Early Intervention Project.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25976

Source
Nationaal Trial Register

Brief title
VIP

Health condition

High risk of cerebral palsy indicated by the presence of definitely abnormal general movements at the corrected age of 3 months.

Sponsors and support

Primary sponsor: BCN
University Medical Centre Groningen
Postbus 30001 9700 RB Groningen
Bezoekadres Hanzeplein 1 Groningen
Prof. Dr. M. Hadders-Algra
Source(s) of monetary or material Support: Johanna Kinderfonds
Stichting Fonds de Gavere

Intervention

Outcome measures

Primary outcome

Neuromotor condition.

Secondary outcome

1. PEDI;

2. KID-N and Bayley MDI;

3. Parameters of postural control;

4. NVOS;

5. MPOC.

Study description

Background summary

The VIP project is designed for children with a high risk of the development of developmental disabilities.
Recently, it has been demonstrated that the quality of general movements (GM), i.e. complex movements which involve head, trunk and legs, at the age of 2 to 4 months corrected age has a predictive value for further developmental outcome.
Definitely abnormal GM's at this age are associated with a high risk for the development of cerebral palsy. The early detection of infants at high risk offers the opportunity for intervention at young age during a phase in which the central nervous system is characterized by high plasticity.
A new type of intervention named COPCA, Coping with and Caring for infants with neurological dysfunction, is evaluated in this project.
The goals of the project are to evaluate the COPCA intervention on motor and psychosocial functioning of the child and autonomy of the child and its parents and to evaluate the application of COPCA in daily practice. To this end, 40 infants with definitely abnormal General Movements in the tenth week corrected age will be selected.
The children will be recruited from the children born in the UMC Groningen. After randomization these children will be allocated into two groups of 20 children, COPCA or control.
The effects of the COPCA intervention are determined at both short (during and immediately after intervention) and long term (1 year after the end of the intervention).
The evaluation focuses on 3 functional levels:
a) neuromotor functioning,
b) psychosocial functioning, including parent-infant interaction,
c) neurophysiological parameters of postural control.

Study objective

Intervention with the recently developed COPCA method improves developmental outocme at

6 and 18 months more than traditional types of early physiotherapeutical intervention.

Intervention

COPCA = COPing with and CAring for infants with neurological dysfunction.

Contacts

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Eligibility criteria

Inclusion criteria

Infants who have been referred to the NICU of the Beatric Children's Hosptial of the UMCG and who have definitely abnormal general movements at the corrected age of 3 months.

Exclusion criteria

1. Presence of severe congenital anomaly;

2.Inappropriate parental understanding of the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2003
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-09-2005
Application type:	First submission

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
NTR-new	NL323
NTR-old	NTR361
Other	: N/A
ISRCTN	ISRCTN85728836

Study results

Summary results

Hospers CH, Van der Graaf-Peters VB, Hadders-Algra M. Het vroegtijdige interventie project in Groningen. Ned Tijdschr Kinderfysiother, 2004; 16, nr 40: 14-16.
Hadders-Algra M, Dirks T, Blauw-Hospers C, De Graaf-Peters V. The Kozijavkin method: giving parents false hope? Lancet 2005; 365:842.
Blauw-Hospers CH, Hadders-Algra M. A systematic review on the effects of early intervention on motor development. Dev Med Child Neurol 2005; 47: 421-32.