LSD microdosing - A repeated dosing study

Gepubliceerd: 17-06-2020 Laatst bijgewerkt: 13-12-2022

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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22020

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Healthy volunteers

Ondersteuning

Primaire sponsor: Maastricht University Department of Psychology and Neurosciences
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1.5 years

Onderzoeksproduct en/of interventie

Placebo and 15 mcg LSD

Contactpersonen

Publiek

Maastricht University
Nadia Hutten

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Wetenschappelijk

Maastricht University
Nadia Hutten

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-02-2020
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-06-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8736
Ander register	METC azM/UM : METC19-038

Resultaten

Samenvatting resultaten
N/A