

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

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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26296

Bron

Nationaal Trial Register

Verkorte titel

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

Aandoening

Nederlands:

-vroeggeboorte

-prematuriteit

-ouder-kind interactie

-interventie

Engels:

- prematurity
- parent-infant interaction
- intervention

Ondersteuning

Primaire sponsor: Initiator: Universiteit van Tilburg

Overige ondersteuning: Stichting Achmea Slachtoffer en Samenleving

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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 specificity (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 $\alpha = 0.80$ to $\alpha = 0.95$. The temporal stability over a range of 4.5 weeks was found to be high ($r = 0.90$) (Isquith, Crawford, Espy & 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 ($r = 0.90$) (Dunn & Dunn, 1997). The test takes approximately 10-15 minutes to administer.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Congenital 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestart

(Verwachte) startdatum: 01-01-2009
Aantal proefpersonen: 210
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 07-05-2012
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36933
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A