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The prevention of developmental and behavioural problems of very preterm infants and parental stress through the use of development care: an intervention program for infants and parents

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/10/2009	Pregnancy and Childbirth	

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
NTR258; ZonMw number: 2100.0072

Study information

Scientific Title

Acronym
LDCS (the Leiden Developmental Care Study)

Study objectives
Developmental care has a positive outcome on the development and behaviour of very preterm infants and parental stress.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee gave approval prior to recruitment.

Study design
Multicentre randomised active controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Developmental and behavioural problems

Interventions
Two interventions (randomised control trials) in two consecutive phases:

Phase 1:
Reducing environmental stress through the use of covers over the incubators to decrease excess light and sound, the use of positional aids such as boundary supports and nests to promote a balance of flexion and extension, versus standard care.

Phase 2:
The use of the NIDCAP® behavioural assessment to create individual care plans for each infant and increasing parents' knowledge of premature infant behaviour and more directly involving them in the care of their baby, versus phase 1 intervention care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

During hospital admission:
1. Number of days requiring mechanical ventilation, CPAP or oxygen therapy
2. Number of days with reported apnoea episodes
3. Growth (weekly weight gain and increase of head circumference) morbidity
4. Parental Stress Scale-NICU (PSS-NICU)
5. The Nurse Parent Support Tool (NPST)
6. Mothers and Babies Scale (MABS)

At follow-up:
The infants participating in the study are examined at term age and after 1 and 2 years in the follow-up clinics of the LUMC and JKZ.

At term age:
A full medical history (including behavior) and physical examination, growth parameters, Prechtl neurological assessment and cerebral ultrasound.

At 1 year of age (corrected for prematurity):
1. Medical examination and growth parameters (weight, length and head circumference)
2. Touwen neurological assessment
3. Developmental outcomes: Bayley Mental and Psychomotor Developmental Index (BOS 2 - 30 Bayley developmental scales/BSID II)
4. Behavioural outcomes will be assessed through a parental questionnaire (ITSEA)
5. Parental stress through the Nijmeegse parental stress index (NOSI(K)) questionnaire
6. Health Related Quality of life through the (TAPCQOL) questionnaire

At 2 years of age (corrected for prematurity):
1. Medical examination and growth parameters (weight, length and head circumference)
2. Hempel neurological assessment
3. Developmental outcomes: Bayley Mental and Psychomotor Developmental Index (BOS 2 - 30 Bayley developmental scales/BSIDII)
4. Behavioral outcomes will be assessed through the CBCL (Child Behaviour list)
5. Parental stress through the NOSI(K)-Nijmeegse parental stress index
6. Health Related Quality of life through the (TAPCQOL) questionnaires

In phase 2: two additional questionnaires:
1. Three months: condition of infant (baby-KIPPPI)
2. Nine months: infant behavior (IBQ)

Key secondary outcome(s))
After inclusion of both interventions in the two phases a self-made questionnaire was given to the nursing and medical staff to assess the implementation of the NIDCAP intervention.

Completion date
01/12/2006

Eligibility

Key inclusion criteria

All premature infants with a gestational age of 32 weeks or less admitted to the neonatal intensive care unit of Leiden University Medical Centre (LUMC) and Juliana Children's Hospital (JKZ) hospitals in the health region of Leiden, Delft, The Hague and Gouda for a period of at least five days.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Infants of drug-addicted mothers and infants with cardiac problems or other major birth anomalies, or those requiring surgery

Date of first enrolment
01/04/2000

Date of final enrolment
01/12/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Amsterdam
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

ROR

https://ror.org/027bh9e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (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	neonatal morbidity, neuromotor development, and growth results	01/02/2008		Yes	No
Results article	Phase 1 intervention results	01/03/2009		Yes	No
Results article	Phase 2 intervention results	01/10/2009		Yes	No