LSD microdosing - a repeated dosing study

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The present study explores the acute and sub-acute effects of repeated-dosing schedule of small doses of LSD (15 µg) on subjective and cognitive effects compared to placebo.

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

Summary

ID

NL-OMON55178

Source
ToetsingOnline

Brief title
LSD microdosing - a repeated dosing study

Condition

- Other condition

Synonym
Performance and mood enhancement in society

Health condition

subjectieve effecten, cognitief functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Beckley Foundation;Oxford;UK

Intervention

Keyword: cognitive performance, Lysergic acid diethylamide, microdosing, subjective effects

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. Recent 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, the use of low doses of LSD twice a week over a longer period of time as so-called LSD microdosing to enhance mood, creativity, and/or performance has been observed. The acute subjective effects of such low doses (between 5 and 20 µg) have recently been investigated in a placebo-controlled dose-finding study, which has shown that doses between 10 and 20 micrograms do show a difference compared to the placebo. However, the subjective and cognitive effects of repeated low doses of LSD (15 µg) have not yet been investigated in placebo-controlled studies with validated psychometric instruments. It is unclear whether repeated doses of LSD produce subjective effects distinct from placebo.

Study objective

The present study explores the acute and sub-acute effects of repeated-dosing

schedule of small doses of LSD (15 µg) on subjective and cognitive effects compared to placebo.

Study design

The present study uses a double-blind, randomized, placebo-controlled, between-subjects design. Participants will receive placebo or 4 microdoses of LSD (15 µg).

Intervention

4 times a placebo or 4 times 15 µg of LSD.

Study burden and risks

Participants will visit our lab 7 times during 5 weeks. Before the first study day, subjects will come for a screening visit. This includes a full medical screening by a licensed physician (medical history review, laboratory screening, electrocardiogram recording). Then the participant will come in for a training session, were the participant is familiarized with all the task procedures. A baseline visit, 2 microdosing days (intake of 15 µg LSD or placebo) and the follow-up visit consist of taking a blood sample (10 ml), completing computer tasks, filling out questionnaires and EEG measurements. The other 2 short microdosing visits consist of completing questionnaires and taking 15 µg of LSD or placebo. 4 weeks after the last intake of the LSD or placebo, participants are asked to complete a few questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* 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

* Having used a psychedelic substance (regular dose) such as LSD, psilocybin, ayahuasca, DMT, Salvinorin, Mescaline, MDMA, NBOMe, 2Cs or any other psychedelic drug within the past 3 months.
* 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)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-12-2019
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	02-10-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	02-09-2020
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL70508.068.19