

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

Submission date 09/09/2008	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 19/09/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 11/02/2009	Condition category Nervous System Diseases	☐ Individual participant data
		☐ 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

Protocol serial number
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)

Primary study design

Interventional

Study design

Randomised single-blind controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 Months

Upper age limit

9 Months

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration