and questionnaires will be filled in by parents at home. Costs/burden of parents/researchers concern mainly about an investment of time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Infants and their families who participated in the VIP project are eligible for this follow-up study.

In the VIP project were infants included who presented definitely abnormal general movements at ten weeks corrected age, which indicates that they were at risk for developmental disorders.

Exclusion criteria

Infants with severe congenital anomalies, such as serious congenital heart disorders, and infants whose caregivers had an inappropriate understanding of the Dutch language were already excluded in the VIP project.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	46
Type:	Anticipated

Ethics review

Not approved	
Date:	03-05-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	ISRTCN52740878
CCMO	NL34198.042.10