LSD microdosing - A repeated dosing study

No registrations found.

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

Summary

ID

NL-OMON22020

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Healthy volunteers

Sponsors and support

Primary sponsor: Maastricht University Department of Psychology and Neurosciences
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The primary objective is to examine the possible positive mood and positive subjective effects following repeated doses of 15 mcg LSD compared to placebo.

Secondary outcome

The secondary objective is to examine the possible induced cognitive performance and increase in neuroplasticity following repeated doses of 15 mcg LSD compared to placebo.

Study description

Background summary

LSD is a psychedelic substance that is used recreationally because of its effects on consciousness. More specifically, LSD induces acute transient alterations in waking consciousness including visual perceptual alterations, audio-visual synesthesia, derealization and depersonalization. Modern experimental studies documented marked changes in perception at a moderate (100 µg orally or 75 µg intravenously) or high 200 µg oral dose of LSD in healthy volunteers. Recently, repeated use of low doses of LSD as so-called LSD microdosing to enhance mood, creativity, and/or performance has been observed. However, the subjective and cognitive effects of repeatedly consuming such low doses (between 5 to 20 µg) have not yet been studied in modern studies using validated psychometric tools. In our recent dose-finding study it is shown that positive effects on mood and cognition are evident in 10 micrograms of LSD and clearly visible in 20 micrograms. However, it is unclear what the acute and sub-acute effects are of a repeated microdosing schedule for four weeks.

Study objective

The study hypothesis is that the LSD group shows an increase in positive mood and subjective effects between baseline and follow-up after 4 weeks of repeated dosing with LSD compared to the placebo group. An additional study parameter is the repeated dose effects on cognitive performance and changes in neuroplasticity under the influence and after repeated dosing of LSD compared to placebo.

Study design

1.5 years

Intervention

Placebo and 15 mcg LSD

Contacts

Public
Maastricht University
Nadia Hutten

0433883522
Scientific
Maastricht University
Nadia Hutten

0433883522

Eligibility criteria

Inclusion criteria

• Having had at least one full-psychedelic experience (regular dose) with LSD, psilocybin, ayahuasca, DMT, Salvinorin, Mescaline, MDMA, NBOMe, 2Cs or any other psychedelic drug, but not within the past 3 months.
• Proficient knowledge of the English language
• Written Informed Consent
• Understanding the procedures and the risks associated with the study.
• Age between 18 and 65 years
• Absence of any major medical condition as determined by medical examination and laboratory analysis
• Absence of any major psychological condition as determined by medical examination
• Free from psychotropic medication
• Participants must be willing to refrain from taking illicit psychoactive substances during the study.
• Participants must be willing to drink only alcohol-free liquids and no coffee, black or green tea, or energy drink after midnight of the evening before the study session, as well as during the study day.
• Participants must be willing not to drive a traffic vehicle or to operate machines within 24 h after substance administration.
• Normal weight, body mass index (weight/height2) between 18 and 28 kg/m2

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 mmHg; systolic > 160 mmHg)
• Current or history of psychiatric disorder (determined by the medical questionnaire and medical examination)
• Psychotic disorder in first-degree relatives
• Any chronic or acute medical condition

• History of cardiac dysfunctions (arrhythmia, ischemic heart disease,...)
• For women: no use of a reliable contraceptive
• Tobacco smoking (>20 per day)
• Excessive drinking (>20 alcoholic consumptions per week)
• Prior exposure to False Memories paradigm

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-02-2020
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	17-06-2020
Application type:	First submission

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	NL8736
Other	METC azM/UM : METC19-038

Study results

Summary results
N/A