Caregiving fathers: do hormones help them along?

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON33567

Source
ToetsingOnline

Brief title
Caregiving fathers and hormones

Condition

- Other condition
- Lifestyle issues

Synonym
caring, fatherhood

Health condition

het gaat niet om een aandoening maar om hormonale invloed op zorg voor kinderen

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: NWO VENI subsidie 016.075.172

Intervention

Keyword: development, hormones, infants, paternal caregiving

Outcome measures

Primary outcome

The main interest of the study is the relationship between hormone levels and caregiving attitudes, interest, and behavior. Besides looking at the relationships between basal levels of 5 different hormones (i.e. oxytocin, vasopressin, testosterone, prolactin, and cortisol) and the caregiving factors, we will also look at how altering the levels of two of the hormones affects these relationships. Therefore, we plan to conduct an experiment that will be carried out three times for each participant. Each session will be used to test the effects of the elevation of one of these hormones or the placebo. The hormones that are tested are oxytocin, and vasopressin. These hormones are administered through an intranasal spray, and past research has shown that hormonal alterations of this kind can affect behavior.
In the experiment we measure indicators of the subjects* caregiving interest in a virtual world. We expect that the participants treated with hormonal spray will show more caregiving interest as compared to the placebo condition. We expect the fathers-to-be to primed for caregiving and therefore to show a larger response towards the sprays as compared to the childless controls.
Specific hypotheses concerning the hormone levels are:

We hypothesize that oxytocin will be positively related to caregiving interest and caregiving behavior.

We hypothesize that prolactin will be positively related to caregiving interest and caregiving behavior.

We hypothesize that cortisol will be negatively related to oxytocin, and to caregiving interest and caregiving behavior.

We hypothesize that testosterone will be negatively related to caregiving interest and caregiving behavior.

We hypothesize that vasopressin has a greater role than oxytocin in actual paternal caregiving.

Secondary outcome

n.a.

Study description

Background summary

First-time fathers stand at the doorstep of a new unfamiliar phase in their lives - a phase with new responsibilities and challenges. Today*s fathers are expected, socially and politically, to participate in the care and upbringing of their offspring. However, fathers show different qualities and interests in caregiving behavior.

Study objective

This proposal centers on hormone-behavior dynamics in paternal caregiving, with the goal of gaining a better understanding of the development of human paternal caregiving. There is limited information on the hormonal basis of caregiving patterns in humans. While there have been some studies of caregiving in women, there have been virtually none involving men. The studies that have been conducted have not related the hormonal changes that occur during the transition into fatherhood to behavioral aspects of paternal caregiving behavior. The scarce studies thus far leave the cause-effect relation between

hormones and care unanswered.

Study design

This longitudinal study consists of a Prenatal Study and a Postpartum study:
The aim of the Prenatal Study, performed around 32 weeks of gestation for the fathers-to-be. The participants will be invited for laboratory visits, and asked to collect biological material (i.e., saliva samples for testosterone and cortisol assessments, and urine samples for vasopressin and oxytocin; bloodspot samples for measuring prolactin will be taken at the lab) and fill in online questionnaires at home (i.e. demographic information, health, personality, sex role, caregiving attitudes, interest, and behavior, work hours).

During the experiment at our laboratory the participants will receive a single dose intranasal oxytocin, vasopressin, and placebo in a double-blind, intra-subject, counterbalanced crossover design. Because the oxytocin and vasopressin may cause possible receptor sensitization effects the experiment will be carried out once a week for a three week research period.
The first-time fathers will continue their participation in the Postpartum Study. When the infants are 3, 6 and 9 months of age both parents will fill in a 4-day diary about parental caregiving activities, and the father will answer a questionnaire on the mother-father distribution of caregiving activities over the last 3 months. During the diary periods fathers will also be requested to collect biological samples to investigate whether for example variations in quantity of care covary with oxytocin16.
Finally at 9 months postpartum fathers will be invited to visit the laboratory together with their infant. This laboratory visit consists of two parts:
(1) Filling in questionnaires (i.e. caregiving attitudes, interest, and behavior, parenting hassles, work hours).
(2) Videotaped observation of father-infant dyad during three activities at the BSI lab: a diaper changing, a short semi-structured playing, and a feeding.

Study burden and risks

The participants visit our lab three times during the first part of the study. Each time we will collect hormones mainly through non-invasive methods, i.e. saliva and urine. Only prolactin is collected by a finger prick which is considered as a relatively mild invasive method. The lab visits are regarded as pleasant and interesting experiences by most participants (personal communication during pilot study). A set of questionnaires are filled in online, time approximately: 30 to 45 minutes.
During the second longitudinal part, the postpartum study, we chose to collect only the minimal necessary data. Therefore we will ask the fathers to collect hormones every 3 months using only the non-invasive methods, i.e. saliva and urine. In addition, they will fill out a very basic caregiving diary during 4 days. When the infant is 9 months old the fathers are invited to come with the

child to the lab for a semi-structured observation including a diaper change, a small feeding session and a play moment.
We are well aware of the time investment of the subjects and during the whole study will take utmost care to accommodate their time schedules and wishes in order to minimize their discomfort and strain.
The medical risks that could be related to the use of the intranasal sprays, Syntocinon and Desmopressin, are considered very low for the following reasons:
(1) Only healthy subjects will participate. The candidates will be screened by means of a health questionnaire. Subjects will be rejected upon indications of health problems, e.g. psychotic symptoms, substance dependence, epilepsy, severe kidney disease, and traumatic brain injury.
(2) The participants will receive each intranasal spray separated by at least one week in order to give sufficient wash-out time to avoid any pharmacokinetic carry-over effect.
(3) The hormonal sprays are synthetic substitutes of normal body hormones. By administrating the intranasal sprays we alter the levels of these hormones for a relatively short period. The hormone levels will reach their peak around 80 minutes after administration6,40 and decline rather rapidly afterwards40.
(4) The intranasal sprays are normally prescribed to vulnerable populations, for example Syntocinon is used to induce milk production in breastfeeding women, and Desmopressin is prescribed mainly for children with bedwetting problems.
(5) The sprays have been extensively tested in clinical trials and the adverse events as mentioned in the product information are relatively infrequent and mild. Moreover, normally adverse events occur only after repeated use, which is not the case in our study. In the VIS study participants will only receive a single dose of each spray on one separate occasion.
(6) Similar intranasal sprays have been used without problem in scientific studies in recent years, for example:
• Bartz JA, Hollander E.(2008).Oxytocin and experimental therapeutics in autism spectrum disorders. Prog Brain Res,170:451-62.
• Bruins J, Hijman R, Van Ree JM. (1992). Effect of a single dose of des-glycinamide-[Arg8]vasopressin or oxytocin on cognitive processes in young healthy subjects. Peptides,13(3):461-8.
• Bruins J, Hijman R, Van Ree JM. (1995). Effect of acute and chronic treatment with desglycinamide-[Arg8]vasopressin in young male and female volunteers. Peptides,16(2):179-86.
• Guastella AJ, Carson DS, Dadds MR, Mitchell PB, Cox RE. (2009). Does oxytocin influence the early detection of angry and happy faces? Psychoneuroendocrinology, 34:220-225.
• Guastella AJ, Mitchell PB, Dadds MR. (2008). Oxytocin increases gaze to the eye region of human faces. Biol Psychiatry. 63(1):3-5.
• Heinrichs M, Domes G.(2008). Neuropeptides and social behaviour: effects of oxytocin and vasopressin in humans. Prog Brain Res,170:337-50.
• Kosfeld M, Heinrichs M, Zak PJ, Fischbacher U, Fehr E. (2005). Oxytocin increases trust in humans. Nature, 435(7042):673-6.
• Pietrowsky R, Strüben C, Mölle M, Fehm HL, Born J. (1996). Brain potential

changes after intranasal vs. intravenous administration of vasopressin: evidence for a direct nose-brain pathway for peptide effects in humans. Biol Psychiatry. 39(5):332-40.
• Von Dawans B, Fischbacher U, Fehr E, Heinrichs M. (2008). Neuropeptides and social behavior: Effects of oxytocin and vasopressin on trust and punishment in humans. 39th Annual International Society of Psychoneuroendocrinology Conference, Dresden, 17-20 July

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The participants will be 60 expectant nulliparous fathers and 30 non-expectant childless men as controls; physically and mentally healthy men; in a relationship and living together with this partner

Exclusion criteria

Unhealthy men, men with previous children or stepchildren, men expecting twins, single men.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	90
Type:	Anticipated

Ethics review

Not approved

Date:	14-04-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL25668.041.09