# Oxytocin and the relation between parenting, fear of failure and ERP.

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Ethical review Approved WMO

**Status** Recruitment stopped

Health condition type Other condition
Study type Interventional

## **Summary**

## ID

NL-OMON32060

#### Source

**ToetsingOnline** 

## **Brief title**

Oxytocin and the relation between parenting, fear of failure and ERP

## **Condition**

Other condition

## **Synonym**

emotional neglect

#### **Health condition**

childhood neglect

#### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Universiteit Leiden

Source(s) of monetary or material Support: Ministerie van OC&W,NWO

#### Intervention

Keyword: EEG, fear of failure, love withdrawal, oxytocin

#### **Outcome measures**

## **Primary outcome**

The main study parameter is the amplitude of the FRN. We will examine the effects of oxytocin, and parental use of love withdrawal and associated fear of failure on FRN amplitude in the different conditions of the feedback task.

#### **Secondary outcome**

Additionaly we will examine whether students reporting high parental use of love withdrawal are indeed higher in fear of failure than those reporting lower parental use of love withdrawal.

# **Study description**

## **Background summary**

Love withdrawal is a punishment strategy that involves withholding expected signals of love and affection when a child misbehaves or fails at a task. Previous investigations have shown that parental use of love withdrawal can lead to fear of failure in the child. Individuals high in fear of failure appear to have learned to define failure as an unacceptable event that carries negative implications for their self-worth and relational security, leading them to vigilantly orient to and seek to avoid failure in achievement situations. The emotion shame plays a central part in this process. In a recent study, a relation was found between fear of failure and shame-proneness on the one hand, and the feedback-related negativity (FRN), a brain-response to feedback, on the other. The FRN is measured using EEG, and is more negative (i.e. stronger) when feedback is more negative than expected. We expect that oxytocin can modulate the effects of love withdrawal and

associated fear of failure on the FRN, because it influences socio-emotional processes that can explain the previously found relation between fear of failure and the FRN, and because it affects brain areas (anterior cingulate cortex and insula) that have been related to both the FRN and fear of failure.

## Study objective

With the proposed study we want to gain insight into the neaural mechanisms underlying (the development of) shame-proneness and fear of failure. We want to investigate whether the administration of oxytocin modulates effects of love withdrawal and associated fear of failure on FRN amplitude.

## Study design

We will employ a randomized, placebo-controlled, double-blind, within-subjects design: Two groups of subjects, reporting either low or high parental use of love withdrawal, will take part in two laboratory sessions during which they complete a computerized feedback-task while the EEG is measured. During one of these sessions oxytocin will be administered to the subjects and during the other session a placebo. The order of the sessions will be counterbalanced across subjects. Neither the subjects nor the investigator conducting the experiment will know which of the substances is administered.

#### Intervention

During one of the laboratory sessions the subjects will take 6 puffs of nasal spray containing 4 IU/ puff of oxytocin (Syntocinon, Novartis), during the other 6 puffs of a placebo-spray (NaCl solution).

## Study burden and risks

Questionnaires will be administered to the participants to measure fear of failure and parental use of love withdrawal (the Love withdrawal-subscale of the Children\*s Report of Parental Behavior (CRPBI) inventory (Schludermann & Schludermann, 1988) and the Concern over mistakes-subscale of the Multidimensional Perfectionism Scale (Frost et al., 1990)).

The participants will also take part in two 2 1/2 hour laboratory sessions. During these sessions they will complete a feedback-task (the same task is used during both sessions), while the EEG is measured. The EEG-measurement is non-invasive, and with the equipment we use, skin-abrasion is not necessary. During both sessions the subjects will take 6 puffs of nasal spray, once containing oxytocin, and once a placebo. 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 IUof 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**

#### **Public**

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## **Trial sites**

## **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

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

## **Inclusion criteria**

18-30 years old female

## **Exclusion criteria**

known neurological impairement use of medication (except oral contraceptives)

drug or alcohol abuse psychiatric disorder nasal disease or obstruction smoking pregnancy breast feeding

# 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): 01-01-2009

Enrollment: 50

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: 23-10-2008

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

No registrations found.

## In other registers

Register ID

EudraCT EUCTR2008-006170-15-NL

CCMO NL23347.058.08