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Family orientated early intervention enhances social-interactive behaviour of premature infants and mother-infant-interaction

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Registration date 13/02/2008	**Overall study status** Completed	
Last Edited 13/02/2008	**Condition category** Neonatal Diseases	

Plain English Summary
Not provided at time of registration

Study website
http://www.betainstitut.de/fue_erg_prima_studie.php

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
PRIMA Study (Prospective Randomized Implementation of the Model-project Augsburg)

Study hypothesis
Condition: Very preterm children who are at an increased risk of cognitive impairments, poor educational achievement and behavior problems and psychopathology. Most consistently, an increased risk for attention problems, hyperactivity and social or peer relationship problems have been reported across a range of hospital and geographically defined cohorts. Improvements in infant self-regulation and mother-infant-relationship may avert longterm behavioural and social relationship sequelae of very preterm birth. A first step in demonstrating such a link is to test in a randomised controlled trial whether an individualised family based approach can alter infant social-emotional regulation.

Hypothesis: Does an individualised family-based early support intervention (case management approach) for mothers of prematurely born infants alter 1) the maternal sensitivity and 2) infant social-emotional regulation and reciprocal quality of mother-infant interaction in the first 6 months of life?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of Rheinische Friedrich Wilhelms University, Bonn, Germany. Approved on 27/11 /2001 (ref: 181/01)

Study design
Randomized, single-blind, single-center trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Condition
Premature infants

Interventions
43 families with 55 children were randomized in the intervention group and 44 families with 53 children in the control group.

The aim of our individualised, family-based intervention was to integrate parents in the care of their babies from the very beginning in the NICU and to support families with social needs by providing parent education, improving care-giving competence, enhancing parent-infant interaction, evaluation of the needs and resources of the family, psychosocial care and emotional support, and establishing a network for the family. Beginning in the first week of life trained nurses, social workers and psychologists as required visited as case managers the mothers in the NICU and at home after discharge of the baby up to six months. The intervention addressed problems in four domains including 1) caregiving environment, 2) infant behaviour and characteristics, 3) home discharge and community resources, and 4) family organisation and functioning. Visiting was every two to three days during hospital stay and 1-2 weekly after discharge as needed by the family. The mean duration of the intervention was 161.9 days (45-277): 35.2 days (1-108) during hospital stay and 126.7 days (14-210) after discharge. The professions involved were: nurses in all families, social workers in 42.6% and psychologists in 4.8%.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure was the improvement in social-interactive behaviour of the infants, mother's sensitivity and the dyadic quality of interaction. Before discharge the nurses assessed the early mother sensitivity with the Boston City Hospital Assessment of Parental Sensitivity (BCHAPS)(Timepoint 1). This questionnaire consists of 13 closed-ended items, evaluating the mother's sensitive responsivness and care giving competence. The items are ranked on 5-point scales from "poor" to "competent" and the scores totalled.

At 6 months corrected age the infant social-interactive behaviour and mother-infant interaction were assessed with the Mother-Infant Structured Play Assessment (MISPA)(Timepoint 2). This is an 8-minute, semi-structured face-to-face play interaction which includes the Still-Face Paradigm, which provides a method to access infant regulatory capacities and illustrates central qualities of the young infant's capacities for interpersonal engagement. For the interaction records the infants were placed on a blanket or mat on the floor and mothers were asked to sit on the floor opposite their infant. A mirror was mounted at an angle, which enabled the examiner to videotape both the face and body of the infant and the face and upper torso of the mother. Standardised instructions were used to explain the procedure to the mothers.

Episode 1 involved the mother playing with her baby with a rattle (warm-up). After 2 minutes (Episode 2) she was cued to lay aside the rattle and play (without a toy) with her baby for another 2 minutes. Then she was asked to get her baby to watch her face, which lasted for 1 minute (Episode 3). Next she was asked to make a still-face for 1.5 minutes (Episode 4) and then finally asked to resume playing with her baby for another 1.5 minutes (Episode 5).

Three existing schemes were modified and adapted to create a suitable coding scheme:
1. The Play Observation Scheme and Emotion Ratings (POSER)

2. The Emotional Availability Scales (EAS)
3. Tronick and Weinberg's Infant and Caregiver Engagement Phases (ICEP)

Each interaction episode was coded with 5-point scales reflecting maternal sensitivity (apart from episode 4) and infant social regulatory behaviour. Maternal Sensitivity consisted of 5 rating scales (sensitivity, positive response, negative facial emotional expression, verbal involvement, undercontrol) that were totalled to gain a measure of maternal sensitivity. Social Regulatory Behaviour was also assessed using 5 rating scales (emotional state, attentiveness, responsivness, vocalisation, clarity of signals).

Quality of dyadic interaction consisted of 2 five-point rating scales (Harmony, Control over interaction) and the scores were totalled. Each of the five episodes in the MISPA was scored separately, and infant, maternal and dyadic behaviours were coded individually. The last episode demonstrating mother-infant reunion after perturbation of interaction was decided to be confirmative for the effect of the intervention. This episode presents the infant with a complex and demanding regulatory task: the infant needs to simultaneously cope with the resumption of the maternal behaviour, as well as the carry-over of negative affect from the still-face episode.

Secondary outcome measures
The demographic characters and the medical and psychosocial burden of the families were recorded with a structured mother-interview at both time points. Several items of the interview ware totalled showing a dyadic adjustment scale and a psyochosocial stress-index.

Overall study start date
01/01/2002

Overall study end date
31/12/2005

Eligibility

Participant inclusion criteria
Families with premature births <32 weeks Gestational Age (GA) or birth weight below 1500 g and cared for in the Neonatal Intensive Care Unit (NICU) of the University Children Hospital, Bonn, Germany, between 1 January 2002 and 31 December 2003.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
87 families with 108 children

Participant exclusion criteria

1. Families living more than 100 km from the hospital
2. Mother did not speak German
3. Infant was transferred to another hospital
4. Infant died or suffered major malformations

Recruitment start date
01/01/2002

Recruitment end date
31/12/2005

Locations

Countries of recruitment
Germany

Study participating centre
Stenglinstr. 2
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Sponsor information

Organisation
Beta Institute for Research and Development in Social Medicine (Germany)

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Kobelweg 95
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Sponsor type
Research organisation

Website
http://www.betainstitut.de

Funder(s)

Funder type

Industry

Funder Name
The study was internally founded by the beta Institute for Research and Development in Social Medicine (beta Institut für Sozialmedizinische Forschung und Entwicklung), Augsburg, Germany.

Funder Name
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Funder Name
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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