

An exploratory study on the impact of acute stress on the neural mechanisms of emotion regulation

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To explore the effect of stress on the neural correlates of emotion regulation, we will combine sophisticated behavioural tasks in a functional magnetic resonance imaging (fMRI) setting with a well-established stress-induction procedure.

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

Summary

ID

NL-OMON38823

Source

ToetsingOnline

Brief title

Emotion regulation under stress

Condition

- Other condition
- Anxiety disorders and symptoms

Synonym

N/A: healthy individuals

Health condition

gezonde deelnemers

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

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

Intervention

Keyword: amygdala, anxiety, prefrontal cortex, stress

Outcome measures

Primary outcome

- * Functional MRI
- * Behavioural measures of attentional bias (reaction time, accuracy)
- * Psychophysiological measures of fear (skin conductance, startle response)

Secondary outcome

- * Salivary hormone concentrations
- * Heart rate
- * Self-report questionnaires

Study description

Background summary

Cognitive emotion regulation emerges from an interaction between prefrontal cognitive and limbic emotional processing regions. Stress is found to have a profound impact on both emotional processing and cognitive functioning. However, how stress affects cognitive emotion regulation is currently unclear.

Study objective

To explore the effect of stress on the neural correlates of emotion regulation, we will combine sophisticated behavioural tasks in a functional magnetic resonance imaging (fMRI) setting with a well-established stress-induction procedure.

Study design

A between-subject design will be used where stress level will be manipulated between subjects while assessing emotion regulation with our experiments. Tests will take place in the afternoon on two consecutive days for both groups. The second day consists for a memory test to assess how stress effects on emotion regulation impact on the encoding of emotional information into memory

Study burden and risks

The established stress induction and anxiety provocation procedures will most likely cause a moderate level of acute subjective distress in these healthy participants. This is inherent to the study topic. However, based on extensive previous experience with these procedures (see for example CMO protocol number 2010/257 and CMO protocol 2011/382) the risk associated with participation can be considered negligible and the burden can be considered minimal. Neither pharmacological nor (otherwise) invasive interventions are applied.

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

- * Because previous work showed that menstrual cycle influences neural functioning and the stress response in free-cycling women, only men and women taking anti-conception will be included in this study.
- * Between 18 and 35 years of age.
- * Predominant right-handedness.
- * Normal or corrected-to-normal vision
- * Normal uncorrected hearing

Exclusion criteria

- * Metal objects in or around the body (e.g., braces, pacemaker, metal fragments, insulin pump, and hearing devices).
- * History of psychiatric treatment or current psychiatric treatment.
- * History of neurological treatment or current neurological treatment.
- * Claustrophobia.
- * Epilepsy.
- * Pregnancy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2013
Enrollment:	96
Type:	Actual

Ethics review

Approved WMO	
Date:	13-06-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	29-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL43437.091.13