

# Psilocybin in patients with fibromyalgia: EEG-measured brain biomarkers of action (Psilopain)

**First published:** 13/09/2022

**Last updated:** 14/03/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS48284

---

### Study ID

48285

---

### DARWIN EU® study

No

---

### Study countries

United Kingdom

---

### Study description

Title: Psilocybin in patients with fibromyalgia syndrome: EEG-measured brain biomarkers of action ('Psilopain'). Aims: To assess brain activity under psilocybin in a cohort of people with fibromyalgia. Design: A single arm, within-subjects study in 20 participants with fibromyalgia as defined by the American Rheumatological Society diagnostic criteria. Outcome Measures: The primary outcome is Lempel-Ziv complexity (LZc) of spontaneous brain activity recorded via EEG. Secondary outcomes will aim to capture broad aspects of the pain experience and related features through Magnetic Resonance Imaging (MRI), self-report measures, behavioural paradigms and qualitative interviews. Eligibility: Over 18 years of age, a good understanding of English language, registered with a primary care practice, no urgent clinical investigations or interventions for pain indicated. Procedure: Two dosing sessions, separated by four weeks with in-session EEG-recordings. Duration: This study will run for 27 months.

---

## Study status

Ongoing

## Research institutions and networks

### Institutions

**Imperial College London**

United Kingdom

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

**Educational Institution**

# Contact details

## Study institution contact

Close James [jclose@ic.ac.uk](mailto:jclose@ic.ac.uk)

Study contact

[jclose@ic.ac.uk](mailto:jclose@ic.ac.uk)

## Primary lead investigator

David Nutt

Primary lead investigator

# Study timelines

## Date when funding contract was signed

Planned: 31/01/2022

Actual: 31/01/2022

---

## Study start date

Planned: 15/08/2022

Actual: 15/08/2022

---

## Data analysis start date

Planned: 02/10/2023

---

## Date of final study report

Planned: 01/10/2024

# Sources of funding

- Other

## More details on funding

Philanthropy

## Regulatory

### **Was the study required by a regulatory body?**

No

---

### **Is the study required by a Risk Management Plan (RMP)?**

Not applicable

## Other study registration identification numbers and links

Imperial College London RGIT Sponsorship Number: 20HH6314, IRAS Project ID: 275349, REC reference: 21/PR/1008 URL: <https://www.imperial.ac.uk/psychedelic-research-centre/trials/psilopain/>

## Methodological aspects

### Study type

### Study type list

**Study type:**

Non-interventional study

---

**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Mechanistic Study

**Main study objective:**

The primary objective of this non-CTIMP (non-Clinical Trial of an Investigational Medicinal Product) early phase experimental medicine study is to utilise a within-subjects design to examine a candidate brain biomarker of increased plasticity (defined as the ability to change) under psilocybin, Lempel-Ziv complexity (LZc).

## Study Design

**Non-interventional study design**

Other

---

**Non-interventional study design, other**

Within-subjects, single arm study

## Study drug and medical condition

**Medicinal product name, other**

Psilocybin

---

**Medical condition to be studied**

## Population studied

### Age groups

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
- 

### Estimated number of subjects

20

## Study design details

### Outcomes

1) Lempel-Ziv complexity (LZc) 2) The Brief Experiential Avoidance Questionnaire (BEAQ), 1) Structural and functional magnetic resonance imaging 2) Patient reported outcome measures 3) Physiology: Heart rate, body temperature, accelerometry 4) Qualitative interviews

---

### Data analysis plan

With an assumption of high co-linearity between core outcomes we will explore data reduction approaches (e.g. factor or principal component analyses or canonical correlation analysis) to investigate key contrasts. Two tailed tests will be performed if findings are not aligned with prior hypotheses. Due to prior hypotheses on directionality, one tailed t-tests will be performed when appropriate. Multiple comparisons corrections and Bayesian analyses will be

performed where deemed appropriate.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

---

### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

**Check conformance**

Unknown

---

**Check completeness**

Unknown

---

**Check stability**

Unknown

---

**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No