

'Expecting parents'

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pregnancy, labour, delivery and postpartum conditions
Study type	Observational non invasive

Summary

ID

NL-OMON39576

Source

ToetsingOnline

Brief title

'Expecting parents'

Condition

- Pregnancy, labour, delivery and postpartum conditions
- Personality disorders and disturbances in behaviour
- Environmental issues

Synonym

disfunctional parenting, perinatal riskfactors

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg

Source(s) of monetary or material Support: ZonMw programma Zorg voor Jeugd ronde 2007,Gemeente Eindhoven

Intervention

Keyword: parental prenatal expectations, parent-child interaction, prenatal screening

Outcome measures

Primary outcome

The quality of the parent-child interaction will be rated from videotapes recorded during a free play situation and a 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).

The *Still Face Procedure* (Tronick e.a., 1978) is a standardised 6 minutes procedure (consisting of 3 phases: contact-, no-contact, and repair phase).

During this procedure the contact between parent and infant is observed (neutral, positive or negative behaviour). The procedure offers the possibility to observe the behavior of both partners.

The development of children is assessed by their parents using the Ages and Stages questionnaires. The *Ages & Stages Questionnaires* (ASQ en ASQ:SE; Bricker & Squires, 1999; Squires, Bricker & Twombly, 2002) are screeningsinstruments to assess the development of young children in the domains of communication, selfregulation, adaptive behavior, affect, and social

skills.

The parents are interviewed on their internal representation of the relationship with their child, according to the Working Model of the Child Interview (WMCI; Benoit et al. 1997). This interview will be conducted during pregnancy and 4 months after birth.

BRIEF-P (Gioia et al., 2001)

BITSEA

ECBQ

At age 5 the SDQ (behavior problems), CBQ (behavior characteristics), NOSI (parenting stress), en MPAS/PRISM (parent-child bond) will be assessed.

Secondary outcome

The relationship between outcome of different measurement instruments and moderator variables will be studied in relation to prenatal riskfactors.

Study description

Background summary

Over the past decades, evidence has emerged of the potential effectiveness of early identification of high-risk families. The key characteristic of successful programmes include the identification of high-risk families during pregnancy or shortly after birth (Cox, 1998). Accurate and timely identification of families at risk of adverse parenting is essential for health care services (Barlow et al., 2006). During pregnancy various riskfactors may be identified by midwives (o.a. Wilson e.a., 1996). However, little is known about the relation between expectations and experiences of parenthood and the moderating role of parental characteristics, such as resiliency, personality characteristics and/or depressive symptomatology. The project fits the advice of the Inventgroup (Hermanns et al., 2005) to signal and screen as early as possible (i.e., during pregnancy) and to examine the risk process after birth by using promising evidence-based instruments. The project is a collaboration of

the CJG (Eindhoven), practices for midwives and health care centers (Zuidzorg).

Study objective

The purpose of the project is a) to examine evidence-based instruments (DFSI, ASQ:(SE) and ITSEA) in the Netherlands in practices of midwives and within the system of health care and b) to gain more insight into the role of specific risk- and protective factors for dysfunctional parent-child interactions and infant development.

Study design

In this prospective longitudinal study, a sample of 240 pregnant women (varying in degree of prenatal psychosocial risk) and their partner will be followed from week 15 during pregnancy up till the child is 12 (24) months old. There will be eight measurementpoints, 6 questionnaires rounds and 2 home-visits.

Study burden and risks

The burden of the research project is limited to answering questionnaires and cooperating with an interview, as well as cooperation of parent and child with an observation during daily routines. parents are free to stop participation if they decide to do so. If parents feel that they need some further support or counseling, possibilities for referral will be checked within the network of the projectgroup en collaborating practices and centres.

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

12 weeks pregnant without medical complications, and be able to understand and speak Dutch or English

Exclusion criteria

medical complications during pregnancy that result in referral to a gynecologist

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-11-2008

Enrollment:	240
Type:	Actual

Ethics review

Approved WMO	
Date:	11-08-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	30-08-2011
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	28-01-2015
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)

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	NL23376.008.08