# Stress reactivity in the context of infant signals

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

## Summary

### ID

NL-OMON36194

**Source**
ToetsingOnline

**Brief title**
Stress reactivity in the context of infant signals

### Condition

- Other condition
- Family issues

**Synonym**
risk for child abuse

**Health condition**

risk for child abuse

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universiteit Leiden
**Source(s) of monetary or material Support:** NWO VICI

## Intervention

**Keyword:** empathy, fMRI, infant crying, oxytocin

## Outcome measures

### Primary outcome

fMRI: we expect changes in brain activation in region involved in emotion regulation during exposure to infant crying compared to control sounds. We also expect a change in activation in these regions when participants are presented with pictures of adults and infant with emotional face expressions, compared to a control task. In addition, we expect oxytocin effects on brain activation during these empathy tasks and during infant crying.

### Secondary outcome

not applicable

# Study description

### Background summary

Annually 30 out of 1,000 children in the Netherlands suffer from child maltreatment. Previous research has indicated that mothers at risk for maltreating their children (often assessed with the Child Abuse Potential Inventory) show increased physiological responses to infant crying sounds and have lower levels of empathy than low risk individuals. However, little research has been done on the neural responses to infant crying and the neural base of empathy in individuals at risk for child abuse. As child abuse is a major cause for deviant child development, the study of the physiological mechanisms

underlying child abuse is crucial.

## Study objective

In this study neural responses to infant crying will be measured with fMRI. In addition, the neural base of emotion understanding will be examined with fMRI. Participants will look at pictures of adults and infant and they have to infer the mental state. Participants have been screened for risk for child abuse in a previous study with the Child Abuse Potential Inventory and have scores on this questionnaire ranging from low to high. We will examine the relation between child abuse risk and neural responses to infant crying and during 2 empathy tasks.

The aim of the study is to gain more insight in the physiological mechanisms that are involved in child abuse. In addition, we want to examine the effects of oxytocin on neural responses to infant crying and on the neural circuitry underlying empathy.

## Study design

This is a randomized, placebo-controlled, double-blind, between-subjects design to assess how oxytocin influences neural responses to infant crying and the neural empathy circuitry. The participants will receive oxytocin or a plabeo (24 IU oxytocin Syntocinon, Novartis) 40 minutes before fmri scanning.

Neural responses to infant crying will be measured with fMRI. In addition, the neural base of emotion understanding will be examined with fMRI. Participants will look at pictures of adults and infant and they have to infer the mental state.

## Intervention

Oxytocin or placebo administration: half of the participants will receive oxytocin or placebo

## Study burden and risks

The maximum duration of the labsession is 1,5 hour. De participants will be scanned with fMRI when they are listening to infant crying and when they are performing 2 empathy tasks. There are no known risks associated with participating in an fMRI study.Numerous children and adults have undergone magnetic resonance studies without apparent harmful consequences. Some people become claustrophobic while inside the magnet and in these cases the study will be terminated immediately at the subject's request. The only absolute contraindications to MRI studies are the presence of intracranial or intraocular metal, or a pacemaker. Relative contraindications include pregnancy

and claustrophobia. Subjects who may be pregnant, who are claustrophobic, who may have metallic foreign bodies in the eyes or head, or who have cardiac pacemakers will be excluded because of potential contraindications of MRI in such subjects.

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

woman, 18-30 years old, without children

### Exclusion criteria

Potential participants for the fMRI session will be prescreened for contra-indications for fMRI, which include metal implants, heart arrhythmia, claustrophobia, and possible pregnancy. They will additionally be prescreened for head trauma, drug or alcohol abuse and psychiatric disorder. Women younger than 18 years old and older than 30 years old and men are excluded.

## Study design

### Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-09-2011 |
| Enrollment: | 50 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Syntocinon |

| | |
|---|---|
| Generic name: | Oxytocin nasal spray |
| Registration: | Yes - NL outside intended use |

## Ethics review

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| Approved WMO Date: | 05-07-2011 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |
| Approved WMO Date: | 14-09-2011 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

## 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 | EUCTR2011-002537-20-NL |
| CCMO | NL37166.058.11 |