Dopaminergic Modulation And Neural Substrates Of Stress-Induced Change in Goal-Directed and Habitual Behaviour

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The main objective of the present study is to determine the role of dopamine and stress in functional connectivity in neural substrates for habitual- and goal-directed behaviour and their effects in subsequent behaviour.

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

Summary

ID

NL-OMON47481

Source
ToetsingOnline

Brief title
Dopamine, stress and behavioural switching

Condition

- Other condition

Synonym
n.a.

Health condition

basaal wetenschappelijk onderzoek

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: NWO vidi

Intervention

Keyword: dopamine, fMRI, instrumental learning, stress

Outcome measures

Primary outcome

Main dependent variables are the fMRI measure of functional connectivity between the medial aspect of the striatum and the orbitofrontal cortex, and between the amygdala and lateral putamen, and the performance on an instrumental learning task.

Secondary outcome

Additional dependent variables are and neuroendocrine stress markers (cortisol and salivary alpha-amylase), and performance on two impulsivity tasks.

Study description

Background summary

Stress is omnipresent in our modern society. Our psychophysiological responses to stress, generally serve adaptive purposes such as promoting the use of simple but fast habits over complex goal-directed behaviour. Nevertheless, such a preference for habitual behaviour under stress may, in vulnerable individuals, constitute a risk factor for psychopathology. For example, stress often precedes emotional eating and binge eating episodes, and is reported by people with a substance addiction as a primary reason for relapsing. Unfortunately, not much is known about the neural mechanism of this stress induced shift towards the use of habits. We do know that different neural circuits govern automatic (amygdala, posterior lateral putamen) and goal-directed (medial striatum, orbitofrontal cortex) behaviour. In addition, dopamine has been shown to play an important role in addictive behaviour, pleasure and reward. What is currently unknown is whether stress and dopamine

activity can modulate communication in the habitual- and goal-directed behaviour neural substrates.

Study objective

The main objective of the present study is to determine the role of dopamine and stress in functional connectivity in neural substrates for habitual- and goal-directed behaviour and their effects in subsequent behaviour.

Study design

The study is a 2x2 (drug*stress) between volunteers, double blind experiment.

Intervention

Participants will receive either a single oral dose of methylphenidate 40 or placebo, and will experience an incidence of stress induction or a no-stress control manipulation

Study burden and risks

Participants will visit our facilities twice. The first visit entails a full medical screening ensuring their safety, which will include taking a blood sample through venipuncture and making an electrocardiogram. The second visit will consist of (1) taking study treatments (methylphenidate or placebo), (2) undergo a stress manipulation or a control manipulation, (3) taking saliva samples, and (4) filling out questionnaires and doing computer tasks inside and outside the magnetic resonance scanner (60 minutes). During the periods that they are not tested (breaks), they will be seated in a waiting room where they will be in close contact with one of the researchers. In case they experience (medical) complaints, the medical supervisor will be contacted. The total discomfort experienced by the volunteer is minimal when all precautions are taken into account. Most important precautions are: determining the absence any mental or physical disorder that may interact with methylphenidate, and having volunteers experience lying inside a dummy scanner. Blood samples will be taken by an experienced member of our team. Finally, the stress manipulation has been shown to be well tolerated.

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

- good physical and mental health as determined by medical history and medical examination, ECG and laboratory examination;
- BMI between 19 and 25 kg/m2;
- use of appropriate contraception;
- written informed consent;
- age between 18-35 (inclusive)

Exclusion criteria

- pregnancy or lactation;
- cardiovascular abnormalities as assessed by standard ECG;
- excessive alcohol use, defined as drinking more than 21 glasses of alcohol per week;
- history of drug abuse or addiction;
- hypertension (diastolic> 90; systolic> 140);
- history of psychiatric and neurological disorders

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 20107
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL57634.068.16
OMON	NL-OMON20107