The role of testosterone in value-based decision making

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24462

Source
Nationaal Trial Register

Health condition

Psychological disorders characterized by abnormal decision-making (such as drug abuse, gambling, (social) fear disorders, heightened BMI, psychopathology, antisocial personality disorders, etc.)

Sponsors and support

Primary sponsor: Prof. dr. Karin Roelofs (Behavioral Science Institute (BSI) & Donders Institute for Brain, Cognition and Behaviour, Radboud University Nijmegen)
Source(s) of monetary or material Support: self-financed

Intervention

Outcome measures

Primary outcome

- Behavioral performance on computerized tasks assessing choice behavior and their underlying psychological mechanisms in contexts including risky choice, intertemporal choice, and reward-history and social learning in reinforcement-based decision making

Secondary outcome

- Salivary cortisol and testosterone hormone levels

- Subjective measurements on self-report questionnaires

Study description

Background summary

Rationale:

Testosterone plays a major role in motivated behavior. However, it remains unknown how testosterone affects the psychological mechanisms underlying value-based decision making and choice behavior. In the current study we will investigate the psychological mechanisms by which testosterone influences important types of decisions, such as risky and intertemporal choices, and learning based on reward history versus social input. We conduct a placebo-controlled double-blind testosterone administration study to causally investigate testosterone's role in these types of decisions.

Study objective:

To identify the psychological mechanisms via which testosterone modulates value-based decision making (we use the term value-based decisions as it covers all the types of decisions we investigate in the study, i.e., decisions in both social and non-social contexts).

Study design:

Participants will be tested in a randomized, double-blind, placebo controlled, between-group design.

Study population:

Participants will be healthy female volunteers between 18 and 35 years of age.

Intervention:

One group of participants will receive a single dose of 0.5 mg testosterone. Another group will receive a similar dose of a matched placebo.

Main study parameters/endpoints:

1. Behavioral performance on computerized tasks assessing choice behavior and their underlying psychological mechanisms

2. Testosterone and cortisol hormone levels measured in saliva

3. Subjective measurements on self-report questionnaires

Study objective

Two often-iterated and relatively widespread, but probably too narrow, views of testosterone are that (a) it is first and foremost a "social" hormone, and that (b) higher levels of testosterone are associated with mainly negative consequences. However, more recent evidence suggests that testosterone effects actually extend beyond the purely social domain and are not only negative but depend on the context. However, under which circumstances which effect is to be expected is not known. Furthermore, very little is known about the underlying (psychological) mechanisms by which testosterone affects decisions and behaviors. Therefore, the current study investigates how testosterone influences value-based decision making in a social versus non-social context, using different paradigms that allow decomposition into underlying mechanisms. Based on the literature, we derived two competing hypotheses:

1) Testosterone has effects in a social context only, and will have negative consequences on decision-making (i.e., resulting in less pro-social choices);

(2) Testosterone will have effects in both a social and non-social context, and will result in more optimal, goal-directed choices (i.e., maximizing own benefit).

Study design

The intervention was completed in a single session of 6 hours and 30 minutes.

Intervention

Participants will receive either 0.5 mg testosterone or a placebo dose by sublingual administration and will perform several computerized tasks and complete several self-report questionnaires. The total duration of the experiment will be 6 hours and 30 minutes, including a 3.5 hours waiting period between drug administration and behavioral testing and 2 hours of experimental tasks. Furthermore, participants will provide 5 saliva samples in total to measure testosterone and cortisol levels.

Contacts

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Eligibility criteria

Inclusion criteria

- Healthy female volunteers between 18 and 35 years of age

- Use of single-phase oral contraception with testing only during the 3-week period they take these contraceptives, and not during menstruation (to control for the possible effect of hormonal changes related to the menstrual cycle)

Exclusion criteria

- Abnormal hearing

- Abnormal and uncorrected vision

- History of prescribed medication within the month prior to the start of the study

- History of ‘over the counter’ medication 2 month prior to the start of the study with exception of occasional use of paracetamol and similar over-the-counter medication (aspirin

etc)

- History of drug- dependence: Alcohol, opiate, LSD, (meth)amphetamine, cocaine, solvents, cannabis, or barbiturate

- Average use of more than 3 alcoholic beverages daily (max. 21 beverages weekly)

- Average use of psychotropic medication or recreational drugs weekly or more

- Use of psychotropic medication, or of recreational drugs over a period of 72 hours prior to the test session

- Use of alcohol within the last 24 hours before the measurement

- History of cannabis usage within 2 month prior to the start of the study

- Habitual smoking, i.e. more than a pack of cigarettes per week and a self-reported inability or unease to cease smoking for 24 hours prior to testing

- Regular use of corticosteroids

- (History of) neurological treatment

- (History of) psychiatric treatment

- (History of) endocrine treatment

- (History of) clinically significant hepatic, cardiac , obstructive respiratory, renal , cerebrovascular, metabolic or pulmonary disease

- (History of) epilepsy

- (History of) autonomic failure (e.g., vasovagal reflex syncope)

- Increased risk for glaucoma

- Diabetes

- Current parodontitis

- Family history of schizophrenia, bipolar disorder or major depressive disorder

- Intense daily physical exercise

- Irregular sleep/wake rhythm (e.g., regular nightshifts or cross timeline travel

- Pregnancy

- Breast-feeding

- Body Mass Index < 18.5 or > 25

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2015
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	21-06-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40950
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5671
NTR-old	NTR5908
CCMO	NL49277.091.14
OMON	NL-OMON40950

Study results

Summary results
N/A