Oxytocin and the placebo effect.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27820

Bron
NTR

Verkorte titel
Oxytocin

Aandoening

Placebo effect in healthy subjects

Ondersteuning

Primaire sponsor: Leiden University
Overige ondersteuning: European Research Council Consolidator Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study outcome is the difference between the oxytocin with positive suggestions group (group 1) and the placebo with positive suggestions group (group 3) on self-reported pain ratings and on self-reported itch ratings. Self-reported pain will be assessed in response to the CPT after the intervention controlled for the baseline CPT self-reported pain ratings.

Self-reported itch ratings will be assessed in response to HI.

Toelichting onderzoek

Achtergrond van het onderzoek

Placebo effects have been demonstrated to decrease pain and itch by means of positive suggestions. It is of high clinical relevance to find ways to maximize placebo effects in order to obtain the best therapeutic results. Oxytocin administration may potentially enhance the placebo effect of positive suggestions but few studies have been performed in this important area with conflicting evidence for pain and no studies for itch so far. The primary objective of the current study is to investigate whether exogenous oxytocin administration enhances the placebo effect induced by positive suggestions as measured by subjective pain intensity and itch ratings in response to validated pain (Cold Pressor Test) and itch-inducing (Histamine Iontophoresis) tasks. In addition, the effects of oxytocin on pain sensitivity and the effects of positive verbal suggestions on pain sensitivity are investigated as secondary outcome parameters. Finally, the influence of expectations, affect and personality characteristics are explored.

Doel van het onderzoek

The primary objective of the current study is to investigate whether exogenous oxytocin administration enhances the placebo effect induced by positive suggestions as measured by subjective pain intensity and itch ratings in response to validated pain (Cold Pressor Test) and itch-inducing (Histamine Iontophoresis) tasks. We hypothesize that oxytocin will enhance the placebo effect as induced by positive verbal suggestions.

Onderzoeksopzet

The study consists of one session in which CPT is performed twice and HI is performed once.

Onderzoeksproduct en/of interventie

A randomized, placebo-controlled study design is used. After initial screening, participants take part in one study visit in which they are randomly allocated to one of four groups: 1) oxytocin group with positive suggestions, 2) oxytocin group without positive suggestions, 3) placebo group with positive suggestions, 4) placebo group without positive suggestions.

Participants perform a baseline CPT (Cold Pressor Test) on which their pain sensitivity and unpleasantness ratings are measured. Subsequently, participants are administered an oxytocin or placebo spray. In the oxytocin with positive suggestions and oxytocin without positive suggestions groups, participants receive a 24 IU dose of oxytocin via a nasal spray. In the placebo groups, participants receive a placebo spray. Participants in two groups (oxytocin with positive suggestions group and placebo with positive suggestions group)

additionally receive positive verbal suggestions about the expected analgesic and itch-relieving effects of oxytocin. After a waiting period for the oxytocin to take effect, a second CPT is performed. The session finishes with transdermal HI (histamine iontophoresis) after which itch ratings, wheal size, and skin temperature are measured. Additionally, questionnaires are administered to assess positive and negative affect, personality and expectations amongst others.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy female volunteers between 18 and 35 years old;

2. Good understanding of written and spoken Dutch.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current psychiatric (DSM-IV) conditions;

2. All conditions that might interfere with the participant's safety and/or the study protocol: e.g., Raynaud’s phenomenon, severe neurological or neurosurgical conditions;

3. (Intended) pregnancy or breast feeding.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	08-04-2016
Aantal proefpersonen:	108
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	31-01-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42756

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6212
NTR-old	NTR6376
CCMO	NL55922.058.15
OMON	NL-OMON42756

Resultaten

Samenvatting resultaten
n/a