

# Implementation of the Dutch national guideline \* perinataal beleid bij extreme vroeggeboorte\* (perinatal practice in extremely premature delivery) : the importance of Prenatal Counseling

## Substudy: Needs and preferences for prenatal counseling from experienced parents

Published: 12-05-2014

Last updated: 24-04-2024

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Neonatal and perinatal conditions
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON40598

### Source

ToetsingOnline

### Brief title

PreCo study: needs and preferences from parents

### Condition

- Neonatal and perinatal conditions

**Synonym**

prenatal counseling at the threshold of viability

**Research involving**

Human

**Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

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

**Intervention**

**Keyword:** parents, premature birth, Prenatal counseling

**Outcome measures****Primary outcome**

Primary outcomes:

1. Practical aspects of prenatal counseling as experienced by parents.
2. Contents of the prenatal counseling as experienced by parents.
3. The amount of decisional conflict and decisional regret parents experienced when they were faced with the decision whether or not to actively resuscitate the infant at 24+0 - 24+6 weeks GA.
4. Needs and preferences of parents regarding ideal prenatal counseling.

**Secondary outcome**

na

**Study description****Background summary**

In the recently updated Dutch national guideline \*perinataal beleid bij extreme vroeggeboorte\* (perinatal practice in extremely premature delivery), the gestational age (GA) at which resuscitation can be offered was lowered from

25+0 weeks to 24+0 weeks. Informed consent of the parents is required for the decision whether or not to actively resuscitate the infant at 24+0 - 24+6 weeks GA. This can only be obtained if parents have received adequate prenatal counseling. The updated national guideline, however, does not provide healthcare workers with instruments for adequate counseling. Consequently, great heterogeneity in prenatal counseling exists.

## **Study objective**

We aim to investigate the current practice of prenatal counseling amongst parents of extremely premature infants since the introduction of the new guideline in 2010. We will explore the contents and the practical aspects of the counseling. Additionally, the decisional conflict and the decisional regret as experienced by parents will be investigated. Furthermore, we aim to explore the needs and preferences of these parents with regards to ideal counseling. Finally we aim to develop a structured national multidisciplinary prenatal counseling guideline based on preferences and needs of both professionals (separate study) and experienced parents.

## **Study design**

Observational study. Current practice among experienced parents (capable adults) (cohort 01102010-01102013, approximately 150-225 parent couples) will be evaluated using questionnaires. This survey will address the prenatal counseling as experienced by the parents. Additionally, decisional conflict and decisional regret will be explored using the validated questionnaires by O'Connor and Brehaut respectively. Lastly, the preferences and needs for ideal counseling based on their experience will be addressed as well.

The questionnaire was presented to the \*Vereniging van Ouders van Couveusekinderen\* (Association for parents whose premature babies have been admitted to the neonatal intensive care unit (NICU)) for evaluation and adjusted according to their advice.

At the end of the survey, parents will be invited to participate in a structured interview for in depth exploration of their needs and preferences at a preferred location. We aim to interview 10 - 20 parent(s). Data collection will continue until data saturation is reached. Ideal counseling tools will be developed based on information obtained from both experienced parents and professionals (separate study) and will be tested in a feasibility study (separate study).

Data analysis: the answers to the questionnaires will be descriptively analyzed using SPSS. The interviews will be qualitatively analyzed using Atlas TI. Analysis will be done independently by two researchers. Discrepancies will be resolved by discussion between the authors until consensus is reached.

## Study burden and risks

The survey contains questions that will remind parents of an emotional period in their lives. The questionnaire might therefore impose a psychological burden on the participants. Parents are prepared for this burden in the introduction letter that will be send to them. They can withdraw their participation at any time. Furthermore, they can contact the researches and the independent doctor if they wish to do so after filling in the questionnaire.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

parents who have delivered an extremely premature newborn (24+0 - 24+6 weeks of

gestation)

## Exclusion criteria

not applicable

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 23-03-2015

Enrollment: 150

Type: Actual

## Ethics review

Approved WMO

Date: 12-05-2014

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 04-09-2014

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 22-12-2014

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL42996.091.13