Clinical Trial of Low Dose Psilocybin for MDD

Principal Investigators: Dr Vince Polito & Dr Jonathan Brett

This clinical trial is investigating the use of low doses of psilocybin to treat major depressive disorder of moderate severity. A number of recent studies investigating psilocybin for the treatment of major depressive disorder have shown promising results. Large doses of psilocybin have been associated with rapid and sustained decreases in a variety of depressive symptoms and improvements in quality-of-life ratings. There is also preliminary evidence that the practice of microdosing psilocybin (regular administration of sub-hallucinogenic doses over a sustained period) may improve mood and reduce symptoms of depression. We hope to add to this scientific literature by investigating the safety, feasibility and efficacy of low doses of psilocybin in a double-blind randomised control trial. Participants will undergo comprehensive psychiatric screening, and, if eligible, will take part in a 6-week intervention with two doses of psilocybin each week. The dose range we are investigating (2-4mg) is sub-hallucinogenic and participants are not expected to notice any marked alterations in their conscious state. There will be the option for those in the placebo group to receive the treatment if clinical efficacy is demonstrated.

Why do we need your help with participants?

Your expertise will help us identify patients that are best suited to participate. We can enrol individuals with a primary mental health diagnosis of moderate depression, who are not currently taking antidepressants or antipsychotic medications. We hope to recruit 266 participants and would value your assistance in identifying potential participants.

What are the risks to your patients?

Psilocybin is a safe, nontoxic drug that is not associated with dependence, overdose or long-term physiological or psychological harm. We are investigating non-hallucinogenic doses and participants are unlikely to experience any psychedelic effects. In recent trials using large doses of psilocybin, some acute adverse effects have been recorded but these are generally transient and not severe in nature. These include anxiety, distress, impaired cognition, nausea, appetite loss, abdominal pain and elevated heart rate. However, we propose using doses roughly 5-10x lower than a standard clinical dose, so we expect minimal adverse events. Participants will have access to qualified medical professionals, including oversight by a psychiatrist, for the duration of the trial.

How do you refer patients?

If you wish to refer a patient, please send a brief referral confirming that the patient meets the eligibility criteria and any additional details on medical or mental health history to any of the contact details listed. Participants are also able to self-refer and you are welcome to share this trial information with potential patients. Patients will be asked to nominate their regular treating GP or psychiatrist when enrolling.

Who should you refer?

Key Inclusion Criteria:

- Major depressive disorder of moderate severity
- Aged 18+
- Fluent in English
- Participants cannot drive on dosing days. We can organise rideshare transport within 20km of Macquarie University or can reimburse $100 per visit if driven by someone else.

Key Exclusion Criteria:

- No comorbid mental illness of greater severity than MDD
- No use of antidepressant or antipsychotic medication in past 3 months
- No moderate to severe suicidal ideation in past 12 months
- No history of psychosis, bipolar disorder, stroke or epilepsy
- No 1st degree relative with psychosis

To make a referral, or for more information, please contact:

MicroDep Trial
Clinical Trials Unit,
Level 3, 75 Talavera Rd,
Macquarie University,
2109

Email: microdep@mq.edu.au
Phone: (02) 7230 1367
Fax: (02) 9850 5747