Nederlands: Het effect van Video Interactie Begeleiding (VIB) bij te vroeggeborenen.

Engels: Effect of Video Interaction Guidance (VIG) in parents of preterm infants.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26296

Source
Nationaal Trial Register

Brief title
Nederlands: Het effect van Video Interactie Begeleiding (VIB) bij te vroeggeborenen. Engels: Effect of Video Interaction Guidance in parents of preterm infants.

Health condition

Nederlands:
-vroeggeboorte
-prematuriteit
-ouder-kind interactie
-interventie
Engels:
-prematurity
-parent-infant interaction

-intervention

Sponsors and support

Primary sponsor: Initiator: Universiteit van Tilburg
Source(s) of monetary or material Support: Stichting Achmea Slachtoffer en Samenleving

Intervention

Outcome measures

Primary outcome

Primary outcome variables at 0-6 months:

1. Parental bonding: Several measures are used to assess parental bonding perspectives:

A. The Yale Inventory of Parental thoughts and Actions (YIPTA; Leckman et al., 1994) is a semi-structured interview that assesses various aspects of parental bonding. It consists of six subscales, i.e., frequency of thoughts and worries, distress caused by thoughts and worries, distress management; compulsive checking; affiliative behaviour, attachment representations and; frequency of caretaking behaviour. The instrument is extensively validated in a longitudinal study by Leckman et al. (2003) with extreme and moderately preterm infants;

B. The Working Model of the Child Interview (WMCI; Zeanah & Benoit, 1995) is a semi-structured interview to assess caregivers' internal representations or working models of their relationship with a particular child and focuses on the parent's subjective experiences from the time of pregnancy to current interactions. The WMCI has been used for clinical and research purposes and has proven widely applicable from low risk to clinical populations (Benoit et al., 1997) with high stability rates and predictive validity with regard to infant-mother attachment (Benoit et al., in press; Zeanah et al., 1994);

C. The Postpartum Bonding Questionnaire (PBQ: Brockington et al., 2001) will be used to assess the quality of bonding and bonding disorders. The PBQ is a new 24 item screening instrument that can be easily administered by mothers and fathers of newborn infants. The instrument has not been validated in the Netherlands and in parents with a premature infant or infant with birth complications. However, because of the design of the study and the use of the YIPTA en WMCI in the present project, the validity of the PBQ screening instrument can be assessed. For practical relevance, a short screening instrument in the neonatal period would be useful to discern mothers at risk for bonding disorders and subsequent adverse parenting behaviour.

2. Parental and infant interactive behaviour:

Parent-infant interaction will be rated from videotapes recorded during a bath/changing diaper situation at home. Four (5 or 9-point) rating scales (Emotional Availability Scales; Biringen, Robinson, & Emde, 1998) will be used to rate parental sensitivity/availability and hostility and two 9-point rating scales to rate infant involvement and responsiveness. In earlier studies of one of the applicants these scales have proven to be valid (van Bakel & Riksen Walraven, 2004) and stable across the first years of life. Even in a community-based sample of one-year-olds, individual differences in parental hostile behaviour can be adequately observed (Van Bakel & Riksen-Walraven, 2002a).

Primary outcome variables at 2 years:

1. Quality of parent-infant interaction will be rated from videotapes recorded during a standard play situation at home;

2. Attachment will be assessed by completing the Attachment Q-Sort (Waters, 1987) by the researcher during a home visit. The AQS consists of 90 cards, each describing a specific behavioural characteristic of infants. After observation, the observer ranks the cards from most descriptive behaviour of the infant to least descriptive behaviour of the infant. The profile that comes up is compared to the profile of a typically secure attached infant;

3. Social-emotional development and temperament:

A. Ages and Stages Questionnaire - Social Emotional. This questionnaire consists of 29 items and is considered a screener for social, emotional development. Internal consistency (overall alpha of 0.82), test-retest reliability (0.94), sensitivity (overall alpha of 0.82) and specifity (overall alpha of 0.92) were high (Squires, Bricker, Heo & Twombly, 2001);

B. Early Childhood Behaviour Questionnaire (very short version). This questionnaire is a parent self report measure of infant’s temperament. The very short form of this questionnaire consists of 36 items;

4. Cognitive development:

A. Ages and Stages Questionnaire -24 months. The Ages and Stages questionnaire is a developmental screener with 40 items that comprises five domains: communication, gross motor, fine motor, problem solving and personal social development;

B. Behaviour Rating Inventory of Executive Function-Preschool version (Gioia, Espy, Isquith, 2003). This questionnaire is a parent report measure of 63 items that measure various aspects of executive functioning; inhibition, working memory, planning/organizing, shifting and emotional control. The internal consistency on all subscales is high, ranging between α = 0.80 to α = 0.95. The temporal stability over a range of 4.5 weeks was found to be high (r= 0.90) (Isquith, Crawford, Epsy & Gioia, 2005);

C. Peabody Pictorial Vocabulary Test measures receptive vocabulary and is correlated with

IQ, as was measured by the Wechsler Intelligence Scale for Children (r ≥ .90) (Dunn & Dunn, 1997). The test takes approximately 10-15 minutes to administer.

Secondary outcome

Secondary outcome variables 0-6 months:

1. Neonatal descriptive variables:

A. Infant health/fitness: Information about the infant's health will be registered using the PERI (Perinatal Risk Inventory). Data concerning gestational age at birth, birth weight, complications around pregnancy and delivery and Apgar scores will be obtained for all infants. Of the preterm group, more detailed clinical data will be obtained from hospital/medical records (e.g., duration of ventilation and tube feeding, breathing problems, and gastrointestinal functioning);

B. Infant temperament: The temperament of the infant will be assessed from the perspectives of the parents, using the ICQ (Infant Characteristics Questionnaire);

C. Infant sensory and regulatory problems:
The Infant/Toddler Symptom Checklist (ITSC; Degangi, Poisson, Sickel & Wiener, 1987) will be used to screen for sleeping and eating problems. The ITSC is designed to screen 6 to 30-month-old infants and toddlers for sensory and regulatory problems who show disturbances in sleep, feeding, state control, self-calming, and mood regulation. Furthermore crying of the infant will be assessed using the 'parental diary of infants cry and fuss behaviour'.

2. Parental descriptive variables:

A. Maternal and paternal information: Will be assessed using a background information questionnaire;

B. Maternal and paternal personality: Will be assessed using the ER89 and the Quick Big Five;

C. Maternal and paternal emotional state: Will be assessed using the EDS (Edinburgh Depression Scale), the STAI (State−Trait Anxiety Inventory), the PPQ (Perinatal Post-traumatic stress disorder Questionnaire) and the STAXI (State-Trait Anger eXpression Inventory);

D. Spousal support: To assess the support mothers and fathers receive from their social network, we will use the Dutch translation of the Brief Social Support Questionnaire (Sarason et al. 1983/1987). Mothers and fathers will be asked to list all individuals who provide them with support in different situations (e.g., when help is needed, when feeling tense and under pressure) and to rate the degree to which they are satisfied with the received support in each situation.
A subscale of the Dutch questionnaire (VGP) for assessing family problems (Koot, 1997) will be used to measure the quality of the support received from the partner, particularly with regard to child–rearing situations. This subscale has proven to be valid and meaningfully

related to parental behaviour in a comprehensive study of one of the co-applicants (van Bakel & Riksen-Walraven, 2002).

3. Parent-infant bonding: The PRISM Task: the Pictorial Representation of Illness and Self Measure (PRISM) method of assessment of suffering, originally described by Buchi et al in 1998, is a fast visual quantitative method of measuring the intrusiveness of illness into a person's/patient's life. The PRISM is being developed as a research tool and has been used effectively in routine clinical practice.

Secondary outcome variables 2 years:

1. Parental risk factors:

A. Child Abuse Potential Inventory (CAPI);

B. Parental Empathy Measure interview (PEM).

2. Postpartum Bonding Questionnaire (PBQ: Brockington et al., 2001) will be used to assess the quality of bonding and bonding disorders. The PBQ is a new 24 item screening instrument that can be easily administered by mothers and fathers of newborn infants. This questionnaire is also completed twice by parents during the first six months. To examine how bonding develops over time, this questionnaire will be included in the follow up study again;

3. Parental emotions variables:

A. Perinatal PTSD Questionnaire (PPQ) is a 14 item questionnaire that will be used to measure post traumatic stress symptoms related to child birth, experienced during the past month. This questionnaire has a high internal consistency ($\alpha = 0.85$) and test-retest reliability ($r= 0.92$), as was found in a study of De Mier, Hynan and Harris (1996);

B. Edinburgh Postnatal Depression Scale (EPDS) is a 10 item self report questionnaire to measure postnatal depression (Cox, Holden & Sagovky, 1987);

C. WHO (five) Well Being Index (WBI-5) is a 5 item questionnaire which measures psychological well-being of the preceding two weeks. Cheerfulness, calmness, feelings of vigour, feelings of being well-rested after sleep, and interest are being assessed.

Study description

Background summary

Studies have consistently found a high incidence of neonatal medical problems, premature

births and low birth weights in abused children (Creighton, 1985; Zelenko e.a, 2000). This has led to the common notion that these problems place a child at a higher risk for maltreatment and neglect. One of the explanations proposed for the relation between child fitness and adverse parenting and negative infant outcomes is a delay or disturbance in bonding between the parent and infant. This hypothesis suggests that due to neonatal disease, the development of an affectionate bond between the parent and the infant is impeded (Egeland & Vaughn, 1981). The disruption of an optimal mother-infant bonding –in its turn- may predispose to distorted parent-infant interactions and thus facilitate abusive or neglectful behaviours. However, this hypothesis has not been tested empirically in a prospective study. In the Netherlands, with approximately 14.000 preterm (< 37 weeks gestation) births per year and an alarming number of young children victimized by maltreatment and neglect (Van IJzendoorn et al., 2007) more insight in this process is badly needed. The purpose of the current study is 1) to further elucidate the bonding process between unhealthy (e.g., high- and low-risk premature) infants and their parents from an evolutionary perspective and 2) to examine the effect of a short term intervention (Video-Interaction Guidance) in preterm infants to enhance parental bonding and to prevent adverse parent-infant interaction in the first months after birth.

Study objective

Hypotheses 0-6 months after birth:

The project consists of two integrated parts. In part A, the development of the bonding process and the consequences for adverse parent-child interaction in premature and unhealthy infants will be studied. In Part B, the effect of a short-term video-feedback intervention (i.e., video interaction guidance) to promote intuitive parenting cq. parental bonding will be examined in a randomized controlled trial.

Main hypotheses Part A:

1. In high and low risk preterm infants the bonding process between parent and child is delayed compared to the bonding process in healthy term parent-infant dyads;

2. A disturbed bonding process results in adverse parental interactive behaviour (e.g., increase in intrusiveness and hostile behaviour), which -in its turn- constitutes a serious risk factor for negative infant outcomes (e.g., sleeping and eating problems, social-emotional delay);

3. Responses to infant (crying) characteristics are determined by maternal, parental and contextual characteristics, such as personality and spousal support.

Main hypotheses Part B:

1. The quality of parental bonding towards the infant is increased in the VIG group compared to the control (Care as usual) group (measured at 1 week, 1 month, 3 months and 6 months after delivery);

2. Parental interactive behavior (i.e., sensitivity/emotional availability) is significantly higher in the VIG group compared to the control (i.e., care as usual) group during week 1, at 3 months and 6 months after delivery;

3. Parents in the VIG group have fewer feelings of anxiety and depression moreover; they show less intrusive and hostile behavior towards their infant at week 1, 1 month and 6 months after delivery as compared to the control group;

4. The infants in the VIG group show less sleeping and less feeding problems compared to the control group.

Hypotheses: 2 years after childbirth:

1. The quality of bonding and parent-infant interaction is a predictor for the quality of attachment at the infants' age of two. Full-term infants have more secure attachment styles compared to preterm infants. In the VIG group there are more parent-infant dyads that show a secure attachment style, compared to the control group;

2. Controlling for gestational age, there is a difference in social-emotional, behavioural and cognitive development between preterm infants and full term infants, in favour of the latter group. The infants' development is moderated by the quality of early bonding, interaction and attachment;

3. The risk of infant abuse is higher in parents of preterm infants compared to parents of full-term infants. The quality of interactive behaviour correlates with the risk of maltreatment, with more intrusive behaviour during interaction in parents with higher risk of abuse;

4. Parents of preterm infants have more mental health problems (PTSD/depression) than parents of full term infants at the age of two.

Study design

The data will be collected using video recordings, questionnaires and semi-structured interviews. At day 1, 3 and 7 and at 1, 3, 6 and 24 months after the delivery, measurements will be conducted.

Intervention

VIG will be applied as intervention. Video Interaction Guidance (VIG) is a method for nurses and pedagogic workers in the clinical (hospital) setting to guide and support the attunement

and positive contact between parent and infant during the hospital stay. VIG uses edited video feedback to help parents identify their strengths and to achieve desired goals. Key elements of the method are adoption of a collaborative and empowering approach to the parent and to offer a framework of theoretically derived communication/contact principles to analyze interactions. Edited film elements are used to provide feedback of “positive exceptions” and, through discussion of these self-modeling examples, to facilitate reflection and develop parental self-efficacy.

The intervention group:

The sessions of the VIG intervention will comprise videotaped parent-infant interactions during hospital stay at the 1st, 3rd and 7th day after birth. The trained nurse or pedagogic worker will show the parents a part of the videotape and comments on selective fragments of the tape thereby showing the parents how to interpret the behaviours of the child. To execute the VIG intervention in a proper manner, a detailed protocol will be made available for all nurses/VIG workers.

Control group:

In the control group (care as usual group) on the first day after birth and at 1 week after birth, the nurse practitioner videotapes an interaction episode but no feedback sessions are conducted.

Contacts

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Eligibility criteria

Inclusion criteria

1. Group 1: Full term infants: Childbirth after 37 weeks gestational age;

2. Group 2: Moderate preterm infants: Childbirth between 32-37 weeks gestational age;

3. Group 3: Extreme preterm infants
Childbirth before 32 weeks of gestational age and/or birthweight below 1500 gram.

Exclusion criteria

1. Congentital malformations;

2. Substance abuse of the mother;

3. Admittance neonatal intensive care unit (except for the extreme preterm group);

4. At least one of the parents must be capable to read/speak the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-01-2009
Enrollment:	210
Type:	Anticipated

Ethics review

Positive opinion
Date: 07-05-2012
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36933
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3270
NTR-old	NTR3423
CCMO	NL24021.060.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36933

Study results

Summary results
N/A