Moderately preterm born children need attention!

Published: 16-02-2011
Last updated: 10-08-2024

The next questions will be addressed in the present study: 1. Do moderately preterm infants differ in development and attention and concentration capacities from a term and very preterm infants during the first years of life? 2. Do attention and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON43962

Source
ToetsingOnline

Brief title
Moderately preterm born children need attention!

Condition

- Neonatal and perinatal conditions
- Cognitive and attention disorders and disturbances

Synonym
attention concentration

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - attention and concentration capacities, - cognitive child development, - preterm

Outcome measures

Primary outcome

- attention and concentration capacities of the child, as measured by both the

mother and eye-tracker apparatus.

- developmental level of the child (Bayley-III scales)

- caretaking behavior of the parents, as measured by both questionnaires and

observations of mother-child interaction

Secondary outcome

- temperament of the child

- child behavior problems

Study description

Background summary

Every year 11.000 children are born with a gestational age of 32-36.6 weeks (moderately preterm) in the Netherlands. This is 6.3% of all births in the Netherlands. A recent Dutch study (van Baar et al., 2009) showed that moderately preterm children at school age (7-9 years) have more attention and concentration problems than term born children. In order to have the possibility to intervene before school age, studies are needed to investigate whether these problems are already visable at earlier age. In what way attention and concentration problems of young children can be assessed and recognized deserves further study. Questionnaires, rated by parents are important, but also more objective data collection, for instance by using an eye tracker system that informs on eye movements, may reveal important aspects of attention
Next to that, studies showed that not all moderately preterm children showed attention and concentration problems. Therefore, it is important to study factors that might be linked to the development of attention and concentration problems. Next to neonatal characteristics, parenting might be an important

factor. There are no recent studies on the influence of parenting on moderately preterm children. Van de Weijer (2009) showed in her study, with severe premature children, that especially a directive interaction style from the mother was beneficial for the cognitive development of these children. How parenting and mother-child interaction are of influence on the development of moderately preterm children needs further study.

Study objective

The next questions will be addressed in the present study:
1. Do moderately preterm infants differ in development and attention and concentration capacities from a term and very preterm infants during the first years of life?
2. Do attention and concentration difficulties as reported by parents, correspond with a more detailed and objective measure of attention and concentration capacities, such as by using eye tracker apparatus, and is this the same for the three groups of children?
3. Is maternal stimulation related to attention and concentration capacities of children during semi-structured interaction tasks? Are maternal personality and well-being of influence on quality of maternal stimulation?
4. Do parents of moderately preterm children report differences in daily care taking and parenting since birth of their children in comparison to parents of a term children and very preterm children?
5. Do moderately preterm children differ from a term and very preterm children on development as assessed with the Bayley-III developmental scales at 2 years of age, the WPPSI and the attention tasks of the TEA-Ch and the NEPSY at 6 years of age?
6. Are developmental capacities of the children related to their attention and concentration capacities and is this the same for all groups of children?
7. Are the assessments of attention, cognition, temperament and behavioral problems and parenting and mother-child interaction at toddler age, related to such asessments at six years of age?

Study design

Three data collection waves (consisting of filling out questionnaires during every wave, and at wave 2 and 3 also a visit to Utrecht University and the local hospital) will be done to study the research questions. For this study, 200 parents of moderately preterm children and 200 parents of a term children and 140 parents of extremely preterm children, from different hospitals in and around Utrecht, will be asked to participate in this study. Taking into account a response rate of 50%, all groups will consist of 70-100 children participating in the three measurement waves. For the first wave, parents are asked to answer frequently used and standardized questionnaires on development and temperament of their children, as well as about their family and their caretaking and stimulation habits. The questionnaires will be sent when the

children are 11-13 months old.
For the second wave, when the children are 16-19 months of age, the parents and children will be invited to the laboratory at Utrecht University to study attention and concentration processes and mother-infant interaction. This visit will take about 30 minutes. Next to that, the parents will again be asked to answer frequently used and standardized questionnaires on development and behavior of their children, as well as on their own background. Some of these questionnaires will be identical to questionnaires from the first wave, in order to be able to follow the development of the children over time.
After 6 months, when the children are 22-25 months of age, the parents and children will be invited by us in the local hospital, for the third wave: assessment of the development of the child, using the Bayley III scales. This visit will take about 1.5 hours. Again parents will be asked to fill in frequently used and standardized questionnaires on the development of their children. Some of these questionnaires will be identical to questionnaires from earlier data waves.

After these three data waves, parents who gave consent to contact them for further study, are contacted and asked if they are willing to participate in a fourth wave when their children are 36 months of age. This wave consists of filling out questionnaires about the development and behavior of their child.

The fifth wave will consist of two visits. For the first visit parents and child are invited to the research facilities at Utrecht University. The second visit will be arranged at school (if possible), where the parents do not need to be present. Time investment for the child will be around 1 hour for the first visiit and 1* hour for the assessment at school. Time investment for the parents will be around 1* uur regarding the interaction task and answering questionnaires. Time investment for the teacher will be around * hour for answering a questionnaire.

Study burden and risks

Parents' participation is voluntary and they are free to withdraw from the study at all times without consequences. The study does not burden the children. Usually the children enjoy the games and play materials very much. If the children do not want to cooperate, or if the parents like to stop, the assessment will be finished. Time investment for the child will be about 30 minutes during the second data wave and 1* hours in the third data wave, resulting in a total of 2 hours. For parents this investment will be about 6 hours in total. They have to fill in questionnaires at all three measurement waves (about 1 hour each time) and have to join the child during the lab- and hospital visit (2 hours in total and the traveling time).

Participation in the fourth data wave will take another 30 minutes from the parents' time.
Participation in the fifth data wave will take around 135 minutes of the

children; 75 minutes of the parents; and 15 minutes of the teachers.

Contacts

Public
Universiteit Utrecht

Heidelberglaan 1
Utrecht 3584 CS
NL
Scientific
Universiteit Utrecht

Heidelberglaan 1
Utrecht 3584 CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Moderately preterm
- Gestational age at birth of 32.0-36.6 weeks
Full term:
- Gestational age at birth of 37.0-42.0 weeks
Extremely preterm:
- Gestational age at birth <32.0 weeks

Exclusion criteria

- dysmaturity (- NICU admittance (not for extremely preterm children)
- severe congenital malformations
- maternal antenetal alcohol and/or drug abuse
- chronic maternal use of psychiatric drugs

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:	Recruiting
Start date (anticipated):	03-03-2011
Enrollment:	270
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-08-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	12-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL34143.041.10