The role of Oxytocin in parenting: validation of a novel "baby social reward task"

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON35803

Source
ToetsingOnline

Brief title
The role of Oxytocin in parenting

Condition

- Other condition

Synonym
not applicable

Health condition

No disorder, effect on Parenting

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO VICI

Intervention

Keyword: crying, infants, Oxytocin, parenting

Outcome measures

Primary outcome

The main study parameter is the amount of effort invested by a subject to sooth an infant and then to protect an infant from a threat (assessed by a computer based *Baby social reward task* with infant faces and accompanying infant sounds).

Secondary outcome

OXTR genotype

Study description

Background summary

Infant smiling and crying are important signaling behaviors that alert the caregiver and elicit nurturance and close physical proximity to the caregiver (Bowlby, 1969; Murray, 1979; Zeifman, 2001). Although these behaviors have evolved to increase survival and to aid infant development, excessive and uncontrollable crying might lead to neglecting and abusive parenting and even infanticide (Lee, Barr, Catherine, & Wicks, 2007; Soltis, 2004).
Although the infant has a profound effect on parents* behavior, parents also differ in their sensitivity towards their infants* signals resulting in different caregiving behaviors. Ainsworth, Blehar, Waters, and Wall, (1978) describe sensitivity as the ability to interpret infant signals correctly and to respond in an appropriate and prompt way. Previous research has indicated that some individuals might respond insensitively and more harshly to aversive infant signals such as crying, as compared to other individuals. Abusive parents also display increased physiological reactivity towards infant crying such as a higher heart rate and skin conductance compared to sensitive parents

(Frodi & Lamb, 1980; McCanne & Hagstrom, 1996). Furthermore, they report more feelings of discomfort and frustration in response to crying infants as compared to sensitive parents who report more empathic feelings (Crouch, Skowronski, Milner, & Harris, 2008).

Study objective

In this study we focus on behavior in response to different infant signals, including crying as well as smiling. More specifically we investigate the behavioral differences of an individual towards different infants who are either perceived as happy and consolable versus infants perceived as distressed and unresponsive. This is assessed by a computer based task called *the baby social reward task* specifically designed for the present proposal. Moreover, the main aim of the study is to explore the effects of oxytocin on adults* behaviors during the task as oxytocin has been implicated in social affiliation and parental behaviors. Research from our group has shown that increased levels of oxytocin induce more sensitive parenting (Naber, Van IJzendoorn, Deschamps, Engeland, & Bakermans-Kranenburg, 2010). Many other researchers have also shown plasma oxytocin levels to be associated with parental sensitivity (Feldman et al., 2010; Gordon, Zagoory-Sharon, Leckman, & Feldman, 2010; Levine, Zagoory-Sharon, Feldman, & Weller, 2007). However, recent studies have shown that oxytocin might have a polarizing effect on human behavior. Specifically, Bartz and colleagues (2010) have demonstrated that individuals with a secure attachment style reported their parents to be more caring after oxytocin administration, whereas individuals with an anxious attachment style reported their parents to be less caring after oxytocin administration as compared to placebo administration. Similarly, De Dreu and colleagues (2010) suggest a *tend and defend* effect of oxytocin in altruistic behaviors towards in-group and out-group members respectively.
To our knowledge, there are no studies showing polarizing effects of oxytocin on parental behaviors. The present proposal aims to establish whether oxytocin only has positive effects on parenting or might result in different effects when the perception about the infants varies from positive (happy and consolable) to negative (distressed and unresponsive), and how this is related to participants* affect while taking care of an infant simulator. Additionally, we also wish to investigate how the effects of oxytocin administration is modulated by individuals* oxytocin receptor genotype (OXTR GG versus AA/AG) as this polymorphism has been previously implicated in parental sensitivity (Bakermans-Kranenburg & Van IJzendoorn, 2008).

Primary Aim:
Modulation of behavioral responses of adults towards infants perceived as happy and consolable versus distressed and unresponsive, by intranasal oxytocin administration.

Secondary Aim:
Association between these behaviors with 1) reported feelings of empathy and

aversiveness in response to infant crying and 2) their oxytocin receptor genotype (GG vs. AA/AG).

Importance of the knowledge to be gained
The proposed study will help us in understanding the complex cognitive and neurobiological mechanisms underlying parenting behaviors. It will also give us insight into the interaction of various factors (infant crying and parental sensitivity differences) which may lead to abusive parenting.

Study design

This is a randomized, placebo-controlled, double-blind, between-subjects design to assess how oxytocin influences individuals* behavior towards happy and consolable infants versus distressed and inconsolable infants (Baby social reward task).

The participants will take part in a laboratory session during which subjects will perform a social baby reward task which will assess their behavior towards infants considered as happy and consolable versus infants perceived distressed and unresponsive.

Study burden and risks

During the session the subjects will take 6 puffs of nasal spray containing 4 IU/ puff of oxytocin (Syntocinon, Novartis), or 6 puffs of a placebo-spray (NaCl solution). Intranasal oxytocin is widely prescribed in lactating women and is well tolerated. High doses (> 60 IU) of oxytocin nasal spray may in some cases lead to headache. Based on the single doses of 24 IU (i.e. 6 puffs, each containing 4 IU of oxytocin) that will be used during this study and the effects of oxytocin nasal spray in general, there will be low risk for the participants in this study.

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

Healthy female subjects (non-parents), 18-30 years old

Exclusion criteria

Neurological impairments, visual and auditory impairment, use of medication (except oral contraceptives), drug or alcohol abuse, psychiatric disorder, nasal disease or obstruction, smoking, pregnancy, and breast feeding.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2011
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Syntocinon
Generic name:	oxytocin nasal spray
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	10-05-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-07-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	26-01-2012
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-001537-17-NL
CCMO	NL36618.058.11