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Early Intervention Project: a multi-level evaluation of early (physiotherapeutical) intervention in infants at high risk for the development of cerebral palsy

Submission date
19/12/2005

Recruitment status
No longer recruiting

Registration date
19/12/2005

Overall study status
Completed

Last Edited
17/06/2019

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof M Hadders-Algra

Contact details
University Medical Center Groningen
Beatrix Children's Hospital
P.O. Box 30001
Groningen
Netherlands
9700 RB
-
m.hadders-algra@med.umcg.nl

Additional identifiers

Protocol serial number
NTR361

Study information

Scientific Title
Early Intervention Project: a multi-level evaluation of early (physiotherapeutical) intervention in infants at high risk for the development of cerebral palsy

Acronym
VIP

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Primary study design
Interventional

Study design
Randomised active controlled parallel group trial

Study type(s)
Treatment

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

Interventions
Intervention: COPCA = COPing with and CAring for infants with neurological dysfunction.
Control: traditional types of early physiotherapeutical intervention.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Neuromotor condition.

Key secondary outcome(s)
1. Pediatric Evaluation of Disability Inventory (PEDI)
2. KID-N and Bayley MDI
3. Parameters of postural control
4. NVOS
5. MPOC

Completion date

29/02/2008

Eligibility

Key inclusion criteria
Infants who have been referred to the Neonatal Intensive Care Unit (NICU) of the Beatrix Children's Hospital of the Unversity Medical Centre Groningen (UMCG) and who have definitely abnormal general movements at the corrected age of 3 months.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
46

Key exclusion criteria
1. Presence of severe congenital anomaly
2. Inappropriate parental understanding of the Dutch language

Date of first enrolment
01/03/2003

Date of final enrolment
29/02/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Centre Groningen (UMCG) (Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Charity

Funder Name
Johanna Children's Fund (Johanna Kinderfonds) (The Netherlands)

Funder Name
The Foundation Fund Gavere (Stichting Fonds de Gavere) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011		Yes	No
Results article	results	01/04/2019	17/06/2019	Yes	No