

Learn to move 0-2 years: early intervention in children with cerebral palsy.

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COPCA (Coping and Caring) intervention in infants at high risk for cerebral palsy will result in better functioning than Traditional Paediatric Therapy.

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

Samenvatting

ID

NL-OMON19995

Bron

Nationaal Trial Register

Verkorte titel

L2M 0-2

Aandoening

Cerebral Palsy; Cerebrale Parese

Ondersteuning

Primaire sponsor: Prof. dr. M. Hadders-Algra

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Overige ondersteuning: ZONMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Motor performance as measured by the Infant Motor Profile (IMP).

Toelichting onderzoek

Achtergrond van het onderzoek

Cerebral Palsy (CP) is the most common cause of physical disability in paediatric rehabilitation. Current interventions in infants with or at high risk for CP do not have a beneficial effect on motor or cognitive performance. Theoretically however, intervention at early age when the brain is very plastic, should be more effective than intervention which starts beyond infancy. Preliminary data of an on-going project on infants with early brain dysfunction mostly not resulting in CP suggest that the new programme "Coping with and caring for infants with neurological dysfunction – a family centred program" (COPCA; Dirks & Hadders-Algra) produces better motor and cognitive outcomes at 18 months than traditional physiotherapeutic care. The present study aims at testing the effectiveness of COPCA in infants with CP.

In a randomized controlled trial 40 infants meeting strictly defined criteria indicating with high certainty the presence of CP at the corrected age of 3-9 months will receive either COPCA or traditional paediatric physiotherapy for the duration of 1 year. Infants and their parents will be assessed with a large set of tests aiming at measuring motor and cognitive function, quality of life and family related measures at baseline and at 3, 6 and 12 months after onset of intervention. In addition working mechanisms of the intervention will be studied by means of detailed analyses of postural development and quantitative video-analyses of therapeutic sessions and daily life activities.

Doel van het onderzoek

COPCA (Coping and Caring) intervention in infants at high risk for cerebral palsy will result in better functioning than Traditional Paediatric Therapy.

Onderzoeksopzet

Baseline, and after 3, 6 and 12 months.

Onderzoeksproduct en/of interventie

COPCA (Coping with and caring for infants with neurologic dysfunction; Dirks & Hadders-

Algra) is a new treatment programme for children with cerebral palsy.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Infants (3-9 months corrected age) at very high risk for CP or with CP and their families.
2. Participating caregivers must have sufficient comprehension of the Dutch language.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Children with additional severe congenital disorders, such as serious congenital heart

disorder

Onderzoeksopzet

Opzet

| | |
|------------------|------------------------|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blinding: | Enkelblind |
| Controle: | Actieve controle groep |

Deelname

| | |
|-------------------------|----------------------|
| Nederland | |
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-01-2009 |
| Aantal proefpersonen: | 40 |
| Type: | Verwachte startdatum |

Ethische beoordeling

| | |
|-----------------|------------------|
| Positief advies | |
| Datum: | 30-07-2008 |
| 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 | NL1368 |
| NTR-old | NTR1428 |
| Ander register | : 890000002 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

Resultaten

Samenvatting resultaten

- Blauw-Hospers CH, De Graaf-Peters VB, Dirks T, Bos AF, Hadders-Algra M. Does early intervention in infants at high risk for a developmental motor disorder improve motor and cognitive development? *Neurosci Biobehav Rev* 2007a; 31: 1201-12.

- Dirks T, Hadders-Algra M. COPCA - Coping with and Caring for infants with neurological dysfunction - a family centered program. Handleiding, nog niet officieel uitgeven, 2003.

- Hadders-Algra M. The Neuronal Group Selection Theory: an attractive framework to explain variation in normal motor development. *Dev Med Child Neurol* 2000a; 42: 566-72.

- Hadders-Algra M. The Neuronal Group Selection Theory: promising principles for understanding and treating developmental motor disorders. *Dev Med Child Neurol* 2000b; 42: 707-15.