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

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In this randomized control trial (RCT) the following hypothesis will be tested: Intranasal administration of oxytocin and vasopressin affect neural and behavioral responses to infant signals and threat to the infant.

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

Summary

ID

NL-OMON48305

Source
ToetsingOnline

Brief title
Fathers Today

Condition

- Other condition

Synonym
n.a.

Health condition

Onderzoek heeft geen betrekking op een aandoening, maar bestudeert de effecten van hormonen op het vaderschap

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: European Research Counsil

Intervention

Keyword: fathers, hormones, neuroimaging, parenting

Outcome measures

Primary outcome

The first main study parameter is activity in documented parenting-related brain areas. We will examine the effects of oxytocin and vasopressin on activity in these areas in fathers during processing of infant signals and threat to infant in tasks designed to elicit protective responses.

The second main study parameter is parenting behavior, including handgrip strength during infant cry sounds, sensitivity, involvement, and protection. We will examine the effects of oxytocin and vasopressin on these parenting dimensions.

Secondary outcome

We will examine the link between neural and behavioral effects of oxytocin and vasopressin administration, and explore the extent to which effects of oxytocin and vasopressin are moderated by father*s early childhood experiences.

We will measure hormonal levels to explore the associations with involvement in infant care (cortisol, testosterone, oxytocin), to control for cross-reactions (oxytocin-vasopressin), and to examine mechanisms (testosterone * estradiol *

oxytocin and testosterone - vasopressin).

Study description

Background summary

Several studies in humans have shown associations of oxytocin and vasopressin levels with parent-child interaction (Apter-Levi, Zagoory-Sharon, & Feldman, 2014* Atzil, Hendler, Zagoory-Sharon, Winetraub, & Feldman, 2012* Bick & Dozier, 2010* Feldman, Gordon, Schneiderman, Weisman, & Zagoory-Sharon, 2010). Furthermore, experimental manipulation of oxytocin and vasopressin levels through nasal administration affects parenting behavior and the neural processing of infant signals (Cohen-Bendahan, Beijers, van Doornen, & de Weerth, 2015* Naber, van IJzendoorn, Deschamps, van Engeland, & Bakermans-Kranenburg, 2010* Riem et al., 2011; Thijssen et al., 2018; Van *t Veer et al., 2019) .

We propose a randomized, double-blind, placebo-controlled within-subject design to gain insight into the hormonal and behavioral dynamics of the paternal role in a critical phase of parenthood: the transition to having the first baby. The focus lies on the 50% of parents who have tended to be neglected in research and *until recently in family policies: fathers. A special focus is on a dimension of parenting that has received considerable attention in animal research but, despite its evolutionary importance, not in studies on humans: the role of the parent as protector. Protection is a crucial aspect of human parenting. This is perhaps demonstrated most convincingly when we are confronted with the absence of parental protection, i.e. neglect, or child physical abuse.

In a seminal paper, Shelley Taylor and her colleagues proposed the tend-and-befriend model as an alternative to the fight-or-flight model of behavioral responses to stress (Taylor et al., 2000). Tending, the protection and care of offspring, and befriending, the formation and maintenance of interpersonal relationships with conspecifics, were proposed as strategies that females use in times of stress to defend themselves and their offspring. A central role in this model is attributed to oxytocin, which provides the neuroendocrinal basis for affiliation with social groups. A second hormone that may play a role in protective fathering is vasopressin. In men, vasopressin levels have been associated with parenting behavior (Abraham & Feldman, 2018). Vasopressin administration to fathers-to-be promotes attention to virtual baby-related avatars (Cohen-Bendahan et al., 2015) and affects neural and behavioral responses to infant cry sounds (Thijssen et al., 2018; Alyousefi-Van Dijk et al., 2019), pointing to a role for vasopressin in responding to infant distress.

In research on parenting quality, parental sensitivity is a key construct. It refers to the ability to attend to infant signals and to respond promptly and appropriately (Ainsworth, Bell, & Stayton, 1974). Studies show that fathers on average are less sensitive towards their infants and toddlers than mothers (Barnett, Deng, Mills-Koonce, Willoughby, & Cox, 2008* Hallers-Haalboom et al., 2014* Schoppe-Sullivan et al., 2006* Volling, McElwain, Notaro, & Herrera, 2002), although seeing infants has similar motivational salience to men and women (Parsons et al., 2011). Similarly to the pattern of associations for mothers, higher levels of paternal sensitivity predict more favorable child outcomes (Lewis & Lamb, 2003). Sensitive parenting starts with the processing of infant signals, which has been shown to be affected by oxytocin levels (Riem et al., 2011) and vasopressin levels (Thijssen et al., 2018)

Mapping parental brain responses to infant stimuli using fMRI has increased our knowledge of brain processes involved in parenting sensitivity. Brain regions expected to be important to parenting are circuitries related to (1) arousal/salience (amygdala, ventral striatum), (2) reflexive care (hypothalamus), (3) emotion regulation (insula, medial prefrontal cortex, anterior cingulate cortex), and cognitive / empathic processing (insula, inferior frontal and orbitofrontal gyri, temporoparietal junction) (Swain et al., 2014; Witteman, 2019). Exposing parents to child stimuli in fMRI studies activates neural systems involved in these regions. Effects of oxytocin and vasopressin on the amygdala and the insula, medial prefrontal cortex, and inferior frontal gyrus have been established in females (Atzil et al., 2012* Riem et al., 2011). Replication in fathers is badly needed.

In this proposed RCT fathers will be observed with their own child, and using standardized infant stimuli. We will test the effects of hormone administration (oxytocin and vasopressin) on the processing of infant crying, on protective parenting, and on the quantity (involvement) and quality (sensitivity) of father-child interaction. Testing the effects of hormone administration on the processing of infant crying, protection, involvement, and sensitivity may help unravel the mechanisms of effective parenting.

Study objective

In this randomized control trial (RCT) the following hypothesis will be tested: Intranasal administration of oxytocin and vasopressin affect neural and behavioral responses to infant signals and threat to the infant.

Study design

We will employ a randomized, double-blind, placebo-controlled within-subject design with 55 fathers of a 2-7 month-old infant. Fathers will participate in three experimental sessions, which take place with intervening periods of 1-2 weeks, with intranasal administration of 24 IU of (1) oxytocin, (2) 20 IU

vasopressin, or (3) a placebo. The three conditions imply six possible counterbalanced orders of conditions, and assignment of participants to order of administration will be random. Administration will be double-blind. The data collection is expected to take approximately 1 year. The study will be conducted at the fMRI facilities at the Spinozacentrum. A successful pilot study has been conducted.

Intervention

administration of (1) oxytocin, (2) vasopressin, or (3) placebo

Study burden and risks

There are no risks associated with the assessments used in this study. Possible side effects of oxytocin and vasopressin are negligible. No adverse effects have been reported in participants/patients undergoing MRI at the currently available field strengths. The pilot study has not revealed any adverse outcomes. We asked fathers to evaluate their participation, and they were positive (*In de evaluatievragen, die digitaal en niet in het zicht van de onderzoeker werd ingevuld, gaven de deelnemers een positieve beoordeling aan het onderzoek: Op een schaal van 1-10 was het gemiddelde *rapportcijfer* voor algemene ervaringen als deelnemer aan dit onderzoek een 7,9 (range 7-10; alle deelnemers gaven dus participatie aan het onderzoek minimaal een *ruim voldoende* *. Uit het verslag van de pilotstudie verstuurd aan de METC, 27 december 2016).

Once we understand the neurobiological underpinnings of good-enough and poor parental sensitivity and protection, better attempts can be made to improve parenting and reduce the adverse effects of poor parenting. The proposed study is ground-breaking in that it includes paternal protection, an important dimension of parenting that has been neglected in all imaging studies and virtually all behavioral studies of parenting to date, maybe because of the almost exclusive focus on mothers

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

Fathers who have had their first baby, child*s age <= 2-7 months; living in the same house as their partner and baby. The baby is a full-term, healthy infant. Both parents must have parental responsibility over the child.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

Endocrine disorders
Smoking
Alcohol and drug abuse
Use of medication potentially interfering with the endocrine system
MRI contraindications, including metallic foreign objects, neurological disorder and claustrophobia
Cardiovascular disease
Nose injuries and disorders

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2019
Enrollment:	55
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-09-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 25106
Source: NTR

Title:

In other registers

Register	ID
CCMO	NL70143.058.19
OMON	NL-OMON25106