Acute and delayed effects of MDMA intoxication on false memories in a legal context

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Primary Objective: to assess the immediate and delayed effects of THC on true and false memories in a legal context (i.e., on eyewitness and offender statements). Secondary Objective(s): to link drug-induced false memory effects to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44349

Source ToetsingOnline

Brief title Effects of MDMA intoxication on false memories

Condition

• Other condition

Synonym

n.a.

Health condition

no health condition is addressed in the research, and healthy volunteers who are occasional MDMA users will be recruited

Research involving

Human

Sponsors and support

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

Intervention

Keyword: dissocation, false memories, MDMA, mock crime

Outcome measures

Primary outcome

Primary: Spontaneous false memories will be measured using the Deese/Roediger-McDermott (DRM) paradigm. Suggestion-based false memories will be assessed via exposing subjects to a virtual reality mock crime and adding suggestive misinformation in subsequent interrogations.

Secondary outcome

Secondary: Dissociative psychopathology (i.e., dissociative traits) will be measured using the Dissociative Experiences Scale (DES). Reality monitoring/dissociative symptoms (i.e., dissociative states) will be assessed using the Clinician Administered Dissociative States Scale (CADSS). Other parameters include constructs related to (false) memory, such as attention, information processing, compliance, arousal, and convergent and divergent thinking.

Study description

Background summary

False memories refer to memories of events/details that did not actually occur (Otgaar, Howe, Brackmann, & Smeets, 2016). False memories frequently occur spontaneously but can also be elicited through suggestive pressure. 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. Such false memories can lead to wrongful convictions. Moreover, eyewitnesses and suspects are often under influence of drugs such as MDMA while no knowledge base exists whether their drugged state makes them more sensitive to spontaneous or suggestion-based false memories. From a practical perspective, examining this issue is highly relevant as MDMA is the second most widely used illicit drug in the world, and is strongly prevalent in the Netherlands. In the courtroom, eyewitness and suspect statements are seen as highly valuable evidence, thus their reliability is important.

Study objective

Primary Objective: to assess the immediate and delayed effects of THC on true and false memories in a legal context (i.e., on eyewitness and offender statements).

Secondary Objective(s): to link drug-induced false memory effects to dissociation

Tertiary objective: to assess functional connectivity in a subset of participants in both treatment and control conditions in order to add to a database of drug-induced changes in the brain, as well as link fMRI data to false memory effects

Study design

The study will be conducted according to a double-blind, placebo-controlled, 2 (Group: Treatment vs. Control) by 2 (Time 1 vs. Time 2) crossover mixed design with Group as a between-subjects factor. Occasional (N=64) MDMA/ecstasy users will receive single doses of MDMA (75mg) and placebo according to a double-blind design in which they will be exposed to either an eyewitness scenario (Study 1a) or a perpetrator scenario (Study 1b). Each participant will be allocated to 1 of 2 groups (n=32 each) that receive eyewitness and perpetrator virtual reality scenarios during opposing treatment conditions. Groups will be matched according to sex, education and age. The major advantage of this approach is that participants will only be exposed once to each scenario (i.e. to exclude carryover and learning effects) while participating in both studies.

Intervention

Placebo (bitter lemon drink) and MDMA (75mg capsules dissolved in bitter lemon drink)

Study burden and risks

The participants will be administered placebo and MDMA in a crossover study. They will view two different virtual reality mock crimes on separate testing days, and subsequently their memory will be assessed. For more information see the research protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Healthy volunteers who have experience with the use of ecstasy/MDMA (maximally 200 times in total, minimally 3 times 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) 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:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

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Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2017

Enrollment:	80
Туре:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MDMA
Generic name:	MDMA

Ethics review

Approved WMO	
Date:	25-09-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO	
Date:	27-09-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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: 25089 Source: NTR Title:

In other registers

Register

ID

EudraCT

EUCTR2016-004982-22-NL

Register

CCMO OMON ID NL62794.068.17 NL-OMON25089