LSD microdosing - a dose finding study

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The present study explores the dose-response relationship in LSD-induced subjective and cognitive effects using small doses of LSD (5, 10, and 20 µg) compared to placebo.

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

Summary

ID

NL-OMON46425

Source
ToetsingOnline

Brief title
LSD microdosing - a dose finding study

Condition

- Other condition

Synonym
Performance and mood enhancement in society

Health condition

subjective effects, cognitive functioning

Research involving
Human

Sponsors and support

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

Intervention

Keyword: altered states of consciousness, cognitive performance, Lysergic acid diethylamide, microdosing

Outcome measures

Primary outcome

The study hypothesis is that higher doses of LSD will be associated with

increasingly greater and potentially also qualitatively different subjective

effects compared to placebo. An additional study parameter is the change in

cognitive performance under the influence of LSD compared to placebo.

Secondary outcome

The secondary objective is to characterize the dose-response relationship in

LSD-induced changes in cognitive performance.

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 as so-called LSD microdosing to enhance mood, creativity, and/or performance has been observed. However, the subjective effects of such low doses (between 5 to 20 µg) have not yet been studied in modern studies using validated psychometric tools. It is unclear whether such doses produce any subjective effects and if whether these effects are similar and just weaker than those induced by a higher dose and/or whether there are dose-related differences in the response.

Study objective

The present study explores the dose-response relationship in LSD-induced

subjective and cognitive effects using small doses of LSD (5, 10, and 20 µg) compared to placebo.

Study design

The present study uses a double-blind, randomized, placebo controlled, crossover design. Participants will placebo and 3 microdoses of LSD (5, 10, and 20 µg).

Intervention

Placebo and 5, 10, 20 µg of LSD in randomized order.

Study burden and risks

Participants will visit our lab 5 times during 5 weeks. Before the first study day, subject will come for a screening visit. This includes a full medical screening by a licensed physician (medical history review, laboratory screening, electrocardiogram recording). The study visits will consist of taking the study treatment (5, 10, and 20 µg of LSD or placebo), taking blood samples, completing computer tasks and filling out questionnaires.

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

* Previous experience with a 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 40 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 > 140 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:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-05-2018
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO

Date:	11-04-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL64747.068.18