The effect of oxytocin on eye contact and trust: a placebo controlled study

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The aim of the study is to understand whether enhanced oxytocin levels lead to increased eye contact between patient and physician, and if this in turn improves the patient-physician relationship as perceived by the patient.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48289

Source
ToetsingOnline

Brief title
OCCHIO

Condition

- Other condition

Synonym
disturbed levels of eye contact and trust

Health condition

psychologische omstandigheden

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: eye contact, oxytocin, patient-physician relationship, trust

Outcome measures

Primary outcome

Level of eye contact: The level of eye contact will be measured using eye tracking and will be operationalized as total eye gaze time towards the eye region of the physician in the video. While participants watch the screen, their eye movements will be tracked using Tobii screen eye tracker. The analysis will be done using automatized *Area Of Interest* definition, and defined through algorithms. The time for each Area Of Interest *eye region, forehead, mouth, other* will be calculated. Total duration (time in seconds and number of subsequent fixations) of participant*s eye gaze during a visit within the area of interest (eye region of physician) will be taken into account in the statistical test.

Participants* perception of the relationship with the physician: Measured with an adjusted version of the Wake Forest Physician Trust Scale (the adjustments entail omitting two items and a slight change of the wording of other items, as our proposed communication process is not a real life situation). This questionnaire is used to provide insight in a patients* trust in their physician and consists of 10 items, answered on a 5-point Likert scale.

Secondary outcome

Satisfaction with the physician: as measured with a visual analogue scale (VAS) ranging from 0 (not likely at all) to 100 (most likely) asking *I would recommend this doctor to a friend or family member.*

Pupillometry: The measurement of pupil size and reactivity (dilation and restriction), measured with the Tobii screen eye tracker.

Satisfaction with the doctors* communication style: Measured with the Doctor Communication Style items (translated to Dutch with forward-backward translation) on two subscales: affiliativeness and dominance/activity. Items are answered on a 5-point Likert Scale from *strongly agree* to *strongly disagree*.

Recall and Recognition (of information as explained during the medical communication video): questionnaire which assesses participants* level of free recall and recognition of information provided by the videotaped physician. The questionnaire will be designed based on the information provided in the video.

Study description

Background summary

To ensure optimal quality of care, the relationship between patient and physician is crucial. Eye contact is crucial for interpersonal communication and has been shown to contribute to the patient-physician relation. Oxytocin plays a central role in the creation of relationships and bonding between

people and may hence play a role in the patient-physician relationship. The administration of oxytocin has been used to enhance the amount of eye contact between individuals.

Study objective

The aim of the study is to understand whether enhanced oxytocin levels lead to increased eye contact between patient and physician, and if this in turn improves the patient-physician relationship as perceived by the patient.

Study design

A randomized double blind placebo controlled crossover trial will be conducted. Participants act as analogue patients, in other words: they will be instructed to interact with a physician in a video while imagining themselves as the patient. They will receive placebo and 24 IU intranasally administered oxytocin in a randomized and counterbalanced order. Both researchers and participants will be blind to this order. Their gazing behaviour during the video will be assessed using eye tracking. In between the two sessions there will be a wash-out time of ideally seven days (at least four days and a maximum of nine days).

Intervention

1 time 24 IU internasal oxytocin and 1 time placebo solution.

Study burden and risks

Oxytocin is a safe drug: the risk classification associated with this study is *minimal excess of negligible risk*. We therefore estimate both the physical and the psychological burden to be negligible.

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

Healthy, male subjects aged 18 to 35 years Subjects must be in good general healthRefrain from alcohol/smoking/caffeine/drugs 24 hrs before the experiment Refrained from food/drinks (except water) and intensive exercise two hours before the administration of oxytocinPrevious experience with healthcare system, in order to ensure that the subject is able to put himself in the role of a patient Subjects must be able to communicate well with the investigator in Dutch, to understand and comply with the requirements of the study, and understand and sign the written informed consentnclusiecriteri

Exclusion criteria

Known hypersensitivity to oxytocin or to any of the excipients of oxytocin or placeboParticipants who did not abstain from alcohol/smoking/caffeine/drugs 24 hrs before the experiment Participants who did not abstain from food/drinks (except water) and intensive exercise two hours before the administration of oxytocinParticipants who did not meet the above specified inclusion criteria

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2019
Enrollment:	76
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	29-07-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-09-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2020

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2020
Application type:	Amendment
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	EUCTR2018-004081-34-NL
CCMO	NL69901.018.19