Attenuating social anxiety: The effect of oxytocin on (inter-)personal space, mimicry, and communication

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The main objective of the present protocol is to investigate to what extent oxytocin modulates specific aspects of interpersonal approach, mimicry, and communication in healthy volunteers with varying degrees of social anxiety.Results from this...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39435

Source
ToetsingOnline

Brief title
OXY & (I)PS

Condition

- Other condition
- Environmental issues

Synonym
n/a

Health condition

social anxiety

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Communication, Inter-/personal space, Mimicry, Oxytocin, Social anxiety

Outcome measures

Primary outcome

Main outcome-measures consist of the results of the test battery measurements including trait questionnaires such as the Liebowitz, Social Anxiety Scale (LSAS; Liebowitz, 1987), the Fear of Positive Evaluation Scale (FPE; Weeks, Heimberg, & Rodebaugh, 2008), the Social Interaction Anxiety Scale (SIAS; Mattick, & Clarke, 1998),the Center of Epidemiologic Studies Depression Scale (CES-D; Ratloff, 1977), the trait versie van de Spielberger State/Trait Anxiety Scale (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), the UCLA Loneliness Scale (Russell, 1996), the partner questionnaire (Newman-Norlund, et al., 2009), the Need for Cognition Scale (NCS, Cacioppo, 1996), the Empathy Quotient (EQ, Baron-Cohen & Wheelswright, 2004)/Systemizing Quotient (SQ-R, Wheelswright, et al., 2006), the Interpersonal Reactivity Index (IRI, Davis, 1983), the Inclusion of Other in the Self Scale (Aron, Aron, & Smollan, 1992) and various self-constructed Visual Analogue Scales (VAS). In addition, testsosterone/cortisol, will be assessed via salivary sampling, and the 'second-to-fourth-digit' ratio of the dominant hand will be measured. This will help to control for hormones that are suspected to influence social behaviors.

The test battery consists of five different paradigms: (1) an IVE task measuring interpersonal distance (2) an IVE task measuring mimicry and (3) a task assessing personal space, a (4) task measuring freeze-behavior and a (5) task that assesses non-verbal communication behavior. These tasks measure behaviors related to social interaction from different angles and aim to reflect everyday social encounters more validly.

Secondary outcome

n/a

Study description

Background summary

Social Anxiety Disorder (SAD) is a common and debilitating mental state, with prevalence rates between 7 to 13% (Fehm, Beesdo, Jacobi, & Fiedler, 2008). High socially anxious individuals (HSAs) exhibit excessive fear of being evaluated negatively. HSAs believe that these evaluations by (significant) others lead to social rejection or exclusion. Consequently, they avoid social interaction or endure these with intense stress. SAD has a chronic course, rarely remits spontaneously, severely disrupts social and occupational functioning, and is relatively difficult to treat (Heimberg, 2002; Heimberg et al., 1998). So far, along with distorted cognitions, most recently, deviations in subtle social behaviors have been identified to play a causal and maintaining role in SAD. HSA, for example have been shown to keep a larger interpersonal space in an interaction (Rinck et al., 2010) and show less behavioral mimicry (Vrijsen, Lange, Becker, & Rinck, 2010). In addition, it is assumed that the non-verbal communication of HSAs differs from that of healthy controls. These behaviors are thought to undermine positive evaluation rather than improve it. Astonishingly, none of these have been investigated with regard to social affiliation, although, the desire to have good contact with others lies at the very basis of SAD. In that light, the neuropeptide oxytocin (OXY) has recently raised considerable interest. OXY is synthesized in the supra-optic (SON) and the parvoventricular (PVN) nuclei of the hypothalamus and its release is under serotonergic control (Gimpl & Fahrenholz 2001). Oxytocin has, next to its peripheral effects (i.e. induction of parturition and lactation), received attention for its role in social behavior. It reduces social-threat perception in healthy humans. It ameliorates communication, affiliation, trust but also

the processing of positive social cues (Campbell 2007; Domes, Heinrichs et al. 2009; Kosfeld et al., 2005; Young 2002; Zak, Stanton et al. 2007). In short, OXY has all effects expected of a successful (psycho-)therapy of SAD without the considerable side-effects of state-of-the-art psychopharmacological treatment. Thus, knowledge about its effect on core features of SAD such the above mentioned behavioral disruptions is of highest importance. Of the only two studies that have ever explored the effect of OXY on SAD, none has looked at these specific characteristics. In addition, both have solely included socially anxious males. This is remarkable as Social anxiety is, after all, more frequently observed in women.
The proposed studies will be the first to investigate the effects of OXY on behaviors distinctly related to social interaction, and characteristic for SAD. The effect of OXY on (a) interpersonal distance (b) mimicry (c) personal space, and (d) communication will be investigated in females with varying degrees of social anxiety. The findings will significantly further the understanding of behavioral distortions in SAD, and of the potential role OXY may play in its treatment. Results of this study will be used to optimize the design of a future study to assess the effects of OXY on cognitive biases in individuals with high and low degrees of social anxiety, and eventually to asses in how far OXY can serve as adjunct to the treatment of diagnosed SAD patients. These, however, will be separately communicated to the local ethics committee at that time.

Study objective

The main objective of the present protocol is to investigate to what extent oxytocin modulates specific aspects of interpersonal approach, mimicry, and communication in healthy volunteers with varying degrees of social anxiety. Results from this study shall give rise to designing a future study on the effects of oxytocin on biased cognitions and in patients diagnosed with social anxiety disorder.

Study design

This proposal consists of a double-blind, placebo-controlled, two-way cross-over experiment. 40 volunteers will be randomly assigned to one of two treatment sequences. Each volunteer will receive a nasal spray containing oxytocin or placebo with an interval of about 28 days between each treatment and subjects will perform a test battery.

Intervention

per session: 24 intranasal units (IU) of oxytocin, administered twice within each of the two experimental sessions via a nasal spray containing 2 IU oxytocin per spray. Two times 12 sprays of oxytocin (6 per nostril) will be administered. Placebo (PLC) will consist of the vehicle fluid contained in the

oxytocin nasal spray without actual oxytocin. Participants will receive 96 IU of OXY in total.

Study burden and risks

n/a

Contacts

Public
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6525 HR
NL
Scientific
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6525 HR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18-30 years old, female, good physical and mental health

Exclusion criteria

- Pregnancy
- Breast-feeding
- Hormonal anticonceptives
- History of medication within 1 month prior to the start of the treatment with trial medication with exception of occasional use of paracetamol
- Febrile illness within 3 days before the first dose.
- Participation in another drug study within 3 months preceding participation in the current study.
- Inability to understand the nature and extent of the trial and the procedures required.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Syntocinon
Generic name:	Oxytocin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-12-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-05-2014
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2011-003257-26-NL
CCMO	NL37553.091.11