Risk taking during decision-making under stress:
The effects of psychological stress on risk taking in feedback-based decision making

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Study 1To determine if and to what extent it is possible to manipulate physiological stress responses (heart rate, systolic and diastolic blood pressure and electrodermal response) using our developed set-up. To this end we will look at the...

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

Summary

ID

NL-OMON40090

Source
ToetsingOnline

Brief title
Risk taking during stress

Condition

- Other condition

Synonym
Not applicable

Health condition

Geen aandoening als zodanig, gezonde participanten worden onderzocht.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Decision-making, Feedback, Stress

Outcome measures

Primary outcome

Study 1

The measured physiological stress responses (heart rate, systolic and diastolic blood pressure and electrodermal response) and cortisol response during all tasks.

Study 2

The amplitude of the P300 and Feedback Related Negativity (FRN) component in response to both positive and negative feedback in the BART task during different stressor intensities.

Study 3

The BOLD response in the striatum, anterior cingulate cortex, insula, dorsolateral and ventromedial prefrontal cortex, amygdala, and orbitofrontal cortex in response to positive and negative feedback and during decision-making, during different stressor intensities, during all BART trials.

Secondary outcome

Not applicable.

Study description

Background summary

This protocol describes three separate studies which together aim to provide novel insights in the underlying (neural) workings of the effects of stress on the neural underpinnings of risk taking in feedback-based decision making.

Rationale:
Feedback-based decision-making is a frequently occurring process in our everyday lives, which is often performed under a certain amount of stress. Also, because by far the most of our decisions contain a level of uncertainty regarding the outcome, risk is an important aspect of this decision-making. It is known that under stress males tend to increase their risk-taking whereas as females tend do decrease their risk-taking. The neural underpinnings hereof are not yet fully elucidated. It is also not yet clear if the processing of positive and negative feedback is a mediator of this effect stress has on risk taking. We aim to gain insight in the neural workings during feedback-based decision-making under stress by using EEG and fMRI during both decision-making and feedback processing in a suited decision-making task, the BART task.

Study objective

Study 1
To determine if and to what extent it is possible to manipulate physiological stress responses (heart rate, systolic and diastolic blood pressure and electrodermal response) using our developed set-up. To this end we will look at the correlation between predicted physiological stress response by the set-up and the actual measured stress response, including the measured cortisol levels.

Study 2
1. Determine the effects of stress on feedback processing in a feedback-based decision-
making task. To this end we establish the effect of stress (aforementioned physiological stress responses) on the amplitude of FRN and P300 EEG components in response to positive and negative feedback during the BART task, and the differences between sex.
2. Determine if this processing of feedback is a mediator of the effect of stress on risk-taking.

Study 3
1. Gain insight in the structures involved in decision-making during stress. To this end we will establish the effect of aforementioned physiological stress responses on the BOLD response in the limbic system during decision-making in BART trials, and the potential differences between sex.
2. To gain insight in the structures involved in feedback processing in a feedback-based decision-making task during stress. To this end we will establish the effect of aforementioned physiological stress responses on the BOLD response in the limbic system in response to positive and negative feedback in BART trials, and the potential differences between sex.

Study design

Studies 1 and 2 are interventional EEG studies three groups (two experimental and one control group), study 3 is an interventional 3T fMRI study with one experimental group.

Intervention

Stress induced through a transient psychological stressor in the form of a digital game.

Study burden and risks

The total duration of the experimental session in study 1 and 2 is around two hours, in study 3 the session is around one hour, all completed in one session. During this experimental session physiological measurements and either EEG or fMRI measurements are performed. Subjects perform computerized tasks during which stressful stimuli can be presented. There are no known risks associated with either the measurements or the presented stimuli in this research. Besides financial remuneration, no immediate benefits are to be expected from participation in this study for the subjects.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 18-65, male or female
Normal or corrected-to-normal vision

Exclusion criteria

- Drug or alcohol abuse over a period of six months prior to the experiment
- Unwillingness to view or hear aversive stimuli from the IAPS or IADS
- Previously diagnosed with, or under treatment for, psychological or psychiatric disorders (e.g. depression, schizophrenia, neuroticism, etc.).
- Previously diagnosed with, or under treatment for, medical indications (e.g. closed- or open-head injury, neurological illness, epilepsy, PTSD, cardiovascular indications, endocrinological dysfunction, etc.).
- Use of medication (chronic/recently)
- Pregnancy
- Ferrous objects in or around the body (e.g. braces, glasses, pacemaker, metal fragments)
- Claustrophobia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	04-02-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29232
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42763.041.13
OMON	NL-OMON29232