The role of testosterone in value-based decision making - An exploratory investigation into the effects of testosterone on choice behavior and its underlying psychological processes

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Primary objective:- To identify the psychological mechanisms via which testosterone modulates value-based decision making, such as testosterone's effects on risk-taking levels, impulsivity and self-control in intertemporal choice, and social...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON40950

Source
ToetsingOnline

Brief title
Testosterone and decision making

Condition

- Personality disorders and disturbances in behaviour

Synonym
antisocial personality disorder, behavioral disorder

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Ministerie van OC&W,NWO

Intervention

Keyword: behavior, choice, decision-making, testosterone

Outcome measures

Primary outcome

- Behavioral performance on computerized tasks assessing choice behavior and

their underlying psychological

mechanisms, including risky choice, intertemporal choice, and reward-history

and social learning in

reinforcement-based decision making

- Steroid hormone levels measured in saliva

- Subjective measurements on self-report questionnaires

Secondary outcome

N/A

Study description

Background summary

Both human and non-human animal studies have shown that the steroid hormone testosterone plays an important role
in motivated behaviors and decision making. Testosterone administration in humans has been reported to have effects
on different types of value-based decisions (such as risky, intertemporal, and

social decisions), but findings have been
inconsistent. Further, knowledge on how testosterone affects the psychological mechanisms underlying such decisions
is scarce. The main objective of our research is therefore to develop insights into how testosterone modulates the
psychological mechanisms by which it affects different types of value-based decisions and choice behavior.

Study objective

Primary objective:
- To identify the psychological mechanisms via which testosterone modulates value-based decision making, such as
testosterone's effects on risk-taking levels, impulsivity and self-control in intertemporal choice, and social learning in
reward-based decision making.

Secondary objectives:
- To examine choices made in contexts such as risky and intertemporal choice, and reward-based choice involving
individual and social learning
- To causally investigate whether and how testosterone effects moderators of decision making, such as impulsivity
versus self-control, use of reward history, and social information in value-based decisions, personality variables and/or
cortisol levels

Study design

Participants will be tested in a randomized, double-blind, placebo controlled, between-group design. The experiment
consists of one test session at the Behavioral Science Institute. Participants will receive either 0.5 mg testosterone or a
placebo dose by sublingual administration and will perform several computerized tasks. In addition, they will complete
several self-report questionnaires. The total duration of the experiment will be 5.5 hours (including a waiting period of
3.5 hours between testosterone administration and task administration).

Intervention

One group of participants will receive a single dose of 0.5 mg testosterone; the other group will receive a similar dose
of placebo.

Study burden and risks

The low dose of testosterone can be administered safely to humans without any relevant risk of serious adverse events
and there are no known side-effects. The sublingual testosterone administration procedure that we will use has been
used extensively for about a decade in psychological studies at Utrecht University (Hermans et al., 2006a, 2006b,
2007, 2008; Schutter & van Honk, 2004; van Honk et al., 2001, 2004, 2005; van Honk & Schutter, 2007), and none of
the studies reported negative side effects. In addition, the PI on this project (Prof dr Karin Roelofs) has been using the
same sublingual testosterone administration procedure in several studies, namely an fMRI study in healthy female
participants at Radboud University (CMO Protocol ID: NL34927.091.10) and two studies at Leiden University, one in
healthy female participants and one in female patients with social anxiety disorder (CMO Protocol ID: P09.164). Thus
far, none of the participants in these studies have reported negative side effects, and no adverse events have occurred
in these studies.
On both the day prior to the test session and on the day of the test session itself participants will adhere to some simple
restrictions with respect to medication, alcohol, and drug intake. During the morning of the test session, participants will
refrain from smoking and consuming stimulant-containing drinks.
The risk associated with participation can be considered negligible and the burden can be considered minimal. No
adverse events are expected and side effects of the treatment are very unlikely.

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

18-35 years old, female, good physical and mental health, predominantly right-handed, BMI between 18.5 and 25

Exclusion criteria

History of psychiatric treatment or current psychiatric treatment - History of neurological treatment or current neurological treatment - History of endocrine treatment or current endocrine treatment - History of heart-related disease - Regular use of corticosteroids - Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2015
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	25-11-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-09-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-12-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-04-2016
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

ID: 24462
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL49277.091.14
OMON	NL-OMON24462