The full scope of oxytocinergic influences on the parental brain: Maternal defensiveness and grandparent-child interactions

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41352

Source
ToetsingOnline

Brief title
Oxytocin, defensiveness, and grandparenting

Condition

- Other condition
- Age related factors

Synonym
Not applicable

Health condition

Adult-child interaction, behavioral and brain responses

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Ministerie van OC&W,NWO: VICI grant no. 453-09-003 and the SPINOZA prize,Dr. Peltola is funded by a travel grant from the Kone Foundation which is an independent and unaffiliated Finnish organization;the aim of which is to promote Finnish academic research.

Intervention

Keyword: grandparenting, oxytocin, Parenting

Outcome measures

Primary outcome

The main study parameters are a) the intensity of the mother*s

defensive/protective responses during the ESP, b) the direction and magnitude

of frontal EEG asymmetry and event-related potentials in response to images of

their own infant in different priming contexts (social threat vs. neutral), c)

observed caregiving sensitivity, d) salivary levels of oxytocin, and e)

self-reported attachment representations.

Secondary outcome

Not applicable

Study description

Background summary

Children require extensive parental care and protection during infancy. Upon childbearing, caregivers need to be able to flexibly change from nurturing and affiliative behaviors to protective behaviors to defend the immature offspring. Such plasticity in behavioral tendencies has been suggested to be supported by dedicated neural and neuroendocrinological systems of which the neuropeptide

oxytocin, in particular, has been suggested to be central in mediating parenting behaviors. Animal studies have shown that the oxytocin system is associated with the level of maternal care and affiliation toward the offspring and also with aggression and defensive reactivity when the offspring are threatened. In humans, evidence is likewise accumulating to show the importance of oxytocin in promoting parental caregiving sensitivity towards and affectionate interactions with infants. No research to date, however, has been conducted on the potential role of oxytocin in promoting protective behaviors and defensive aggression in threatening contexts in the parents of human infants. In addition, the role of the oxytocin system in grandparent-grandchild interactions is largely neglected. Thus, to gain a comprehensive picture of the neural bases of (grand)parenting behaviors in humans, research is needed to investigate the role of oxytocin in influencing parental and grandparental reactions to their (grand)children. By testing infants, mothers, and grandmothers simultaneously, the project will tackle these issues.

Study objective

Our primary aims are 1) to test with observational and electrophysiological techniques whether intranasal oxytocin administration to mothers of young infants increases their defensive reactivity and protective approach responses in mildly threatening contexts, and 2) to expand the current field of research on oxytocin to ageing populations by measuring whether intranasal oxytocin administration increases grandmothers* sensitivity towards their grandchildren similarly as in parents. The secondary aims are to measure the concordance in all participants* salivary oxytocin levels and to assess the mothers* and grandmothers* attachment representations of one another and the potential modulation of such representations by oxytocin administration.

Study design

A placebo-controlled, double-blind, within-subjects design with two laboratory visits is used to measure the influence of oxytocin on mothers* defensive reactivity and grandmothers* sensitivity to their grandchildren.

Intervention

The participants will take part in two identical laboratory sessions one month apart which differ only by the content of the intranasal substance (oxytocin vs. placebo). The laboratory sessions consist of an observational paradigm (the Enthusiastic Stranger Paradigm; ESP), a recording of electroencephalography (EEG) from the mother, assessments of caregiving sensitivity with both the mother and the grandmother, collection of saliva samples to measure the participants* salivary oxytocin levels, and short questionnaires to measure the participants* attachment representations. The ESP is a semi-naturalistic observational paradigm in which an unfamiliar adult (a trained member of the

research team) approaches the infant in a slightly intrusive manner and may trigger defensive/protective responses from the mother (e.g., hypervigilance, verbal or behavioral attempts to interrupt the stranger). In the EEG task, we will use a subliminal affective priming paradigm to investigate whether oxytocin increases mothers* approach responses (measured with frontal EEG asymmetry in the alpha frequency band) and vigilance/attentiveness (measured with event-related brain potentials) toward images of their own vs. an unfamiliar infant after being primed by pictures depicting social threat. The grandmother*s sensitivity to her grandchild will be measured during the mother*s EEG recording and the mother*s sensitivity will be measured at the end of the laboratory session.

Study burden and risks

The study will include two visits to the Centre for Child and Family Studies, Leiden University, both of which will last less than 2 hours. The mother will undergo an EEG measurement for ca. 20 minutes. Other measures include observational measures for assessing caregiving sensitivity (mothers and grandmothers) and maternal defensive reactions (the ESP), and saliva samples (3 per session) for assessing the levels of salivary oxytocin. Oxytocin and placebo are administered intranasally (1 puff of nasal spray to each nostril) to the mother and grandmother. The experimenters need to be in physical contact with the participants: 1) the ESP includes an experimenter gently touching the infant and 2) preparation of the EEG requires physical contact with the mother. These forms of physical contact pose no risks to the participants and are painless. The ESP includes a brief encounter with a mildly intrusive stranger. Some of the mothers may experience this as uncomfortable. It is, however, part of the nature of this paradigm to be mildly uncomfortable to trigger the mother*s motivation to interrupt the stranger.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
-Mothers: healthy female subjects, 25-40 years old
-Grandmothers: healthy female subjects, 50-65 years old
-Infants: healthy infants, 5-6 months old during the first laboratory visit

Exclusion criteria

A potential subject who meets any of the following criteria during a telephone prescreening will be excluded from participation in this study:
-Breastfeeding
-Any known neurological, visual, and auditory impairment
-Use of medication (except oral contraceptives)
-Drug or alcohol abuse
-Psychiatric disorder
-Nasal disease or obstruction
-Smoking
-Pregnancy

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:	Recruitment stopped
Start date (anticipated):	05-12-2014
Enrollment:	100
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	20-02-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	19-06-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-02-2015

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-08-2015
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	EUCTR2013-000453-44-NL
CCMO	NL42746.058.13

Study results

Date completed:	13-11-2020
Actual enrolment:	10

Summary results
Trial is onging in other countries