

# 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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/10/2009	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Celeste Maguire

### Contact details

Leiden University Medical Centre  
Pediatrics, J6-S  
Albinusdreef 2  
P.O. Box 9600  
Amsterdam  
Netherlands  
2300 RC  
+31 (0)71 526 4082  
c.m.maguire@lumc.nl

## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

**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 measure**

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)

### **Secondary outcome measures**

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.

### **Overall study start date**

01/04/2000

### **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

### **Age group**

Neonate

### **Sex**

Both

### **Target number of participants**

360

### **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)

**Sponsor details**  
Albinusdreef 2  
P.O. Box 9600  
Leiden  
Netherlands  
2300 RC

**Sponsor type**  
University/education

**Website**  
<http://www.lumc.nl/>

**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**

**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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	neonatal morbidity, neuromotor development, and growth results	01/02/2008		Yes	No
<a href="#">Results article</a>	Phase 1 intervention results	01/03/2009		Yes	No
<a href="#">Results article</a>	Phase 2 intervention results	01/10/2009		Yes	No