The effects of three small morning and evening doses of LSD on mood, biological and psychological measures of sleep, neuroplasticity, and well-being

No registrations found.

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

Summary

ID

NL-OMON27302

Source
NTR

Brief title
TBA

Health condition

Healthy volunteers

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Mind Medicine Inc.

Intervention

Outcome measures

Primary outcome

Primary objective is to investigate the effects of three repeated morning vs evening doses of

LSD (20 µg) on mood.

Secondary outcome

Secondary objectives are to investigate the effects of three repeated morning vs evening doses of LSD (20 µg) on neuroplasticity, sleep parameters, cognitive performance measures, emotion regulation, markers of well-being, cortisol, and endocannabinoid levels.

Study description

Background summary

Psychedelic research has seen a revival in the past decades, leading to a wave of new studies investigating the effects of psychedelic substances in clinical populations as well as in healthy volunteers. Psychedelics, such as psilocybin and LSD, have shown to be a potential alternative treatment option for psychiatric conditions, such as stress-related disorders and addiction. Also in healthy volunteers, a psychedelic acutely induced positive effects on mood and participants described it as being among the most personally meaningful experiences of their lives. Recently, the practice of repeatedly using small doses of a psychedelic has received increasing scientific interest and is better known as ‘microdosing’. Both healthy and clinical populations who microdose do this to enhance cognitive performance and mood. To understand the full potential of microdosing, knowledge about the underlying neurobiological mechanism of the positive effects on mood and behavior are pivotal. A potential mechanism underlying these positive effects that has not been investigated yet, is the effect of microdosing on sleep. Nearly all of the successful treatments for mood disorders seem to affect circadian rhythms (sleep) and enhance neuroplasticity (brain-derived neurotrophic factor, BDNF), the present project seeks to investigate the effect of small doses of a psychedelic (LSD, 20 µg) on these parameters in healthy volunteers. Studies have suggested the involvement of serotonin 1A and 2C receptors in the normalization of the circadian rhythm, and LSD is a potent agonist of these receptors, it is therefore expected that LSD affects sleep. Additionally, a recent study from our lab showed that low doses of LSD enhance BDNF levels, a marker of neuroplasticity. We hypothesize that the aforementioned effects on sleep and BDNF underlie the positive effects of LSD on mood and well-being.
Another finding is that psychedelics’ effects on sleep are dependent on the time of administration. To understand the effect of the timing of LSD administration on sleep, neuroplasticity and mood subsequently, the effect of three repeated small morning and evening doses of LSD will be compared in healthy volunteers on assessments of sleep, neuroplasticity (SW sleep and BDNF) and mood.

Study objective

A positive effect on mood is expected after LSD (20 µg) compared to placebo. The effect of LSD on mood is expected to differ depending on time of drug administration (morning vs evening).

Study design

3 dosing days interspersed with one day x 4

Intervention

LSD (20 µg) and to placebo

Contacts

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Eligibility criteria

Inclusion criteria

• Written Informed Consent
• Understanding the procedures and the risks associated with the study.
• At least 18 years of age
• 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.
• Participants are asked to not make any substantial changes in their diet.
• Participants must be willing to comply with guidelines regarding their bedtime.

• 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)
• Experience with a full dose of a psychedelic within the last three months

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2021
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	01-11-2021
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	NL9821
Other	METC azM/UM : METC21-020

Study results

Summary results
N/A