CHOICE study: time-dependent modulation of stress-induced effects on social decision making

Published: 19-08-2011
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Study objectives• Primary objective: Elucidate the effect of stress on modulation of social decision making and its time dependency • Secondary objectives: o Reproduce the Trier Social Stress Test for Groups in both male and female participants with...

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

Summary

ID

NL-OMON38225

Source
ToetsingOnline

Brief title
Stress and social decision making

Condition

- Other condition

Synonym
Sociale decision making under stress

Health condition

Effecten van stress in gezonde vrijwilligers

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Social Decision Making, Stress, Trier Social Stress Test

Outcome measures

Primary outcome

• performance on various social decision making tasks

Secondary outcome

• saliva cortisol and alpha amylase response

• autonomic heart rate, blood pressure and skin temperature response

• saliva immune response

• subjective stress response using questionnaires.

• Genotype

• Epigenetic DNA methylation

Study description

Background summary

Stress * both in real life and experimentally induced* can influence cognitive and emotional functioning. Immediately after stress, subjects rapidly adjust behavior to promote short-term instinctive behavior, whereas later on in the aftermath of stress, behavior is aimed at restoring higher cortical functions with more flexible and explorative behavior. Decision-making studies attempt to understand our fundamental ability to process alternatives and to choose an optimal course of action. Under conditions of acute stress, decision making processes have been found to be impaired. Recently, the time-dependent consequences of stress on decision making have been tested. Given that we live in highly complex social environments, many of our important decisions are made in the context of social interactions. Therefore, we aim to target the

time-specific effects of stress on social decision making performance and possible gender effects. We hypothesize that directly following stress more socially risky and egoistic decisions are made, whereas later on, more advantageous long-term and altruistic decisions are chosen. Subjects will be tested using the Trier Social Stress Test for Groups (TSST-G), which has recently been proposed as a socially evaluative stress test that can test multiple subjects simultaneously. If comparable or increased stress can be induced while testing multiple subjects at the same time, this will lead to a more efficient and robust protocol to induce standardized laboratory stress in humans.

Study objective

Study objectives
• Primary objective: Elucidate the effect of stress on modulation of social decision making and its time dependency
• Secondary objectives:
o Reproduce the Trier Social Stress Test for Groups in both male and female participants with a placebo control task in our experimental setup.
o Associate changes in autonomic and hormonal parameters after stress exposure TSST subjects with (epi)genetic background.

Study design

Healthy adult participants will participate in this study. Half of the participants are randomly assigned to the stress group; the other half are assigned to the control group, both in a group protocol with 4 persons entering the protocol at a time. Social decision making tests are administered either directly after the stress/control condition (2 subjects) or 90 minutes following the stress/control condition (2 subjects). The social-evaluative group stress test consists of a public speaking task and an arithmetic test which is an adaptation of the classic individual Trier Social Stress Test. The control condition has a comparable cognitive load, while lacking the social evaluative aspects of the stress condition. Throughout the study, heart rate en skin temperature will be continuously measured. Furthermore, saliva samples will be taken at different time points: before, during and after the stress test to assess the hormonal, autonomic and immunological stress response. Participants also complete various subjective stress questionnaires before, during and after the stress/control condition. To prevent the possible confound of a group stress test on social decision making directly after stress, an additional experiment with individual stress and control conditions in male healthy volunteers will be carried out.

Study burden and risks

Risks for volunteers are minimal. The stress test consists of a short public

speech test and/or a socially evaluated arithmetic test and does not lead to extreme perceived stress levels. The time spent in the laboratory is limited to 3 hours and participants have sufficient time for breaks. No direct benefits are present for volunteers. Concerning the risk analysis, a negligible risk for participants is estimated. The stress test is often applied without any known lasting disadvantageous effects.

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

Volunteers are eligible if they are 18 years or older and healthy

Exclusion criteria

* smoking (positive urine screen)
* any psychiatric disorder
* current or past drug use (positive urine screen on the presence of amphetamines (including MDMA), barbiturates, cannibinoids, benzodiazepines, cocaine and opiates), and alcohol use 24 hours prior to testing
* present use of any medication which might influence the stress response, including benzodiazepines, psychotropics, beta blockers, ACE inhibitors and any hormonal treatment excluding any hormonal anticonceptives
* lack of fluency in the Dutch language
* speech impairments;Acute exclusion criteria are:
- any acute illness
- fever
- having a severe cold
- physical exertion within the last 2 hours
- drink other than water or any food within the last 2 hours
- ingestion of coffee or any caffeine-containing drink within the last 4 hours
- alcohol use on the testing day (breath alcohol level above 0%)

Study design

Design

Study type:	Observational 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):	28-10-2011
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	19-08-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-12-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-07-2012
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

No registrations found.

In other registers

Register	ID
CCMO	NL36329.041.11