

Fathers Today: The Role of Hormones in Father's Sensitive and Protective Parenting

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

Samenvatting

ID

NL-OMON25106

Bron

NTR

Verkorte titel

Fathers Today

Aandoening

hormones, fathers, parenting, neuroimaging

Ondersteuning

Primaire sponsor: ERC (Horizon 2020), Spinoza (NWO)

Overige ondersteuning: The present study is funded by an European Research Council (ERC) Advanced Grant (AdG) (ERC AdG 669249) awarded to M.J. Bakermans-Kranenburg and a Spinoza prize awarded to Marnius H. van IJzendoorn.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome:

We will examine the effects of oxytocin and vasopressin administration on quality of infant-father interactions, protective paternal behaviors, and use of handgrip force when fathers listen to infant cry sounds

Toelichting onderzoek

Achtergrond van het onderzoek

Summary:

Whereas previous research has mostly focused on the hormonal, behavioral and neural correlates of maternal caregiving, the present study will examine the hormonal, behavioral, and neural dynamics of paternal behavior in first-time fathers during a specific phase of fatherhood: between 2 and 7 months after the baby has been born. The study includes a randomized, double-blind, placebo-controlled within-subject design to examine the effects of intranasal administration of oxytocin and vasopressin on parenting behavior and the neural and behavioral responses to infant signals. In addition, we will examine whether effects of oxytocin and vasopressin are moderated by fathers' early childhood experiences.

Study population:

A total of 55 first-time fathers of a child aged between 2 and 7 months old will visit our lab for three experimental sessions. The experimental sessions include the following conditions: intranasal administration of (1) oxytocin, (2) vasopressin, and (3) a placebo. Participants will be randomly assigned to order of administration. Participants and researchers are blind to order of administration. The experimental sessions will take place with intervening periods of 1 to 2 weeks.

Intervention:

Participants are randomly assigned to one of the six counterbalanced orders of conditions. Participants are instructed to self-administer oxytocin (Syntocinon®, 24 IU/ml, registered in the Netherlands as RVG 03716), vasopressin (Vasostriect®, 20 IU/ml), or placebo (Chlorbutanol solution) using a nasal spray. Self-administration takes place under supervision of a researcher blind to condition. All experimental medication is prepared by the hospital pharmacy of the Amsterdam University Medical Centre. Randomization of administration is performed by an independent researcher who is not involved in the study. Randomization is performed before the start of the interventions using a computer-generated randomization sequence. Researchers and participants are blind to order of assignment.

Doel van het onderzoek

Our primary hypotheses are:

1. We hypothesize that infant-father interactions in the oxytocin and vasopressin condition are characterized by enhanced stimulatory and sensitive play and increased paternal protective behavior as compared to the placebo condition.
2. We expect that oxytocin and vasopressin administration affect behavioral responses to infant cry sounds and neural responses to infant cry sounds and threat to the infant.

Onderzoeksopzet

Participants will visit our research centrum for three experimental sessions.

Onderzoeksproduct en/of interventie

Administration of oxytocin, vasopressin, and placebo. Participants are randomly assigned to one of the six counterbalanced orders of conditions.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Fathers having their first baby, child's age = 2-7 months; living in the same house as their partner and the baby. Both parents must have parental authority.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

History of or current neurological disorders, endocrine diseases, psychiatric disorders, cardiovascular diseases, use of psychoactive medications, nose injuries and disorders, or magnetic resonance imaging contraindications.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	02-12-2019
Aantal proefpersonen:	55
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting

N/A

Ethische beoordeling

Positief advies

Datum: 30-10-2019
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48305
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8124
CCMO	NL70143.058.19
OMON	NL-OMON48305

Resultaten

Samenvatting resultaten

N/A