# Sub(acute) Profiling of 2C-B Versus Psilocybin

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON28125

**Source**
NTR

**Brief title**
PREDICT

**Health condition**

N/A

### Sponsors and support

**Primary sponsor:** Maastricht University
**Source(s) of monetary or material Support:** Open competition NWO grant/Maastricht University

### Intervention

### Outcome measures

**Primary outcome**

Acute dosing day performance as assessed by the digit symbol substitution task.

**Secondary outcome**

1. Acute cognition:
Sustained attention as measured by the Psychomotor Vigilance Task on each dosing day at +2:35 h
Sensorimotor function as measured by the Motor Screen Task on each dosing day at + 2:15 h
Executive function as measured by the Tower of London on each dosing day at + 2:20 h
Emotional memory encoding and recollection as measured by the Emotional Memory Task on each dosing day at +2:40h and +1 day follow-up at + 0:50 h
Visuospatial memory encoding and recollection as assessed by the Spatial Memory Task on each dosing at day + 2:50 h and + 3: 25 h
Cognitive tempo as assessed by Matching Familiar Figures task on each dosing day at + 3:30 h

2. Acute behaviour:
Self-hood using Virtual Reality self-location task at +5 hours on each dosing day
Cognitive and emotional empathy as assessed by the Multifaceted Empathy Test and Interpersonal Reactivity Index on each dosing day at + 4 h and +6 h respectively
3. Acute fMRI:
Functional connectivity (within-network, between-network) as measured by resting-state fMRI at + 1:30 h
GABA, glutamate concentrations as measured by magnetic resonance spectroscopy seed analysis at + 1:45 h
Emotional regulation and processing as measured by Affective Misattribution Task at + 2 h.
fMRI resting-state introspection profiling as measured by the Amsterdam Resting State Questionnaire (ARSQ) at + 2:10 h.

4. Acute pharmacokinetics and metabolomics:
Metabolite and drug quantification measured using hourly blood samples at baseline, +1 to+6 h
Metabolite and drug quantification measured using earwax samples at baseline, +1 to +6h

5. Acute subjective effects:
Drug intensity as measured by intensity visual analogue scale and Bowdles visual analogue scale hourly (baseline, +1 - +6h)
Mood as measured by the Profile of Mood States questionnaire hourly (baseline, +1 - +6h)
Depersonalisation as measured by the Clinician Administered Dissociative States Scale hourly (baseline, +1 - +6h)

6. Acute retrospective effects:
Altered states of consciousness as measured by the Hallucinogen Rating Scale, Altered States of Consciousness Rating Scale and The Ego-Dissolution Inventory at + 6 hours.

7.Subacute behavioural metric change:
Impulsivity as measured by the 4-choice Serial Reaction Time Task at +24 h (1-day follow-up) and the Barratt Impulsivity Scale 11 at + 24 h (1-day follow-up) and +120 h (5-day follow-up)
Self-other cognition as measured by the Probabilistic False Beliefs Task +24 h (1-day follow-up)
Perspective taking as measured by the Visuospatial Perspective taking task at +24 h (1-day

follow-up)
Cognitive flexibility as measured by the Stroop Colour and Word task at + 24 h (1-day follow-up)
Reactive aggression and aggressive tendencies as measured by the Point Subtraction Aggression Paradigm, Aggression Visual Analogue Scale and Single Category Implicit Association Task at + 24 h (1-day follow-up)
Daily self-reported aggression as measured by the The Buss-Perry Aggression Questionnaire (BPAQ)
Positive and negative affect as measured by the Positive and Negative Affect Schedule at + 24 h (1-day follow-up) and +120 h (5-day follow-up)
Social connectedness as measured by the Revised Social Connectedness Scale at + 24 h (1-day follow-up) and +120 h (5-day follow-up)
Social connectedness/one-ness as measured by the Inclusion of Other in The Self Scale at 24h (1-day follow-up) and +120 h (5-day follow-up)
Decentering as measured by the Experiences Questionnaire at 24 h (1-day follow-up) and +120 h (5-day follow-up)
Emotional regulation style as measured by the Difficulties in Emotional Regulation Scale at+120 h (5-day follow-up)
Persisting psychedelic effects as measured by the Persisting Effects Questionnaire at +120h (5-day follow-up)
Drug-related side effects as measured by the participant diary at +120 h (5-day follow-up)
Morality schema using the Defining Issues Task 2 at baseline and 8 weeks
Cognitive flexibility using the Cognitive Flexibility Scale at baseline and 8 weeks

# Study description

### Background summary

2C-B is a novel psychoactive substance (NPS) which is widely used among recreational drug users, serving as a template pro-drug for new drugs of abuse and sharing phenomenological similarities with well characterised compounds such as psilocybin and MDMA.
The study intends to provide a comprehensive neuropsychopharmacological evaluation of 2C-B's acute and persisting effects versus psilocybin. The overarching goal is to develop an imaging-metabolomics machine learning algorithm, which can predict the risk-profile of NPS using point of care blood samples.

### Study objective

2C-B generates distinct acute and subacute effects from Psilocybin and placebo

### Study design

Dosing day (day 1), Follow-up 1 (day 2), Follow-up 3 (day 5) x 3

**Intervention**

Latin square randomisation of 3 condition arms:
1. 20 mg oral 2C-B (powder, dissolved in bitter lemon drink)
2. 15 mg oral psilocybin (powder, dissolved in bitter lemon drink)
3. 200 ml bitter lemon drink (non-active control, administration solvent)
Each drug is to be administered as a solution on separate 6 hour dosing days with follow-ups the
morning after (+1 days) and 5 days later.
There will be a 2 week washout period between drug administrations.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Previous experience with at least one psychedelic substance (e.g., psilocybin, LSD, DMT, ayahuasca, psilocybe fungi ≥1 times) but not within the past three months.
2. Aged between 18 and 40 years.
3. Free from medication (any drug prescribed for a medical indication).
4. The participant is, in the opinion of the investigator, generally healthy based on assessment of
medical history, physical examination, vital signs, electrocardiogram (ECG), and the results of the
haematology, clinical chemistry, urinalysis, serology, and other laboratory tests.
5. A resting pulse and heart rate (as read on the ECG) ≥51 bpm and ≤100 bpm. For participants in
good physical condition, the lower limit is ≥45 bpm.
6. A resting systolic blood pressure ≥91 mmHg and ≤140 mmHg and a resting diastolic blood

pressure ≥51 mmHg and ≤90 mmHg.
7. Clinical laboratory test values within clinical reference ranges at screening. Borderline values
may be accepted if they are, in the opinion of the investigator, clinically insignificant.
8. Normal binocular visual acuity, corrected or uncorrected.
9. Absence of any major medical, endocrine and neurological condition, as determined by the medical history, medical examination, electrocardiogram and laboratory analyses (haematology,
clinical chemistry, urinalysis, serology).
10. Normal weight, body mass index.
11. Written informed consent.

### Exclusion criteria

1. Previous experience of serious side effects to psychedelic drugs (anxiety or panic attacks).
2. Use of medication (other than paracetamol).
3. History of drug addiction (determined by the medical questionnaire, drug questionnaire and
medical examination).
4. Excessive alcohol consumption (>20 units a week).
5. Excessive smoking (>20 cigarettes a week).
6. Current or history of psychiatric disorder (determined by the medical questionnaire and medical examination).
7. Hypertension (diastolic >90 mmHg; systolic >140 mmHg).
8. Liver dysfunction (hepatitis, cirrhosis, cancer, biliary cholangitis, hemochromatosis, alcoholic
liver disease, etc as determined by the medical examination).
10. Renal insufficiency (as indicated by the medical examination).
11. History of cardiac dysfunctions (arrhythmia, ischemic heart disease, etc).
12. Pregnancy or lactation.
13. For women: absence of reliable contraceptive measures.
14. fMRI contraindications (pacemakers, metal implants, claustrophobia, permanent eye makeup).

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |

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| Masking: | Double blinded (masking used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 04-08-2021 |
| Enrollment: | 18 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

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|---|---|
| Date: | 04-08-2020 |
| 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 | NL8813 |
| Other | METC azm/UM : 043-3876009 |

## Study results