Aggressive Impulse Management (testosterone administration)

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

Summary

ID

NL-OMON40794

Source
ToetsingOnline

Brief title
Aggressive Impulse Management (testosterone administration)

Condition

- Personality disorders and disturbances in behaviour
- Gender related factors

Synonym
emotion/anger regulation problems

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: National Science Foundation (NSF)

Intervention

Keyword: anger, motivation, regulation, testosterone

Outcome measures

Primary outcome

Anger will be induced using a validated procedure (Keltner, Ellsworth, & Edwards, 1993; Strack, Schwartz, & Gscheidinger, 1985). Aggression and feelings of anger will be measured with an aggression task of which the construct validity is well established (DeWall et al., 2013; Slotter et al., 2012). It has been used for decades as a reliable and valid measure of laboratory aggression.

Secondary outcome

Individual differences in trait anger (Trait Anger Scale, TAS; Spielberger, 1999) and in behavioral activation and behavioral inhibition (Behavioral Inhibition Scale/ Behaviral Activation Scale, BIS/BAS; Carver & White, 1994) will be conducted as well. To see whether effects of motivation and testosteron on aggression depends on individual differences.

Study description

Background summary

Understanding the causes of human aggression is among the most urgent issues in modern behavioral science. Aggression takes a tremendous toll on society, by causing widespread agony and suffering, and through the costs of protecting, treating, and compensating victims. It is therefore vital to learn how people may withhold their aggressive impulses.
We propose the Aggressive Impulse Management (AIM) model, which suggests that reducing approach motivation may take away the impulse to aggress. The interventions suggested by the AIM model require little effort or cognitive

skills, and thus these interventions may reduce aggression when traditional cognitive strategies for anger management are ineffective. To test the validity of the AIM model, we propose an experiment on the role of approach/avoidance motives and levels of testosterone in anger management. We hypothesize that compared to approach motivation, avoidance motivation can attenuate aggression and anger especially when testosterone levels are high.

Study objective

This study will investigate the counter impulse hypothesis. According to the counter-impulse hypothesis, avoidance motivation counters aggressive impulses. Consequently, this regulatory impact should be especially effective when people*s aggressive impulses are high, for example when testosterone levels are high.

Study design

The experiment uses a 2 (approach vs. avoidance) X 2 (testosterone vs. placebo) between subjects design.

Intervention

Participants will be administered testosterone/placebo.

Study burden and risks

No health risks are related to administrating testosterone. The emotion induction we use is mild and the debriefings thoroughly, so it is unlikely that participants will experience negative effects. The anger inducing provocation is used in various previous experiments, also by our own lab, and in general participants find the type of experiments we do interesting and fun to do.

This research is part of a larger project including 10 experiments that systematically test the Aggressive Impulse Management model. This present proposed study is the first to investigate how motivational tendencies interact with testosterone on anger and aggression. The study can have important implications for further development of instruments to reduce anger and aggression and benefit anger management trainings.

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

We will control for influences of hormonal change due to menstrual cycle by only including women who use single-phase contraceptives, and testing them during the 3-week period they are on these contraceptives and not during menstruation. In this time window, menstrual-cycle influences are virtually absent.
In order to be eligible to participate in this study, a subject must also meet all of the following criteria:
- Age 18-65.
- Fluent in Dutch

Exclusion criteria

Subjects will be screened to exclude psychiatric, metabolic, and neurological conditions participated in the experiment. Volunteers who use medication or report noxious health behaviors (drug abuse including excessive alcohol, smoking, and caffeine, and abnormal sleeping habits, e.g., too little sleep), chronic health problems, or psychopathology are excluded from the study. Additionally, participants are screened for depression and anxiety using the 13-item Beck Depression Inventory (Bouman, Luteijn, Abersnagel, & van der Ploeg,

1985) and the State-Trait Anxiety Inventory (Van der Ploeg, Defares, & Spielberger, 1980). Also, to control for extraneous variables, participants will abstain from caffeine containing drinks or food, smoking, and minimize physical exercise on the day of the study.

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):	12-09-2016
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	testosterone
Generic name:	testosterone

Ethics review

Approved WMO

Date:	26-06-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2014-001194-14-NL
CCMO	NL47938.029.14