Oxytocin and reactivity to infant signals in mothers postpartum depression

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Ethical review	Approved WMO
Status	Completed
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON53882

Source
ToetsingOnline

Brief title
Oxytocin and Postpartum Depression

Condition

- Mood disorders and disturbances NEC

Synonym
postnatal depression, postpartum depression

Research involving
Human

Sponsors and support

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

Intervention

Keyword: infant signals, mother-infant relationship, oxytocin, postpartum depression

Outcome measures

Primary outcome

Main study parameters are:

- Maternal sensitivity during interaction with mother*s own infant and with a crying infant simulator

- Maternal stress reactivity, assessed with heart rate and salivary cortisol

- Recognition of infant facial emotional expressions

Secondary outcome

• We will examine the extent to which effects of oxytocin are moderated by mothers* early childhood experiences. Early childhood experiences are known to moderate effects of nasally administered oxytocin (Ellis et al., 2021, see research protocol), possibly also in mothers with postpartum depression.

• We will examine whether oxytocin affects mothers* mood and the perceived relationship with her child.

Study description

Background summary

Postpartum depression is a serious mental health concern affecting 10-15% of all mothers in Western societies. Postpartum depression does not only negatively impact on the mother, but has also been associated with insensitive caregiving and with poor child outcomes. One candidate that may play a crucial role in the relation between depressed mood, maternal care, and child outcomes is oxytocin, a hormone important for affiliation and parenting. Previous studies have shown that oxytocin levels are lower in mothers with postpartum symptoms and that intranasal oxytocin administration can positively affect the

perceived relationship with the child. However, still little is known about the effects of oxytocin on caregiving behavior in mothers with postpartum depression. Here, we propose to conduct a randomized double-blind within-subject control study to test the effects of intranasal oxytocin on caregiving behaviors of mothers with depressive symptoms in the postpartum period.

Study objective

In a randomized control trial (RCT) with mothers with postpartum depressive symptoms the following main hypotheses will be tested:
• Oxytocin will promote more sensitive caregiving during mother-infant interactions and while interacting with a life-like crying infant simulator.
• Oxytocin will reduce depressed mothers* stress reactivity while interacting with their own infant and the crying infant simulator, as reflected in reduced heart rate activity and cortisol.
• Oxytocin administration will result in a bias towards the recognition of happy infant emotions.
Secondary objectives are 1) to examine whether oxytocin affects mothers* mood and the perceived relationship with her child and 2) to examine the extent to which effects of oxytocin are moderated by mothers* early childhood experiences.

Study design

A randomized controlled-trial with a within-subject design. Mothers with postpartum depression will be invited for two lab sessions during which they will receive a nasal spray containing 24 IU oxytocin or a placebo.

Intervention

24 IU intranasal oxytocin and placebo

Study burden and risks

There are no risks associated with the assessments used in this study. Possible side effects of oxytocin are negligible. No adverse effects have been reported in participants/patients. The burden for participants consists of spending time on two lab sessions (approximately 75 minutes each), during which four saliva samples will be collected, heart rate will be measured, questionnaires will be completed, an infant emotion recognition task will be performed, and mother-infant interactions will be observed. Although there is no direct benefit to the participants from the proposed research, there are greater benefits to society from the potential knowledge gained from this study. Once we understand the neurobiological underpinnings of poor maternal sensitivity among mothers with postpartum depression, better attempts can be made to

improve parenting and reduce the adverse effects of poor parenting. Moreover, the study will reveal insight into the potential therapeutic effects of oxytocin administration in mothers with depressive symptoms. Thus, the importance of the benefits gained from this research outweighs the minimal risks involved.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

• Mothers with a healthy infant between 0 and 9 months of age
• With a diagnosis of postpartum depression, that is, scores of >=7 on the Edinburgh Postnatal Depression Scale and a postpartum depression diagnosis

confirmed through the Structured Clinical Interview for the DSM-5

Exclusion criteria

• Current mental disorder other than depression or an anxiety disorder
• PPD with psychotic symptoms
• Neurological disorders, endocrine diseases, cardiovascular diseases, nose injuries and disorders, use of medication other than oral contraceptives or anti-depressant medication
• Regular use of soft drugs, hard drug use within the past three months, or excessive alcohol intake
• Pregnancy
• Preterm birth (< 37 weeks)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	08-05-2023
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Oxytocin

Generic name:	Syntocinon
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-04-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	05-08-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-08-2023
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2022-000603-12-NL

Register	ID
CCMO	NL80655.000.22