



# (Psi)locybin in (De)pression (R)esistant to standard treatments: a randomised, placebo controlled trial

## Information for **CLINICIANS**

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### Treatment Resistant Depression

Major depressive disorder is common, costly and disabling. About 30% of people with depression are 'treatment resistant' (unimproved despite  $\geq 2$  medical/psychological therapies). Others recover incompletely, suffer unacceptable side effects or are dissatisfied with daily psychotropic medication. Those who are treatment resistant are at higher risk of suicide and long-term disability, so trials of alternative treatments are needed.

### Psilocybin with Psychological Support

Psilocybin is the active component of so-called 'magic' mushrooms. It has a long history of use in non-medical settings and was a licensed medicine prior to 1970. It is physiologically non-toxic relative to other drugs. Pilot research in the UK, Europe and the US suggest that psilocybin given in a supportive setting may lead to long-term positive changes in mood for some people with TRD, but this pilot research needs to be followed up with randomised, placebo-controlled research. This trial aims to do this.

### Trial Details

Chief Investigator: **Prof Allan Young**  
Principal Investigator: **Dr James Rucker**  
Research Assistant: **Tim Mantingh**  
Sample size: **60** participants  
Trial type: **RCT** Funder: **NIHR**  
Trial start: **late 2019** Trial end: **late 2022**  
Location: **King's College Hospital Clinical Research Facility, Denmark Hill, London, SE5 9RS**

EudraCT: 2018-003573-97

### Inclusion Criteria

- ✓ Current diagnosis of major depressive disorder
- ✓ Currently moderately-severely depressed
- ✓ Have failed 1 or more antidepressants and/or NICE recommended psychological therapy
- ✓ Aged between 25 and 80
- ✓ Willing to stop current medical treatments for depression
- ✓ Willing and able to consent
- ✓ Willing to complete assessments and complete study visits

### Exclusion Criteria

- ✗ Bipolar disorder or prolonged psychotic episodes
- ✗ Severe personality disorder
- ✗ Current drug/alcohol misuse
- ✗ A history of serious violence towards others
- ✗ A serious suicide attempt in the past year
- ✗ Serious medical comorbidities
- ✗ Pregnant, lactating or planning to conceive children (male or female)

### Refer/Get Involved

For more information, please refer overleaf. To refer participants or if you are interested to help the study team then email us:

[psilocybin@kcl.ac.uk](mailto:psilocybin@kcl.ac.uk)

or visit

<http://psider.info>



## PsiDeR Trial Description

We are recruiting up to 60 adult participants with treatment resistant depression to take part in a randomised, double blind, placebo-controlled trial of up to 2 doses of psilocybin given in a supportive hospital setting at King's College Hospital. Psychological and psychiatric support will be given before, during and after treatment.

Current depression treatments will be tapered off by a study psychiatrist prior to treatment. During this time participants will be given psychoeducation and meet a therapist who will support them through the trial.

Initially, participants will receive a single dose of either psilocybin or placebo given at the Clinical Trials Facility at King's College Hospital. Participants will return home after treatment. Follow up will be for 6 weeks with telephone and face to face meetings. We will also ask participants to have a brain scan, perform cognitive tests and donate blood samples before and after treatment. After 6 weeks of follow up all participants will be offered a further, open label dose of 25mg of psilocybin (unless there is a clinical reason not to), with a further 3 months of follow up.

**Please note** that most people who volunteer for this study will, for one reason or another, turn out not to be eligible. The study team reserve the right to exclude participants who we do not feel can be safely exposed to

this experimental treatment. **FINAL ELIGIBILITY IS NOT CONFIRMED UNTIL THE TREATMENT VISIT.**

We cannot accept participants who:

- Are desperate to receive psilocybin
- Are likely to deteriorate if they are on a waiting list
- Are a high risk to themselves or others
- Have ongoing drug and alcohol problems
- Are homeless or socially unstable
- Don't have a social support network
- Can't easily get to the hospital
- Are looking for a 'quick fix' for their depression. This is not how this treatment works.

Those who may be suitable include:

- Those who have responded incompletely to medical or psychological treatment for depression, discontinued due to unacceptable side effects (or both).
- Those who appear psychologically 'stuck' in psychotherapy or unable to process a difficult or traumatic life event despite adequate support.
- Those who want to receive psilocybin therapy.

All appointments will take place at King's College Hospital during usual office hours. We will pay reasonable travel expenses but cannot fund hotel accommodation or other expenses. Participants will not be paid for participation in this trial. All referrers will be participation. We are unable to provide crisis services.

## Schedule of Visits

| Visit                                  | 1   | 2                   | 3               | 4                 | 5                   | 6                 | 7                 | (8)                            |
|--|---|---------------------|-----------------|-------------------|---------------------|-------------------|-------------------|--------------------------------|
| <b>Description</b>                     | Screening Visit                               | Baseline Visit      | Treatment Visit | Follow Up Visit 1 | Follow Up Visit 2   | Follow Up Visit 3 | Follow Up Visit 4 | (Open Label Extension)         |
| <b>Time</b>                            | 1-8 weeks                                     |                     | 1 day           | 6 weeks           |                     |                   |                   | (12 weeks)                     |
| <b>Location</b>                        | King's College Hospital, Denmark Hill, London |                     |                 |                   |                     |                   |                   |                                |
| <b>Length of Visit</b>                 | 4 hours                                       | 4-6 hours           | 8 hours         | 4 hours           | 4-6 hours           | 4 hours           | 2 hours           | (Variable)                     |
| <b>Optional Activities (see below)</b> | Mobile Phone Data                             | Brain Scan & Bloods | None            | Bloods            | Brain Scan & Bloods | Bloods            | Bloods            | (Further psilocybin treatment) |

Table 1: Schedule of Visits. KCH CRF = King's College Hospital Clinical Research Facility