Effects of MDMA on memory when witnessing or committing a simulated crime

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25089

Source NTR

Brief title MDMA study

Health condition

Participants are healthy volunteers

Sponsors and support

Primary sponsor: Maastricht University Source(s) of monetary or material Support: NWO

Intervention

Outcome measures

Primary outcome

Spontaneous and suggestion-based false memories will be assessed by using established false memory paradigms (associatively-related word lists, mock crime).

Secondary outcome

Dissociative states and traits will be assessed using both established self-report and clinicianadministered measures. Functional connectivity will be assessed using resting state fMRI.

Study description

Background summary

Rationale: Legal cases have shown that eyewitnesses and innocent suspects can falsely remember to have seen non-existing details of a crime or falsely confess to have committed a crime due to suggestive interrogation tactics of the police. Eyewitnesses and suspects are often under the influence of the party-drug ecstasy (MDMA) but little knowledge exists whether their drugged state makes them more vulnerable to spontaneous or suggestion-induced false memories.

Objective: Objectives of this study are twofold. The current project will examine the impact of MDMA intoxication on susceptibility to false memories and dissociation. Additionally, the effect of MDMA on functional connectivity between the striatum and the prefrontal cortex will be studied using fMRI in a subset of participants.

Study design: Acute and delayed influences of MDMA on false memory formation will be assessed in a placebo-controlled study in occasional MDMA users, using a virtual reality (VR) eyewitness and a perpetrator scenario. The order of treatments and scenarios will be counterbalanced across participants.

Study population: Sixty-four healthy, occasional MDMA users, aged 18-40.

Intervention (if applicable): Placebo and MDMA (75mg)

Main study parameters/endpoints: Spontaneous and suggestion-based false memories will be assessed by using established false memory paradigms (associatively-related word lists, mock crime). Dissociative states and traits will be assessed using both established self-report and clinician-administered measures. Functional connectivity will be assessed using resting state fMRI.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants will visit our lab five times. The first visit includes a full medical screening by a licensed physician ensuring their safety, which will include a medical history review, a blood sample (12 ml), and an electrocardiogram recording. The second includes a short training session to familiarize them with the testing procedures and (potentially) the MRI scanner. During the third and fourth visit, participants will be administered placebo and

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MDMA (capsule) and be exposed to two distinct mock crime Virtual Reality (VR) scenarios on two separate occasions, each followed by an immediate and a one-week follow-up assessment, including measures of true and false memory and dissociative states and traits. Moreover, a subset of 12 participants will undergo a resting state functional connectivity assessment inside the magnetic resonance scanner (time in MRI scanner is ~20 minutes). Finally, participants will return a week later for a brief follow up visit (20 minutes) in which they will receive follow-up false memory tests.

Study objective

It is expected that participants in the MDMA condition will be more susceptible to false memory formation, and that this will be mediated by dissociation.

Study design

week 0: medical screening

- week 1: training
- week 2: testing session 1
- week 3: testing session 2
- week 4: followup

Intervention

75mg dose of 3,4-methylenedioxymethamphetamine (MDMA) vs placebo

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- Experience with the use of MDMA/ecstasy (maximally 200 times in total, minimally 3 times
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in total; and at least once in the past 12 months): This will be assessed by means of a drug history questionnaire and an interview by the medical supervisor

- Age between 18 and 40 years
- Good physical health as determined by medical examination and laboratory analysis
- Normal weight, body mass index (weight/height2) between 18 and 28 kg/m2
- Written Informed Consent

• Good knowledge and understanding of the English language (at least 5 years of English language education; assessed in the prescreening)

Exclusion criteria

• History of drug abuse (other than the use of MDMA) or addiction (determined by the medical questionnaire, drug questionnaire and medical examination)

• Pregnancy or lactation (pregnancy test, if needed)

• Use of psychotropic medication (i.e. medication prescribed by a physician, such as antidepressants or antipsychotics, not including contraceptives or painkillers such as ibuprofen)

- Any major medical, endocrine and neurological condition]
- Decreased liver function
- Hypertension (diastolic> 90; systolic> 140)
- Current or history of psychiatric disorder (determined by the medical questionnaire and medical examination)
- Liver dysfunction
- (Serious) side effects due to previous MDMA consumption

• History of cardiac dysfunctions (arrhythmia, ischemic heart disease,...)/ cardiovascular abnormalities as indicated by (1) The medical questionnaire and/or (2) the standard 12-lead ECG

• Previous participation in study NL60303.068.16, "Acute and delayed effects of THC intoxication on false memories in a legal context"

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-11-2017
Enrollment:	64
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	12-09-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44349 Bron: ToetsingOnline Titel:

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

No registrations found.

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In other registers

Register	ID
NTR-new	NL7423
NTR-old	NTR7665
ССМО	NL62794.068.17
OMON	NL-OMON44349

Study results