ISRCTN10441504 https://doi.org/10.1186/ISRCTN10441504

Psilocybin as a treatment for anorexia nervosa

Submission date
27/01/2021

Recruitment status
No longer recruiting

Registration date
05/02/2021

Overall study status
Completed

Last Edited
08/07/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Anorexia is an eating disorder and serious mental health condition. People who have anorexia try to keep their weight as low as possible by not eating enough food or exercising too much, or both. This can make them very ill because they start to starve. They often have a distorted image of their bodies, thinking they are fat even when they are underweight. Currently, there are no effective drug treatments for anorexia nervosa, and fewer than half of those diagnosed make a full recovery. As such, there is a great need for new treatments to be explored.
The main purpose of this study is to test whether psilocybin - a controlled drug that is the active component of “magic mushrooms”- is a feasible and effective treatment for anorexia nervosa. An additional aim of this study is to explore how psilocybin treatment effects the brain. For this, all study participants will also undergo Magnetic Resonance Imaging (MRI) and Electroencephalography (EEG) before and after taking psilocybin. While this is only a small pilot study, it is hoped that this will provide the basis for further, large-scale clinical trials to explore the therapeutic potential of psilocybin.

Who can participate?
We are looking for female participants who have a primary diagnosis of anorexia nervosa, which has been established by their eating disorder care team to have been present for >3 years, and who have found other forms of treatment ineffective. All participants must live in the UK, be between 18 and 65 years old, and be in the care of an eating disorder service.

What does the study involve?
Once eligibility has been confirmed (at a screening visit),
participants will partake in 8 study visits over a 6-week period, including three psilocybin dosing sessions. Psilocybin dosing sessions will take place in a supportive environment, in the presence of two trained guides. A mixture of remote and in-person “preparation” and “integration” will occur around each dosing day. This is where participants will spend time with their guides to prepare for the psilocybin experience, and to process the content that came up during the experience. Across these 8 visits, there will also be 2 MRI scans, 5 EEG recordings and a range of psychological measures (questionnaires and interviews). There will be a follow-up period of 12 months following the final study visit.

What are the possible benefits and risks of participating?
The possible benefits of participating in this study include improved well-being, and decreased

eating disorder symptoms and feelings. Previous studies have shown that psilocybin can improve feelings of well-being in participants and decrease symptoms of depression, anxiety, addiction, and obsessive-compulsive disorder.
However, any participant who wishes to be involved must come off any anti-depressant medication they are currently on, which can take weeks and can be difficult. We will liaise with each participant's care team to make sure that this is done safely.
Psilocybin is incredibly safe, but there are a few minor side-effects while under the influence of the drug, and immediately after. The most common are acute nausea (vomiting is very rare) and increases in blood pressure and heart rate, however, not to dangerous levels. It is not uncommon for people to feel anxious after being given the drug, however, participants will be psychologically supported throughout the entire experience so this anxiety should be short-lived. Some participant may experience a mild headache for a few days. While there are some reports of "flashbacks" or a "reliving" of the psychedelic experience in the literature, this results when people take psilocybin in an unsupportive environment and, to the best of our knowledge, this has never occurred in any modern clinical trials of psilocybin.
As this is a novel treatment, we cannot be sure that all participants will experience direct benefit from taking part. However, the results of this study could lead to improvements in treatments available to those suffering from an eating disorder. It is possible that participants in this study may not respond to the study medication and they may even deteriorate further. However, we will be working closely with care teams and support people to ensure that each participant is monitored closely throughout the entire study. The study team will be available for contact at any time should there be any concerns.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
December 2018 to June 2024

Who is funding the study?
The founders of the Centre for Psychedelic Research (UK)

Who is the main contact?
Ms Hannah Douglass, hannah.douglass@auckland.ac.nz

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04505189

Clinical Trials Information System (CTIS)
2019-004054-28

Integrated Research Application System (IRAS)
266759

Central Portfolio Management System (CPMS)
45514

Study information

Scientific Title
Psilocybin as a treatment for anorexia nervosa: a pilot study

Acronym
Panorexia V1

Study objectives
The primary aim of this study is to assess the acceptability and efficacy of treating anorexia nervosa with psilocybin. The secondary aim of this study is to use Magnetic Resonance Imaging

(MRI) and Electroencephalography (EEG) to examine the neuronal underpinnings of treatment with psilocybin in this patient group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/06/2020, Brent Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8129; brent.rec@hra.nhs.uk), ref: 20/LO/0474

Primary study design
Interventional

Study design
Feasibility/pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anorexia nervosa

Interventions
Current interventions as of 09/02/2021:

We will recruit 20 participants for this trial. Eligibility will be principally determined by the study psychiatrist. Supporting information from relevant mental health professionals and/or general practitioners will be sought prior to entry into the trial to confirm diagnosis and ensure that all participants meet the inclusion criteria.
The study will involve 9 visits to the Clinical Research Facility (CRF) at Imperial College London. Following screening (visit 1), the time from baseline visit (visit 2) to primary endpoint (visit 9) will be six weeks. The 9 study visits will involve three psilocybin dosing days (visits 3, 5, and 7). Dosing sessions involve psychological support which has 3 components: 1) Preparation: getting to know the participant, building trust, and informing them on what to expect from the experience, 2) Supervision: being physically and emotionally present for the participant before, during and after the dosing session, 3) Integration: non-judgmental, compassionate listening to the participant's experience, enabling them to contextualize and assimilate their experience. In addition to an in-person preparation session before the first dosing session (visit 2), preparation before the second and third dosing sessions can either be in-person, or remotely via phone /Skype/Zoom, depending on each participant's preferences. Each dosing session will be followed by an in-person integration session (visits 4, 6, and 8). The final visit will be a final follow-up (visit 9). The baseline day (visit 2) and follow-up day (visit 9) will include a magnetic resonance imaging (MRI) scan, while electroencephalography (EEG) will be included at baseline, follow-up, and on integration days. Participants will be asked to complete questionnaires throughout the process. There will also be an extended follow-up period of 12 months, which will include a follow-up interview at 6 months.
The next-of-kin study:

We will also ask participants' significant others/next-of-kin for ratings of the patient's eating disorder symptoms both via brief questionnaires and a semi-structured interview. The

questionnaire will be sent to participants via email both before the trial begins (ie., between visits 1 and 2) and 2 weeks after the final dose session (i.e., corresponding to visit 9). The interview will be performed approximately 2 weeks after the final dose session, at the same time as the questionnaire is completed. Participants and their next-of-kin will be made aware that although contact with the next-of-kin is required as part of the trial, participation in the next-of-kin study (i.e., the questionnaire and interview) are not.

Measure time points:
Screening (visit 1)(+ no set time)
Baseline/preparation day 1 (visit 2) (Remote measures emailed 1 week prior to baseline visit)
Dosing day 1 (visit 3)
Integration day 1 (visit 4)
Preparation day 2 (optional in-person, expected remote)
Dosing day 2 (visit 5)
Integration day 2 (visit 6)
Preparation day 3 (optional in-person, expected remote)
Dosing day 3 (visit 7)
Integration day 3 (visit 8)
Primary endpoint (visit 9)
Monthly for 6 months (primary endpoint + 6 months)
12 month (+ 6 months)

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Previous interventions:

This study involves three doses of psilocybin (up to 25 mg [actual doses not given here to ensure blinding]) in up to 20 completing patients who have had a primary diagnosis of anorexia nervosa for more than 3 years, and have found other past or current treatments ineffective. 'Completion' is defined as completion of the final follow-up visit/primary endpoint. The study will involve 9 visits to the Clinical Research Facility (CRF) at Imperial College London over a period of approximately 10-12 weeks. Following screening (visit 1), the time from baseline (visit 2) to primary endpoint (visit 9) will be six weeks. There will also be an extended follow-up period of 12 months.

Screening (+ no set time)
Baseline (day 0 – remote questionnaires emailed 1 week prior to preparation day 1)
Preparation day 1 (day 1), dosing day 1 (day 2), post-dosing 1 (day 2), integration day 1 (day 3)
Weekly 1 (day 9)
Preparation (day 15), dosing day 2, (day 16), post-dosing 2 (day 16), integration day 2 (day 17)
Weekly 2 (day 23)
Preparation day 3 (day 29), dosing day 3 (day 30), post-dosing 3 (day 30), integration day 3 (day 31)
Weekly 3 (day 37)
6-week follow-up (day 44)
1 month (day 58), 2 month (+1 month), 3 month (+1 month), 4 month (+1 month), 5 month (+1 month), 6 month (+1 month), 12 month (+6 months).

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Psilocybin

Primary outcome(s)
Current primary outcome measure as of 09/02/2021:

Primary psychological outcome measures:
1. Readiness and Motivation Questionnaire (RMQ). There will be an increase in readiness and motivation to recover from preparation day 1 (visit 2) to the primary endpoint (visit 9), which will be related to long-term improvements in psychopathology measured using the EDE and EDE-Q (6-month)
2. Eating Disorder Examination (EDE) and Eating Disorder Examination Questionnaire (EDE-Q). There will be a decrease in eating disorder psychopathology from preparation day 1 (visit 2) to the primary endpoint (visit 9), and continued improvements to 6 months

Primary imaging outcome measures:
1. Functional Magnetic Resonance Imaging (fMRI). There will be changes in blood oxygen level dependent (BOLD) signal during rest and disorder relevant tasks between preparation day 1 (visit 2) and the primary end point (visit 9)
2. Electroencephalography (EEG). There will be electrophysiological changes during rest both post-acutely (visits 3 & 5) and between preparation day 1 (visit 2) and the primary endpoint (visit 9)

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Previous primary outcome measure:

1. Readiness and motivation to recover measured using the Readiness and Motivation Questionnaire (RMQ) at baseline and 6 weeks
2. Decrease in eating disorder psychopathology measured using Eating Disorder Examination (EDE) at baseline, 6 weeks and 6 months

Key secondary outcome(s)
Current secondary outcome measures as of 09/02/2021:

1. Eating disorder psychopathology is measured using:
1.1. The Yale-Brown Cornell Eating Disorder Scale (Y-BCEDS) at baseline and the primary endpoint.
1.2. The Pros and Cons of Anorexia scale (P-CAN) at baseline, preparation day 1, preparation day 2, preparation day 3, the primary endpoint, then monthly up to 6 months after the primary endpoint, then again at 12 months.
2. Relaxed beliefs are measured using the (Relaxed) Embodied Beliefs Questionnaire ((R)EB-Q) at preparation day 1, dosing day 1, preparation day 2, dosing day 2, preparation day 3, dosing day 3, and the primary endpoint.
3. Adverse childhood experiences are documented using the Adverse Childhood Experience Questionnaire (ACE) baseline.
4. The participants' definitions of recovery are assessed using the Recovery Interview at baseline and the primary endpoint.
5. The clinical impairment caused by the eating disorder is measured using the Clinical

Impairment Assessment (CIA) at baseline, the primary endpoint, then monthly up to 6 months after the primary endpoint, then again at 12 months.
6. Rumination is measured using the Rumination Response Scale for Eating Disorders (RRS-ED) at baseline and the primary endpoint.
7. Psychological well-being is measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at baseline, preparation day 2, preparation day 3, and the primary endpoint.
8. Trait anxiety is measured using the State-Trait Anxiety Inventory Trait subscale (STAI-T) at baseline and the primary endpoint.
9. State anxiety is measured using the State-Trait Anxiety Inventory State subscale (STAI-S) at dosing day 1, dosing day 2, and dosing day 3.
10. Depressive symptoms are measured using the Quick Inventory of Depressive Symptomology (QIDS-16) at screening, then weekly from the baseline until the primary endpoint, then monthly up to 6 months after the primary endpoint, then again at 12 months.
11. Absorption is measured using the Modified Tellegen Absorption Questionnaire (MODTAS) at baseline and the primary endpoint.
12. Expectations are measured using the Credibility/Expectancy Questionnaire at baseline.
13. Psychological insight is measured using the Psychological Insight Scale (PIS) at dosing day 1, dosing day 2, dosing day 3, and the primary endpoint.
14. Absorption in music is measured using selected items from the Absorption in Music Scale (AIMS) at baseline and the primary endpoint.
15. Tolerance to uncertainty is measured using the Intolerance of Uncertainty Scale at baseline and the primary endpoint.
16. Social and environmental connectedness is measured using the Watts Connectedness Scale at baseline and the primary endpoint.
17. Experiential avoidance is measured using the Brief Experiential Avoidance Questionnaire (b-EAQ) at baseline, integration day 1, integration day 2, integration day 3, and then primary endpoint.
18. Eating habits are documented using the Eating Habits Questionnaire weekly from baseline until one week after the last dosing day.
19. Psychological flexibility is measured using the short form Multidimensional Psychological Flexibility Inventory (MPFI) at baseline, preparation day 2, preparation day 3, and the primary endpoint.
20. Sexual perceptions are measured using the 2-item Sexual Perceptions Questionnaire (SPQ) at baseline and the primary endpoint.
21. Openness is measured using selected items from the 44-item Big Five Inventory (BFI) at baseline and primary endpoint.
22. The impact of the psychedelic experience on participants' lives is measured using the Centrality of Events Scale (short version) at the primary endpoint, and then monthly up to 6 months after the primary endpoint, then again at 12 months.
23. The ability of participants to make sense of and integrate their psychedelic experience is measured using the 3-Item Meaning Making Questionnaire at the primary endpoint, then monthly up to 6 months after the primary endpoint, then again at 12 months.
24. The importance of the preparation and integration sessions in gaining the most from the psychedelic experience is measured using the 1-item Assessing Experience Questionnaire at the primary endpoint.
25. The impact of the eating disorder on embodiment and identity is measured using the Identity and Eating Disorders Questionnaire (IDEA) at baseline, the primary endpoint, then monthly up to 6 months after the primary endpoint, then again at 12 months.
26. Integration of the psychedelic experience is measured using the Multifaceted Psychological Integration Assessment (M-PIA) at integration day 1, integration day 2, integration day 3, the primary endpoint, then monthly up to 6 months after the primary endpoint, then again at 12 months.

27. The suggestibility of participants is measured using the Short-Suggestibility Scale (SSS) at baseline.
28. Self-compassion is measured using the Self-Compassion Scale (SCS) at baseline, preparation day 2, preparation day 3, the primary endpoint, then monthly up to 6 months after the primary endpoint, then again at 12 months.
29. Self-compassion and the experience of receiving compassion from others is measured using the Self-Compassion and Compassion from others subscales of the Compassionate Engagement and Action Scale at baseline, preparation day 2, preparation day 3, and the primary endpoint.
30. Interoceptive awareness is measured using The Multidimensional Assessment of Interoceptive Awareness (MAIA) at baseline and the primary endpoint.
31. Cognitive flexibility is measured using the Cognitive Flexibility Scale (CFS) at baseline, preparation day 2, preparation day 3, the primary endpoint, then monthly up to 6 months after the primary endpoint, then again at 12 months.
32. Self-criticism is measured using the Function of Self-Criticising/Attacking Scale (FSCS) at baseline and the primary endpoint.
33. Embodiment is measured using the Experience of Embodiment Scale (EES) at baseline, preparation day 2, preparation day 3, the primary endpoint, then monthly up to 6 months after the primary endpoint, then again at 12 months.
34. The set and setting before the psychedelic experience is documented using The Psychedelic Predictor Scale at dosing day 1, dosing day 2, and dosing day 3.
35. The occurrence of a mystical-type experience during the experience is measured using the Mystical Experience Questionnaire (MEQ) at dosing day 1, dosing day 2, and dosing day 3.
36. The occurrence of altered states of consciousness during the experience are measured using the 11 Dimension Altered States of Consciousness Scale (11D ASC) at dosing day 1, dosing day 2, and dosing day 3.
37. The occurrence of a challenging experience during the experience is measured using the Challenging Experience Questionnaire (CEQ) at dosing day 1, dosing day 2, and dosing day 3.
38. The occurrence of an emotional breakthrough during the experience is measured using the Emotional Breakthrough Inventory (EBI) at dosing day 1, dosing day 2, and dosing day 3.
39. The ability of participants to zoom out during the experience is measured using the Imperial Overview Item at dosing day 1, dosing day 2, and dosing day 3.
40. The setting of the experience is assessed using the Setting Questionnaire (SQ) at dosing day 1, dosing day 2, and dosing day 3.
41. The relationship of the participants with their therapy team is assessed using the Scale to Assess the Therapeutic Relationship (STAR) at preparation day 1, preparation day 2, and preparation day 3.
42. Acute embodiment during the experience is measured using the Acute Embodiment Questionnaire (AEQ) at dosing day 1, dosing day 2, and dosing day 3.
43. Subjective body sensations during the experience are measured using the State of Mindfulness Scale Body subscale (SMS-Body) at dosing day 1, dosing day 2, and dosing day 3.
44. The participants' experiences of the music during the experience are measured using the Psychedelic Music Questionnaire (PMQ) at dosing day 1, dosing day 2, and dosing day 3.
Secondary behavioural outcome measures
45. Preferences for different foods are assessed using the Leeds-Oxford Food Preference Task at baseline, preparation day 2, preparation day 3 and the primary endpoint.
46. Cognitive flexibility is assessed using:
46.1. The Trail Making Task (TMT) at preparation days and the primary endpoint.
46.2 The Wisconsin Card Sorting Task (WCST) at preparation days and the primary endpoint.

Secondary imaging outcome measures
EEG
47. Visual Long-Term Potentiation (LTP) will be measured on integration days.

MRI
48. Structural changes (morphometry, cortical thickness and diffusion imaging) are measured using MRI at baseline, integration day 1, integration day 2, integration day 3, and the primary endpoint.

Previous secondary outcome measures:

Changes in blood oxygen level dependent (BOLD) signal during rest and disorder relevant tasks measured using Functional Magnetic Resonance Imaging (fMRI) at baseline and 6 weeks

Completion date
12/06/2024

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/11/2022:

1. DSM-V primary diagnosis of Anorexia Nervosa
2. Current diagnosis of Anorexia Nervosa, established by specialist eating disorder care team to have likely been present for >3 years
3. Current or past treatments have not been successful to maintain remission
4. 21 - 65 years old
5. Female
6. Be in the care of a specialist eating disorder team in the UK
7. Have a GP and/or specialist eating disorder team in the UK who can confirm diagnosis
8. Sufficiently competent in English and mental capacity to provide written informed consent
9. BMI >14kg/m² and medically stable
10. Capacity to consent
11. Agree to have us maintain contact with an identified next-of-kin for the duration of the study
12. Agree to have us maintain contact with their specialist eating disorder team/care team as required for the duration of the study

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Previous inclusion criteria:

1. DSM-V diagnosis of Anorexia Nervosa
2. >3 years of illness diagnosis
3. Current or past treatments have not been successful to maintain remission
4. 21 - 65 years old
5. Female
6. Be in the care of a specialist eating disorder team in the UK
7. Have a GP and/or specialist eating disorder team in the UK who can confirm diagnosis
8. Sufficiently competent in English and mental capacity to provide written informed consent
9. BMI >15kg/m² and medically stable
10. Capacity to consent

11. Agree to have us maintain contact with an identified next-of-kin for the duration of the study
12. Agree to have us maintain contact with their specialist eating disorder team/care team as required for the duration of the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
21

Key exclusion criteria
1. Current or previously diagnosed psychotic disorder
2. Immediate family member with a diagnosed psychotic disorder
3. Unstable physical condition e.g., rapid weight loss > 2kg in the prior month
4. Abnormal serum electrolytes, raised cardiac enzymes, hepatic or renal dysfunction
5. Medical condition that is unsuitable for the EEG components of the study (e.g., epilepsy, severe migraine)
6. Other physical conditions that are unsuitable for the psychedelic component of the study (e.g., diabetes, epilepsy, severe cardiovascular disease, hepatic or renal failure e.g., CrCl < 30ml/min etc.)
7. MRI contraindications
8. Have a history of laxative abuse in the last 3 months (defined as laxative use more than twice a week for 3 months)
9. History of serious suicide attempts or presence of a suicide/ serious self-harm risk at screening
10. Currently an involuntary patient
11. Significant history of mania (determined by study psychiatrist and medical records)
12. Emotionally unstable personality, or other psychiatric problem that the screening clinician feels may jeopardize the therapeutic alliance and/or safe exposure to psilocybin
13. Blood or needle phobia
14. Positive pregnancy test at screening or during the study, or woman who are breastfeeding
15. If sexually active, participants who lack appropriate contraceptive measures
16. Drug or alcohol dependence within the last 6 months
17. No email access
18. Patients presenting with abnormal QT interval prolongation at screening or with a history of this (QTc at screening above 470ms)
19. Patients who are currently, or have recently (within 6 months) been enrolled in another CTIMP

Date of first enrolment
15/04/2021

Date of final enrolment

01/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College Healthcare Trust Clinical Research Facility
Hammersmith Hospital
Du Cane Rd
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W12 0HS

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research organisation

Funder Name
The founders of the Centre for Psychedelic Research

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/07/2026	08/07/2026	Yes	No
Protocol article		20/10/2021	13/01/2022	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes