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

No registrations found.

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

Summary

ID

NL-OMON19995

Source
Nationaal Trial Register

Brief title
L2M 0-2

Health condition

Cerebral Palsy; Cerebrale Parese

Sponsors and support

Primary sponsor: Prof. dr. M. Hadders-Algra
University Medical Centre Groningen
Developmental Neurology (Postbox CA85)
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Source(s) of monetary or material Support: ZONMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- Neurological condition according to Touwen
Infant motor skills as measured with AIMS, GMFM, and Bayley Scales, Psychomotor Development Index.

- Cognitive development as measured with Bayley Scales, Mental Development Index.

- Daily life functioning as measured with the VABS and PEDI.

- Quality of life as measured with the ITQOL.

- Family related outcomes: video-analysis of caregiver's behaviour, UCL, NOSI-K, MPOC, FES.

- Working mechanisms: postural control by means of multiple surface EMG recordings and Kinematics. Assesment of actual contents of COPCA and TPP sessions by means of video recordings. Weekly diaries and DAIS.

Study description

Background summary

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.

Study objective

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

Study design

Baseline, and after 3, 6 and 12 months.

Intervention

COPCA (Coping with and caring for infants with neurologic dysfunction; Dirks & Hadders-Algra) is a new treatment programme for children with cerebral palsy.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2009
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-07-2008
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	NL1368
NTR-old	NTR1428
Other	: 890000002
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

- 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 officiëel 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.