

# MDMA and prosocial behavior.

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26647

### Source

Nationaal Trial Register

### Brief title

MDMA & PSB

### Health condition

prosocial behavior, oxytocin, 5-HT1a receptor, MDMA

## Sponsors and support

**Primary sponsor:** Dr. Kim Kuypers,

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**Source(s) of monetary or material Support:** Netherlands Organisation for Scientific Research (NWO)

## Intervention

## Outcome measures

### Primary outcome

1. Dependent variables of the empathy and social interaction tasks, measured with computertasks;
2. Treatment concentrations and oxytocin concentrations in the blood (bloodsample).

### **Secondary outcome**

Dependent variables of the control task: Word learning task.

## **Study description**

### **Background summary**

The aim of the present study is to investigate the roles of oxytocin and the 5-HT1A receptor in MDMA-induced prosocial effects. Eighteen participants will go through four treatment conditions on four occasions, separated by a minimum of 7 days washout. Social behavior and mood will be assessed in the laboratory. It is hypothesized that oxytocin will mimic MDMA-induced prosocial effects and that the 5-HT1A receptor is an important mediator of these effects.

### **Study objective**

1. Oxytocin will mimic MDMA-induced prosocial effects;
2. Blockade of the 5-HT1A receptor will prevent occurrence prosocial effects after MDMA intake (acute, not on subsequent occasions);
3. MDMA users carrying the fast working SERT genotype variant (LaLa) will experience more pronounced prosocial effects compared with the users carrying the slow working variant.

### **Study design**

1. Medical screening;
2. Training of the computer tasks;
3. 4 testdays separated by a minimum of 7 days washout.

Total study burden= 18,5 hours, spread over minimally 5 weeks.

### **Intervention**

Administration of treatments\* and collection of a blood sample each test day to determine treatment concentrations and oxytocin concentrations in the blood.

\*There are 4 treatment conditions and these will be:

1. A single dose of MDMA (75mg);
2. Syntocinon (32 international units);
3. MDMA (75 mg) combined with Visken (20 mg);
4. Placebo.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

1. Experience with the use of MDMA (maximally 100 times in total, minimally 2 times in total; and at least once in the past 12 months);

2. Age between 18-40 years;
3. Free from medication (except oral contraception);
4. Good physical health as determined by examination and laboratory analysis;
5. Absence of any major medical, endocrine and neurological condition;
6. Normal weight, body mass index (weight/height<sup>2</sup>) between 18 and 28 kg/m<sup>2</sup>;
7. Written Informed Consent;
8. Native Dutch speaker (as some tasks require this).

## Exclusion criteria

1. History of drug abuse (other than the use of MDMA) or addiction;
2. Women: Pregnancy or lactation;
3. Cardiovascular abnormalities as assessed by standard 12-lead ECG;
4. Excessive drinking (> 20 alcoholic consumptions a week);
5. Hypertension (diastolic > 100; systolic > 170);
6. Current or history of psychiatric disorder.

## Study design

### Design

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

## Recruitment

NL  
Recruitment status: Pending  
Start date (anticipated): 01-02-2011  
Enrollment: 18  
Type: Anticipated

## Ethics review

Not applicable  
Application type: Not applicable

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 36227  
Bron: ToetsingOnline  
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL2518
NTR-old	NTR2636
CCMO	NL34859.068.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36227

## Study results

### Summary results

N/A