From expecting to experiencing: The role of parenting cognitions in the transition to parenthood

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Study 1 is aimed to describe normative trajectories of parenting efficacy from pregnancy to early parenthood. Study 2 is focused on the question whether mental representations of attachment are protective in the context of parenting stress and its...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43819

Source
ToetsingOnline

Brief title
Parenthood: From expecting to experiencing

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym
nvt

Health condition

congenitale aandoeningen, niet nader gespecificeerd

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,NWO,Fonds Nutsohra,Fonds Nutsohra;Stichting Tot Steun Nederland,Prénatal (financiering in de vorm van cadeaubonnen (ter verloting onder proefpersonen deelstudie 1)

Intervention

Keyword: attachment representations, congenital abnormalities, Highrisk samples, parental self-efficacy

Outcome measures

Primary outcome

The most important dependent variable of study 1, 2 and 3 is parental self-efficacy. Study 2 and 3 are aimed to test mental representations of attachment as predictor of parental self-efficacy trajectories. The primary dependent variables of project C are parental self-efficacy, sensitivity and the quality of the attachment relationship with the child. The aim is to investigate whether unresolved trauma, anxiety and depression, are predictors for parental self-efficacy trajectories and the mother-child attachment relationship.

The main outcome of Study 6 is methylation status. Follow up 2 years: study 1- the relation between parental characteristics (level and course of self-efficacy, selfcontrol and motivation) and experienced social and professional support is studied. Study 2 - tested is whether the relationship between parental characteristics (self-efficacy, selfcontrol and motivation) and changes in parental behavior is moderated by the use and perception of social and professional support. project C - tested is whether use of professional support is related to improvements in living conditions, parenting

characteristics (self-efficacy, selfcontrol and motivation) and parenting behavior of at-risk mothers.

Follow-up 4 years- part A: Study 1 - The primary objective of study 1 is to test whether self-regulation of both fathers and mothers is a predictor for the development of self-regulation of the child. Study 2 - The effect of parenting factors such as scaffolding and autonomy support on self-regulation of the child will be investigated. Project C: The relationship between parenting risk factors such as anxiety and depression and stress regulation on child outcomes in self-regulation will be investigated. Furthermore, In studies 1, 2 and C the effect of specific genetic polymorphisms in interaction with parenting factors on self-regulation of the child will be investigated. Follow-up 4 years- part B: Study 1 * The effects of parenting behaviours, such as autonomy support, on the social-emotional (social competence) and cognitive development (self-control/executive functioning) will be investigated. Additionally, we will examine whether factors such as parental self-efficacy in the school context, teacher self-efficacy, and the quality of the parent-teacher relationship predict these parenting behaviours. Follow-up 7 years: Study 1: The effects of self-reported parental characteristics on developmental outcomes (socio-emotional, cognitive, physical and motor development) will be investigated. Additionally, we will study the role of parental characteristics in the relationship between risk factors and developmental outcomes of the child. Study 2 and project C: The effects of observed parental characteristics on developmental outcomes (socio-emotional, cognitive, physical and motor development) will be investigated. Additionally, we will study the role of

parental characteristics in the relationship between risk factors and developmental outcomes of the child. The stability in quality of parental support will be assessed between 12 months
and seven years of age.

Secondary outcome

Secundary dependent variables are physiological reactivity (study 2) and quality of the attachment relationship with the child (study 2 and 3), which were examined in relation tot parenting self-efficacy and attachment representations. In project C a secundary parameter is self-regulation of the child, which is studied in relationship to physiological reactivity of the mother and parental self-efficacy. An other secundary parameter is self-regulation of the child, which is studied in relationship to physiological reactivity of the mother and parental self-efficacy. In study 6, epigenetic changes will be explored in relation to attachment representation, parental sensitivity, parental self-efficacy and parental stress. Follow-up 2 years: study 1 - child outcomes (selfcontrol and behavior) are studied in relation to parental characteristics. Study 2 - a secondary paramater is child outcomes (selfcontrol and behavior). project C - a secondary paramater is the quality of the attachment relationship with the child. Follow-up 4 years: Secundary parameters are physiological reactivity (stress regulation) of the parent and child in relation to sensitivity and scaffolding of the parent in study 2 and project C. Follow-up 7 years: A secundary parameter is the child's perceived competence in the cognitive, social and motor domain.

Study description

Background summary

This study will examine parental self-efficacy in relation to caregiving stress. The question is whether this stress can be influenced, for example by experiences and information which may strengthen or weaken parental self-efficacy. Future parents who have been informed about a congenital abnormality diagnosis of their baby are faced par excellence with caregiving related stress, even during pregnancy. The question is which caregiver characteristics may moderate the impact of this stress factor. This study is focused on caregivers' mental respresentations of attachment, based on the link between this representations and successful parenting on the one hand and more effective regulation of stress on the other hand. Furthermore, the effects of anxiety and depression on parental self-efficacy, sensitivity and attachment relations are studied. It will be investigated whether variations in attachment representations moderate the effects of anxiety and depression.

Study objective

Study 1 is aimed to describe normative trajectories of parenting efficacy from pregnancy to early parenthood. Study 2 is focused on the question whether mental representations of attachment are protective in the context of parenting stress and its influence on parental self-efficacy. This will be examined in a simulated parenting task. It is also examined whether robustness of self-efficacy as well as optimal regulation of stress during the parenting task are predictive of the stability of self-efficacy during pregnancy and early childhood on the one hand and the quality of the parent-child relationship on the other hand. Study 3 is aimed to test a short cognitive-behavioural therapy designed for parents dealing with a prenatal diagnosis of a congenital abnormality. Furthermore the protective influence of mental representations of attachment on dealing with a prenatal diagnosis will be tested.
The most important objective of project C is to examine the protective influence of mental representations of attachment and social support on the intergenerational transmission of risk in mothers with an unresolved trauma. Another objective is to investigate whether stress-reactivity and self-efficacy expectations explain the relationship between unresolved trauma on the one hand and self-regulation and the mother-child attachment relationship on the other hand. The third objective is to test in how far parental self-efficacy mediates the association between anxiety and depression of the mother on one hand and her sensitivity to het child and the quality of the attachment relation between mother and child on the other hand. In addition the role of attachment representations of the mother is investigated. Study 6 focuses on epigenetic comparisons between two groups of of first-time mothers, mothers exposed to traumatic caregiving and mothers without these experiences. Examining epigenome

in these two groups will help to identify epigenetic changes (and genes) which are specific for high-risk women. Follow-up 2 years: the follow-up is aimed at gaining insight in parental characteristics, parenting behavior and characteristics of the child that play a role in problems concerning upbringing and the effects of social support and professional help. Follow-up 4 years- part A: The follow up examines the role of parenting characteristics and genotype on the self-regulatory capacity of the child. Focusing on self-regulation will help identify the factors that benefit children in the transition to school. Follow-up 4 jaar- part B: The follow-up examines the effects of parenting behaviours, such as autonomy support, on the social-emotional and cognitive development of the child. This follow-up will also help to identify factors that are predictive of these parenting behaviours. Follow-up 7 years: The follow-up seven years is aimed at studying the relationship between parental characteristics and parenting behaviour and developmental outcomes in the socio-emotional, cognitive and physical and motor domain. Furthermore, the role of parental characteristics and parenting behaviour in the relationship between risk factors and developmental outcomes will be examined. The stability in parental support between 12 months and seven years of age will be assessed.

Study design

Prospective observational cohort studies

Intervention

Study 3 is aimed to test an intervention:
Control group: standard psychosocial care
Therapy group: short-term psychotherapeutic program.

Study burden and risks

On five time-points (three during pregnancy and two after pregnancy), all women are questioned about their functioning. Additional measurements are made in the subsamples (study 2, 3,project C), which included an interview (T2: study 2, 3, project C), a parenting task (T2; study 2, project C), an observation of children's self-regulation and parent-child interaction (T4, project C) an observation of the child's temperament and the mothers sensitivity (T5: study 2), observation of the parent-child relation (T4: project C; T6: study 2, 3, project C), an interview on perinatal health and care by telephone (at T4 and T6) (and a diagnostic interview (CIDI) by telephone (T6: study 4 and 5). Study 6: Saliva form mother and child is taken during a home-visit in order to perform a 'genomewide methylation scan'. Follow-up 2 years: study 1 fills in questionnaires, study 2 and project C fill in questionnaires and a home visit is carried out. Follow-up 4 years- part A and B: Study 1: Questionnaires will be filled in by mothers, fathers and teachers. 2 ml of saliva for genotyping

will be collected from mothers, fathers, the child and any potential siblings with saliva collection kits sent to the home. Study 2 and project C: In addition to questionnaires and saliva samples, children will conduct a series of executive control tasks and a parent-child observation task in the university lab. Follow-up 7 years: study 1 fills in questionnaires, study 2 and project C fill in questionnaires and a visit to the sports facility of the VU in Amstelveen is carried out.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria for samples I, II, and for sample C : First pregnancy or previous pregnancy which ended in a miscarriage before 10 weeks. Supplementary inclusion criteria sample II: Pregnancy in week 20-22 . Supplementary inclusion criteria sample III: pregnant women

considered to be at higher risk of having a baby with a congenital abnormality, based on advanced ultrasonography between 14-32 weeks of gestation.
Supplementary inclusion criteria for sample C a. Pregnant women who have been in contact with mental health services or child protection agencies before the age of 18, who are currently in contact with mental health care or who had one or more traumatic experience before the age of 18. b.Positive screening for depression (BDI >13) and / or positive screening for anxiety disorder (STAI > 40) on at least one timepoint during pregnancy. c. Negative screening for depression (BDI<13) and anxiety disorder (STAI<40) at all time points during pregnancy. This sample (controle groep) is taken from the larger cohort of study II. Supplementary inclusion criteria sample for Study VI: a. Participants from Sample C: childhood trauma, ACE score > 4. b.Participants from sample 2: Absence of childhood trauma, indicated by responses to the Adult Attachment Interview (question 9), negative screening depression and anxiety on all measurements (BDI <13 and STAI <40), and age mother between 18 and 35. Supplementary inclusion criteria Follow-up study (2 years postpartum): participation in study 1, 2 or project C. Supplementary inclusion criteria Follow-up study (4 years postpartum)- part A and B: participation in study 1, 2 or project C. Study 6: participation in Study 2 or C. Follow-up study (7 years postpartum): participation in study 1, 2 or project C.

Exclusion criteria

Exclusion criteria for sample I, II, III and sample C: Insufficient mastery of Dutch language. Supplementary exclusion criteria for sample II, and sample C: a. prenatal diagnosis of a congenital abnormality b. Abortion or interruption of pregnancy before 24 weeks pregnancy. Supplementary exclusion criteria for Sample III: a. Pregnant women considered to be at higher risk of having a baby with a congenital abnormality, based on invasive diagnostics early in pregnancy (10-12 weeks). b. Isolated growth delay of the fetus. c. Pregnant women with possible congenital abnormality, based on ultra-sound scans at a centre of primary care, but not confirmed at the VUmc or other specialized centres. d. Previous pregnancy of a child with a congenital abnormality. e. Insufficient mastery of Dutch or English language. Supplementary exclusion criteria for sample VI: participants from sample C: child with a congenital abnormality. Participants from sample 2:one or more childhood trauma's (AAI), positive screening anxiety and depression (STAI > 40 en/ of BDI >13) and child with a congenital abnormality.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	1850
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-07-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-09-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-08-2011
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-01-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-12-2016
Application type:	Amendment

Review commission: METC Amsterdam UMC

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	NL24319.029.08