The effect of oxytocin on prosocial behavior.

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This study hypothesizes that an oxytocin inhalation will increase prosocial behavior and reduces social anxiety during social interaction specifically in patients with SAD in comparison to a clinical and healthy control group.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20361

Bron
Nationaal Trial Register

Verkorte titel
OXT in SAD

Aandoening

Social Anxiety Disorder
Social Phobia
Sociale angststoornis
Sociale fobie

Ondersteuning

Primaire sponsor: Maastricht University
Faculty of Psychology and Neuroscience
Department of Clinical Psychological Science
Overige ondersteuning: NWO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

This research project examines the extent to which administering oxytocin improves specific social bonding behaviors (i.e., reciprocal self-disclosure and mimicry) and likeability and reduces social anxiety in SAD patients in comparison to a clinical and healthy control group.
To asses social bonding behaviors of the participants the participants conduct a 15-minutes social interaction with a trained confederate. Trained video-observers rate at several time-points the level of self-disclosure responses and amount of mimicked behavior and likeability of the participants. Heart rate and self-report of social anxiety at several time-points during the task are used to assess anxiety responses of the participants.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Patients with social anxiety disorder (SAD) are characterized by a persistent, excessive anxiety during social interactions. Recent studies indicate that they show deficits in prosocial behaviors that are essential for the development of friendships such as reciprocal self-disclosure (sharing of personal information) and mimicry (subconscious mimicking of others postures). SAD is one of the most prevalent anxiety disorders and has a great impact on quality of life. Recently is has been speculated that the hormone oxytocin plays an important role in the etiology and maintenance of SAD and in future may even develop into a medicine for treatment of this disabling disorder. Oxytocin is originally known for its role during labor and breastfeeding. Moreover, it plays an important role in the mother-child attachment. Recent studies show that this hormone also stimulates prosocial behavior in both men as women. In addition it reduces anxiety responses. Therefore, it has been speculated that oxytocin could have a positive effect for patients with SAD. It would not only reduce their social anxiety but also stimulate pro social behavior.

Objective:

This study hypothesizes that an oxytocin inhalation will increase prosocial behavior and reduces social anxiety during social interaction specifically in patients with SAD in comparison to a clinical and healthy control group.

Study design:

This is a double-blind randomized placebo controlled experimental study.
Study population: 40 patients with SAD, 40 patients with other anxiety disorders and 40 healthy volunteers without psychopathological disorders, 18-60 years old will participate in this study.

Intervention:

Half of the participants receive a 24 IU oxytocin inhalation and the other half with receive a placebo inhalation.

Main study parameters/endpoints:

Videoraters will rate the amount of two social bonding behaviors, reciprocal self-disclosure and mimicry, and the likeability of the participants at several time-points during a 15-minutes social interaction. Participant rate their level of subjective social anxiety at several time-points during this social interaction. Furthermore, it is examined whether SAD patients are less liked at first sight compared to a clinical and healthy control group. Last, the impact of SAD and possible oxytocin effects on economic decision-making are assessed by two short computerized tasks.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The assessment will take 4 hours. This includes an interview concerning psychopathological complaints, various questionnaires and a 15-minutes social interaction task with a confederate and two short computerized economic decision-making tasks. Participants receive either a placebo or an oxytocin inhalation. Oxytocin inhalations are widely studied and well tolerated.

Doel van het onderzoek

This study hypothesizes that an oxytocin inhalation will increase prosocial behavior and reduces social anxiety during social interaction specifically in patients with SAD in comparison to a clinical and healthy control group.

Onderzoeksopzet

One time point.

Onderzoeksproduct en/of interventie

Treatment will consist of an oxytocin or placebo inhalation. Oxytocin (Syntocinon®) will be administered intranasally. This neuropeptide crosses the bloodbrain barrier reliably after intranasal administration (see review by MacDonald & MacDonald). Oxytocin had a short plasma half life (1-2 minutes) but a longer central half-life (30 minutes) (MacDonald & MacDonald). Peak effects on social behavior will be reached 45 minutes after administration (Heinrichs, 2000; Heinrichs & Domes, 2008). As in previous studies (see Heinrichs, 2000; Heinrichs & Domes, 2008), the spray will be administered 45 minutes before the onset of the social task. Each administration will consist of three inhalations of the spray into each nostril, with a time-interval of 45 seconds between each inhalation. Each inhalation will contain approximately 4 international units (IU) (total: 24 IU). This dose falls in the range usually used in oxytocin research (see review by MacDonald & MacDonald, 2010).

The placebo inhalation consists of all elements of the active oxytocin substance but without the active oxytocin ingredient. This is mainly saline solution.

Contactpersonen

Publiek

Maastricht University
Faculty of Psychology and Neuroscience
Department of Clinical Psychological Science
PO Box 616
M.J. Voncken
Maastricht 6200 MD
The Netherlands

Wetenschappelijk

Maastricht University
Faculty of Psychology and Neuroscience
Department of Clinical Psychological Science
PO Box 616
M.J. Voncken
Maastricht 6200 MD
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Group 1: Patients with SAD:

1. Meet the diagnostic criteria of a SAD according to the DSM IV as first diagnosis;

2. Age between 18 and 60 years;

3. IQ above 80;

4. Able to read and write in Dutch;

5. Free of medication, except for hormonal contraceptives. In case of use of benzodiazepine or beta-blockers patients are only included if they refrain from this medication on the testing day;

6. Women free of contraceptives are assessed during the mid-luteal phase of their menstrual cycle.

Group 2: Clinical control group:

1. Meet the diagnostic criteria of an anxiety disorder, except SAD, according to the DSM IV as first diagnosis;

2. Age between 18 and 60 years;

3. IQ above 80;

4. Able to read and write in Dutch;

5. Free of medication, except for hormonal contraceptives. In case of use of benzodiazepine or beta-blockers patients are only included if they refrain from this medication on the testing day;

6. Women free of contraceptives are assessed during the mid-luteal phase of their menstrual cycle.

Group 3: Healthy control group:

1. Age between 18 and 60 years;

2. IQ above 80;

3. Able to read and write in Dutch;

4. Free of medication, except for hormonal contraceptives. In case of use of benzodiazepine or beta-blockers patients are only included if they refrain from this medication on the testing day;

5. Women free of contraceptives are assessed during the mid-luteal phase of their menstrual cycle.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Group 1: Patients with SAD:

1. Women: pregnancy or breastfeeding;

2. Acute or chronic nasal diseases or obstruction;

3. Major medical condition;

4. Habitual use of anxiolytic medication such as benzodiazepines, SSRI’s, TCA’s, or antipsychotic medication. In case of incidental use of benzodiazepines or betablockers participants are asked to refrain from this medication at the testing day;

5. Acute psychotic complaints, risk for suicide or automutilation;

6. Dependent on alcohol or drugs.

Group 2: Clinical control group:

1. A first or comorbid diagnosis of SAD according to the DSM IV;

2. Women: pregnancy or breastfeeding;

3. Acute or chronic nasal diseases or obstruction;

4. Major medical condition;

5. Habitual use of anxiolytic medication such as benzodiazepines, SSRI’s, TCA’s, or antipsychotic medication. In case of incidental use of benzodiazepines or betablockers participants are asked to refrain from this medication at the testing day;

6. Acute psychotic complaints, risk for suicide or automutilation;

7. Dependent on alcohol or drugs.

Group 3: Healthy control group:

1. A current or past diagnosis of any anxiety disorder (including SAD) according to the DSM IV;

2. Women: pregnancy or breastfeeding;

3. Acute or chronic nasal diseases or obstruction;

4. Major medical condition;

5. Habitual use of anxiolytic medication such as benzodiazepines, SSRI’s, TCA’s, or antipsychotic medication. In case of incidental use of benzodiazepines or betablockers participants are asked to refrain from this medication at the testing day;

6. Acute psychotic complaints, risk for suicide or automutilation;

7. Dependent on alcohol or drugs.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2013
Aantal proefpersonen:	126
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37767
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3496
NTR-old	NTR3672
CCMO	NL38026.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37767

Resultaten

Samenvatting resultaten
N/A