In search of child abuse potential: real life

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The aim of the study is to gain more insight in the physiological mechanisms that are involved in child abuse.

| Ethical review | Approved WMO |
|-----------------------|----------------------------|
| Status | Will not start |
| Health condition type | Other condition |
| Study type | Observational non invasive |

Summary

ID

NL-OMON36505

Source ToetsingOnline

Brief title In search of child abuse potential: real life

Condition

- Other condition
- Family issues

Synonym

child abuse

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: child abuse, empathy, fMRI, infant crying

Outcome measures

Primary outcome

Task-FMRI: change in activation of emotion (regulation) brain regions during the perception of infant stimuli compared to control sounds and during the empathy task (infer mental state) compared to the control task (gender discrimination), caregiving behaviors, heart rate, skin conductance and hand grip strength.

Secondary outcome

We will also investigate whether the CAP Inventory and infant simulator show diverging predictive power: is risk for child abuse as indicated by the infant simulator more strongly related with neural responses to infant crying than risk for child abuse as indicated by the CAP Inventory?

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

The aim of the study is to gain more insight in the physiological mechanisms that are involved in child abuse.

Study design

Two groups of subjects will participate in two laboratory sessions, the first group is at risk for child abuse, the second group has low risk for child abuse. Risk for child abuse will be measured with the Child Abuse Potential Inventory. In the first laboratory session, heart rate, skin conductance and hand grip strength will be assessed when participants are listening to infant crying and laughing. Heart rate, skin conductance and caregiving behaviors will be assessed when participants atke care of an infant simulator. A device within the doll records how the simulator is handled, for example whether the simulator has been shaken, received head support or was placed in the wrong position. The participants will be asked to take the infant simulator home and to take care of it for 24 hours. Buccal swaps will be collected to determine OXTR genotype. Neural responses to infant crying and laughing will be measured with fMRI in the second laboratory session. 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.

Study burden and risks

The first laboratory session takes 2,5 hours, the second session 1,5 hours. The participant will be left with the infant simulator for 90 minutes. They will be instructed to take care of the infant simulator and grip strenght, heart-rate and skin conductance will be assessed. The CAP Inventory will be used to measure child abuse risk. This is a frequently used questionnaire is research an clinical settings. The subjects will be asked to fill in two guestionnaires about their own childhood experiences. After the labsession, participants are asked to take the infant simulator home and take care of it for 24 hours. In the second session participants will be scanned with functional magnetic resonance imaging (fMRI) while they are listening to infant crying and laughing and while they are performing empathy tasks. There are no known risks associated with participating in an fMRI study. Numerous human subjects 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 and subjects with one of these contra-indications will be

excluded from the 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

| Study type: | Observational non invasive |
|---------------------|---------------------------------|
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Basic science |

Recruitment

| NL | |
|---------------------|----------------|
| Recruitment status: | Will not start |
| Enrollment: | 40 |
| Туре: | Anticipated |

Ethics review

| Approved WMO | |
|--------------------|--|
| Date: | 24-03-2011 |
| 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

ССМО

ID NL33753.058.10