

Early Intervention Project.

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Intervention with the recently developed COPCA method improves developmental outcome at 6 and 18 months more than traditional types of early physiotherapeutical intervention.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25976

Bron

Nationaal Trial Register

Verkorte titel

VIP

Aandoening

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

Ondersteuning

Primaire sponsor: BCN

University Medical Centre Groningen
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Bezoekadres Hanzeplein 1 Groningen
Prof. Dr. M. Hadders-Algra

Overige ondersteuning: Johanna Kinderfonds
Stichting Fonds de Gavere

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Intervention with the recently developed COPCA method improves developmental outcome at 6 and 18 months more than traditional types of early physiotherapeutical intervention.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Presence of severe congenital anomaly;
2. Inappropriate parental understanding of the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-03-2003
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	12-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL323
NTR-old	NTR361
Ander register	: N/A
ISRCTN	ISRCTN85728836

Resultaten

Samenvatting resultaten

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.