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Learn to Move 0-2 years: Early intervention in children with cerebral palsy

Submission date	Recruitment status	[X] Prospectively registered
09/09/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/09/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/02/2009	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
60-61300-98-003

Study information

Scientific Title

Acronym
L2M0-2

Study objectives
One year of intervention with the new physiotherapeutic programme COPCA (see Interventions) results in a better motor developmental outcome than one year of intervention by means of traditional paediatric physiotherapy in infants at very high risk for cerebral palsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 11/02/2009: Medical Ethics Committee of the University Medical Centre Groningen gave approval on the 24th October 2008 (ref: METc2008.176)

Study design
Randomised single-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cerebral palsy

Interventions
COPCA = "COPing with and CAring for infants with neurological dysfunction" programme:
The COPCA programme is a home based programme, and will be delivered by specially trained paediatric physiotherapists. The COPCA programme has motor and educational goals.

The motor goals:
a. To increase the infant's motor repertoire
b. To improve the ability to select a specific strategy fit for function in a specific daily life situation

Educational goals:
a. Promotion/restoration of intuitive parenting capacities, which in general are seriously

affected in caregivers of infants with neurological disability
b. Coaching family members in such a way that they are able to cope well with life, including the developmental problems of the child

Schedule of the COPCA programme: 1 hour/session, 2 sessions per week for the first 6 months, and then 1 session every 2 weeks for the next 6 months (total duration of the programme: 1 year)

Description of the COPCA programme can be found at: http://www.ncbi.nlm.nih.gov/pubmed/17555816

The participants in the control group will receive traditional paediatric physiotherapy for 1 year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Score on the Infant Motor Profile (IMP) at baseline, after 3, 6 and 12 months after start of intervention.

Secondary outcome measures
1. Neurological condition, assessed at 3, 6 and 12 months
2. Alberta Infant Motor Scale (AIMS), assessed at 3, 6 and 12 months
3. Gross Motor Function Measure (GMFM), assessed at 3, 6 and 12 months
4. Bayley Scales of Infant Development (BSID), assessed at 3, 6 and 12 months
5. Vineland Adaptive Behavior Scales (VABS), assessed at 6 and 12 months
6. Pediatric Evaluation of Disability Inventory (PEDI), assessed at 12 months
7. Nijmeegse Ouderlijke Stress Index (NOSI-K), assessed at 12 months
8. Utrecht Coping List (UCL), assessed at 12 months
9. Family Empowerment Scale (FES), assessed at 6 and 12 months
10. Measure of Processes Of Care (MPOC), assessed at 12 months

Overall study start date
01/01/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Both males and females, corrected age at enrolment 3 to 9 months
2. At very high risk for cerebral palsy (CP), based on the presence of one of the following:
a. Cystic periventricular leukomalacia (PVL), diagnosed on serial ultrasound assessment of the brain
b. Uni- or bilateral parenchymal lesion of the brain

c. Term/near term asphyxia resulting in Sarnat 2 or 3 with brain lesions on magnetic resonance imaging (MRI) and/or neurological dysfunction during infancy suggesting the development of CP
d. Neurological dysfunction suggestive of development of CP

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Months

Upper age limit
9 Months

Sex
Both

Target number of participants
40 (2 groups of 20 children)

Key exclusion criteria
1. Caregivers have insufficient understanding of the Dutch language
2. Infants who have an additional severe congenital disorder, such as a serious congenital heart disorder

Date of first enrolment
01/01/2009

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
PO Box 30001
Groningen
Netherlands
9713 GZ

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details
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Sponsor type
Research organisation

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http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)
(ref: 60-61300-98-003, thema II [kinderen])

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration