Development of (moderately) preterm infants: regulation skills, parent-infant interaction and parental emotions.

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The main question in the study isHow do moderately preterm infants and their parents differ from term, as well as extreme preterm infants in (a) development and self regulation skills of the infants, (b) interaction patterns and relationship between...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31497

Source
ToetsingOnline

Brief title
Development of (moderately) preterm infants

Condition

- Structural brain disorders
- Neonatal and perinatal conditions
- Developmental disorders NEC

Synonym
Prematurity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: attachment, development, parent-child interaction, Prematurity

Outcome measures

Primary outcome

The development of the children is assessed by their parents with the Ages and Stages questionnaires (ASQ; Squires, Potter & Bricker, 1999) en de Ages and Stages questionnaires - Social Emotional (ASQ-SE; Squires, Bricker & Twombly, 1999). The Infant Toddler Scales (ITSC; DeGangi et al., 1995) specifically evaluates infants selfregulation skills. The Child Behavior Checklist (CBCL; Achenbach & Rescorla, 2001) is used to study behaviourproblems. Development of extreme preterm children is studied at the follow up clinic of the NICU with the Bayley Scales of Infant Development (BSID II; Van der Meulen et al. 2002) The General Health Questionnaire (GHQ; Koeter & Ormel, 1991) asks for well being and stress of the mothers. The DS14 (Denollet, 2005) evaluates personality characteristics as negative emotionality and social inhibition. The Hospital Anxiety and Depression Scale (HADS, Spinhoven et al., 1997) specifically focusses on anxiety and depressive complaints of the mothers. Mother-infant interaction is observed during a daily meal and assessed with the Emotional Availability Scales (EAS; Biringen) as well as an evaluation of eating behaviour (Chatoor et al., 2000). The Working Model of the Child Interview (WMCI; Zeanah, Benoit, Barton & Hirshberg, 1996) informs on the quality of the relationship between mother and child.

Secondary outcome

The relationship between outcome of different measurement instruments will be

studied within the groups.

Study description

Background summary

Moderate preterm birth constitutes an insult for the still immature brain of the infant. At 34 weeks gestational age the overall brain weight is only 65% of term weight and dendritic arborization is still poor (Kinney, 2006). Despite these risk factors and the large number of infants involved (6,2% is born between 32 and 36.6 weeks in the Netherlands, around 11.000 infants per year), information on developmental outcome of moderate preterm infants is scarce. Research in our own region in The Netherlands was done on a group of 377 moderately preterm children (M=34.7, SD=1.2 weeks), without need for neonatal intensive care, no dysmaturity and no congenital malformations, assessed around 8 years of age and compared with 183 term children concerning school situation, IQ, concentration, behavior problems, ADHD and fear characteristics (Van Baar, Knots et al., 2008 en Van Baar, Couturier et al., 2008). Results showed that 7,6% of the preterm group needs special education compared to 2,9% in the Dutch population, and 19,5% versus 8,3% of the comparison children repeated a class. Of the 76 preterm children with school problems (defined as special education or grade retention), 65% were boys, their parents had a lower education level, and they had a 100 grams lower mean birth weight than the preterm children without school problems.
It was concluded that regulation difficulties are found in moderate preterm children at school age. Further study should focus upon the early (interaction) processes that shape regulative capacities during infancy, in relation to parental characteristics, including maternal anxiety (Zelkowitz et al., 2007).
A structured follow up programme for moderately preterm children might be necessary.
Comparisons of the outcome in moderately preterm children with term born children, as well as with extreme preterm born children are important in view of differences in brain maturation at birth, as well as differences in the amount of parental stress and anxiety.

Study objective

The main question in the study is
How do moderately preterm infants and their parents differ from term, as well as extreme preterm infants in (a) development and self regulation skills of the infants, (b) interaction patterns and relationship between parent-infant dyads, and (c) health and personality of their parents. A second question concerns the

groups differences that are found when the infants are 6-7 months of age (corrected for prematurity); will these differences become stronger or weaker when the children are older, at 18 - 23 months of age.

Study design

Two cohorts of 6-7 and 18 -23 months old children will be studied cross sectionally using parent questionnaires concerning the development and behaviour of the children and their own health and personality characteristics, as well as and interview and an oberservation of parent child interaction. By following up the youngest group also a longitudinal study of their development is possible. The study aims to include 300 moderatly prterm children, 50 extreme preterm children and 150 term children.

Study burden and risks

The burden of this research is limited to answering questionnaires and cooperating with a video recording of an interview, as well as cooperation of mother and child with an observation during a daily routine. Parents are free to stop participation if they decide to do so. If parents or children feel that they need further support, couseling ot treatment, possibities for referral will be checked within the network of cooperating hospitals.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Birth between 32 and 32+6 weeks gestational age; birth before 30 weeks gestational age; term birth between 37 and 42 weeks gestational age; 6-7 months or 18-23 months old (corrected age)

Exclusion criteria

Congenital malformations, substance abuse, Neonatal intensive care admittance (except for the extreme preterm subgroup)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-02-2008
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	31-01-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL20937.060.07