Effect of Video Interaction Guidance in families with preterm infants.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Neonatal and perinatal conditions
Study type	Interventional

Summary

ID

NL-OMON36933

Source
ToetsingOnline

Brief title
Effect of Video Interaction Guidance in families with preterm infants.

Condition

- Neonatal and perinatal conditions
- Developmental disorders NEC

Synonym
prematurity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Achmea Slachtoffer en Samenleving

Intervention

Keyword: intervention, parent-child interaction, prematurity

Outcome measures

Primary outcome

Parent-infant bonding

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.

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).

The Postpartum Bonding Questionnaire (PBQ: Brockington et al., 2001) will be used to assess the quality of bonding and bonding disorders in the postpartum

period at Time 1 and Time 2. The PBQ is a new 24 item screening instrument that can be easily administered by mothers who gave birth to an infant. 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.

Quality of parent-infant interaction

• Parental and infant interactive behaviour 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).

• Infant outcomes.

The Infant/Toddler Symptom Checklist (ITSC; Degangi, Poisson, Sickel & Wiener, 1987) will be used at 6 months to screen for sleeping and eating problems. The ITSC is designed to screen infants and toddlers for sensory and regulatory problems who show disturbances in sleep, feeding, state control, self-calming, and mood regulation.

The agres and stages questionnaire (Bricker & Squires, 2001) is a developmental screnner for five domains: communication, gross motor, fine motor, problem solving and personal social development.

Secondary outcome

The relationshop between outcomes of different instruments and moderator variables will be studied within the groups.

See protocol for measures and variables

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 retrospective 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

The project aims to gain more insight in the process of bonding between parents and prenature infants, to validate a screening instrument that can be easily

adopted in maternity wards of (general) hospitals to detect parents and children at risk for adverse parent-infant problems and to evaluate Video Interaction Guidance in parents with low and high risk premature infants.

Study design

In this study, a group of extremely premature, moderately premature and a term children will be followed from the first days after birth untill the children are six months old.
The premature children (both extreme and moderate) will be randomly split into two groups, an intervention group and a control group. The children in the intervention group will receive Video Interaction Guidance. This enables us to evaluate the effectiveness of Video Interaction Guidance for premature children.

Intervention

Video Interaction Guidance (VIG) will be applied as intervention. The sessions of the VIG comprise video-taped parent-infant interactions during hospital stay at the first day, after 3 days and at 1 week after birth. The trained nurse or pedagogic worker shows the parent part of the video-tape and comments on selective fragments of the tape. The nurse shows the parent how to interpret the behaviours of the child. A detailed protocol is made available for all nurses/VIG workers.
In the control group (care as usual group) on the first day after birth and at 1 week after birth an interaction episode is video-taped by the nurse-practitioner but no feedback sessions are conducted.

Study burden and risks

Participation in this study entails no extra risk for the families. The burden for the participants is limited to being videotaped during an interaction moment, answering questionnaires and cooperating with an interview. If this is too much of a burden for the family, they are free to stop participation at any moment if they decide so. This will have no consequences for further treatment. If parents or children feel that the need further support, counseling or treatment, possibilities for referral will be checked within the network of the cooperating hospitals and organisations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

I: birth before 32 weeks gestational age,
II: birth between 32 and 37 weeks gestational age,
III: birth after 37 weeks gestational age.

Exclusion criteria

Congenital malformations, substance abuse of the mother, neonatal intensive care admittance (except for the extreme preterm group)

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	210
Type:	Anticipated

Ethics review

Approved WMO Date:	21-10-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-05-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-08-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	26-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26296
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL24021.060.08
OMON	NL-OMON26296