Combining emotion recognition training with oxytocin administration: A psychobiological approach

Published: 30-03-2020
Last updated: 15-05-2024

The primary aim of this study is to examine the effectiveness of a psychobiological intervention combining oxytocin administration with ERT. We hypothesize that the combined intervention will be more effective in improving emotion recognition skills...

Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON49988

Source
ToetsingOnline

Brief title
Emotion recognition training with oxytocin

Condition

- Psychiatric and behavioural symptoms NEC

Synonym
antisocial behavior, externalizing problems

Research involving
Human

Sponsors and support

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

Intervention

Keyword: antisocial behavior, emotion recognition training, oxytocin

Outcome measures

Primary outcome

The primary study parameter is the change in emotion recognition skills from baseline to post-training and follow-up between the two groups (oxytocin+ERT vs placebo+ERT).

Secondary outcome

The secondary parameters are the change in aggression, and delinquency from baseline to post-training and follow-up between the two groups (oxytocin+ERT vs placebo+ERT). We also examine whether psychological and environmental factors influence the effectiveness of the intervention.

Study description

Background summary

Youth with antisocial behavior often exhibit deficits in emotion recognition that contribute to aggression and delinquency. A new emotion recognition training (ERT) has been developed and empirical evidence has supported its effectiveness in juvenile offenders who showed improved emotion recognition after training and a significant reduction in the severity of crimes. In addition, oxytocin administration can also improve emotion recognition in healthy samples and residential youth. A novel approach is to combine oxytocin administration with ERT to examine whether this combination can lead to better treatment outcomes.

Study objective

The primary aim of this study is to examine the effectiveness of a psychobiological intervention combining oxytocin administration with ERT. We hypothesize that the combined intervention will be more effective in improving emotion recognition skills compared to the ERT combined with placebo. As

secondary objectives, we investigate whether the combined training can reduce aggression or delinquency and whether the effectiveness of the intervention is moderated by psychological and environmental factors.

Study design

This is a randomized, double-blind, placebo-controlled, between-subjects study including five steps: screening, baseline measurement, training, post-training measurement, and follow-up. During the training (3 sessions), participants will be randomly allocated to either oxytocin or placebo condition. Participants in oxytocin condition will receive the ERT in combination with 24 IU of oxytocin with a nasal spray 30 minutes before each treatment session, whereas participants in the placebo condition will receive the ERT with placebo.

Intervention

One group will receive a dose of 24 IU oxytocin with a nasal spray before each session of the emotion recognition training and the other group will receive placebo before the emotion recognition training.

Study burden and risks

Previous meta-analyses revealed that oxytocin administration has no severe side-effects or adverse events and it is safe in research settings. The participants will be directly benefited from the study as a combined intervention will be administered aiming at improving emotion recognition skills. The emotion recognition training is brief and easy for the participants without any significant burden.

Contacts

Public
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6525HR
NL
Scientific
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6525HR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The inclusion criteria are: male, aged 12-20, living in residential youth care facilities, capable to read and comprehend the Dutch language, exhibit antisocial behavior and deficits in emotion recognition skills, and provide written informed consent.

Exclusion criteria

The exclusion criteria are: medication for severe medical problems, presence of severe nasal disease or history of severe nasal surgery, renal or hepatic impairment, latex allergy or intolerance.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	80
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:	30-03-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-06-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-12-2022
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

ID: 20174
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2019-001910-40-NL
CCMO	NL70016.091.19
OMON	NL-OMON20174