The neurochemical basis of decision-making

Published: 17-11-2020
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To carry out a large-scale replication study of a previous study that reported that a single dose of intranasal oxytocin (i.e. oxytocin vapour inhaled through the nose) increased trust between humans.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON54161

Source
ToetsingOnline

Brief title
Decisions and the brain

Condition

- Other condition

Synonym
learning and social behaviour

Health condition

psychologische functies

Research involving
Human

Sponsors and support

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

Intervention

Keyword: decision-making, experimental psychology, oxytocin, trust

Outcome measures

Primary outcome

The amount of money transferred from one human (*the investor*) to another human (*the trustee*); a proxy measure of interpersonal trust during a well-validated investment game.

Secondary outcome

Correlations among the amount of money invested into the trustee and a range of psychological variable assessed using validated rating instruments (including reward and punishment sensitivity, extraversion, propensity to trust others).

Study description

Background summary

The neuropeptide oxytocin has been linked to a range of human social functions, including empathy, bonding, and interpersonal trust (the degree to which humans trust each other). In recent years mixed results have been reported about the link between oxytocin and interpersonal trust.

Study objective

To carry out a large-scale replication study of a previous study that reported that a single dose of intranasal oxytocin (i.e. oxytocin vapour inhaled through the nose) increased trust between humans.

Study design

A randomized double-blind placebo-controlled between subjects design using two groups: a group receiving a single dose of oxytocin (Syntocinon 24 I/U; n=110), and a group receiving placebo (saline solution; n=110)

Study burden and risks

The participation risks are minimal. Study participation consists of two sessions. Session 1 is a digital 1-hour session that can be completed at the participant*s convenience, and does not require a laboratory visit. There are no known risks associated with this session. Session 2 is a max. 2-hour laboratory session during which two participants play an investment game. Prior to playing the game, participants inhale a nasal spray containing Syntocinon or placebo. Syntocinon is a very well-tolerated and safe nose spray containing oxytocin, and produces no to mild (headache, dizziness) side-effects, even when administered repeatedly, in higher doses, or is used for prolonged periods of time. The use of a well-established low dose, the availability of a medical expert, the short half-life of the spray, and a number of risk minimization strategies (see section 13) ensure that participation risks are minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Male
Age 18-32

Exclusion criteria

Psychiatric (including substance abuse/dependence) or neurological disorder
Current treatment by a psychologist or psychiatrist for mental health-related problems
Current use of psychoactive medication for mental health-related problems: antidepressants, antipsychotics, benzodiazepines, anxiety medication, neuroleptics, anticonvulsants, stimulants
Latex allergy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-04-2021

Enrollment:	260
Type:	Actual

Ethics review

Approved WMO Date:	17-11-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-03-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-06-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-01-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-10-2024
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL74615.068.20