

Psilocybin as a tool for enhancing cognitive flexibility”

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25919

Source

NTR

Health condition

psilocybin, divergent thinking, neurotransmission

Sponsors and support

Primary sponsor: University Maastricht (UM)

Source(s) of monetary or material Support: University Maastricht (UM)

Intervention

Outcome measures

Primary outcome

To use psilocybin as a research tool in order to enhance divergent thinking, and facilitate relative goal-directed versus habitual behaviour during and after drug intoxication, and to assess whether psilocybin will deter a stress induced shift from goal directed to habitual behaviour.

Secondary outcome

To assess cortical-subcortical functional connectivity alterations, as well as the relationship

between metabolic activity and behavioural outcomes. Furthermore, subjective experience and drug concentration levels will be assessed in relation to the aforementioned variables.

Study description

Background summary

Posttraumatic stress disorder (PTSD) is an anxiety disorder in which an individual's ability to function is impaired by emotional responses to memories of a traumatic event. It is typically a chronic illness associated with high rates of psychiatric and medical comorbidity, disability, suffering, drug abuse, and suicide. However despite the high incidence of PTSD, current therapies provide limited effectiveness, with many people being unresponsive to treatment. Suggestions for effective treatments for PTSD include a hypothetical drug that would be capable of enhancing divergent thinking, a cognitive process used to generate as many innovative ideas as possible. A recent study from our lab showed that psychedelics significantly increased divergent thinking after drug intake. Furthermore, imaging studies have shown that the classic psychedelic, psilocybin, promotes a de-synchronization in the default mode network that is suggested to result in cognitive flexibility and enhanced creative thinking. Taken together these studies suggest that psilocybin can enhance divergent thinking, which may provide therapeutic potential in facilitating goal directed over habitual behaviour. Principal demonstrations showing that psilocybin facilitates cognitive flexibility would be very relevant for future support of clinical applications of psilocybin assisted therapy in PTSD patients, and may provide therapeutic potential for patients whom current options are not effective.

Study objective

The study will assess drug-induced change in performance in divergent thinking and goal-directed behaviour when comparing psilocybin to placebo, before and after an induction of stress. Additional study parameters include frontal-subcortical connectivity alterations and neurotransmission of glutamate and GABA between treatment conditions, as well as subjective questionnaires, pharmacokinetics, and cortisol.

Study design

Measurements will take place up until 360 minutes after drug intake on testing day one. Testing day two includes up to 2.5 hours of follow up measurements.

Intervention

psilocybin (.17 mg/kg) bodyweight or placebo;
Maastricht acute stress test or placebo

Contacts

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Eligibility criteria

Inclusion criteria

- Previous experience with a psychedelic drug, but not within the past 6 months.
- Age between 18 and 40 years
- Free from psychotropic medication
- Good physical health as determined by medical examination and laboratory analysis
- Absence of any major medical, endocrine and neurological condition
- Normal weight, body mass index (weight/height²) between 18 and 28 kg/m²
- Proficient knowledge of the English language, defined as having at least 5 years of English language education (in high school or other education)
- Written Informed Consent

Exclusion criteria

- History of drug addiction (determined by the medical questionnaire, drug questionnaire and medical examination)
- Previous experience of serious side effects to psychedelic drugs (anxiety or panic attacks)
- Pregnancy or lactation
- Hypertension (diastolic > 90; systolic > 140)
- Current or history of psychiatric disorder (determined by the medical questionnaire and medical examination)
- Liver dysfunction
- History of cardiac dysfunctions (arrhythmia, ischemic heart disease,...)
- For women: no use of a reliable contraceptive

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2017
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:

Not applicable

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
NTR-new	NL6007
NTR-old	NTR6505
Other	METC : 173006

Study results