Clinical Trial of Low Dose Psilocybin for MDD

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We are seeking participants for a clinical trial is investigating the use of low doses of psilocybin to treat moderate depression. Psilocybin is a naturally occurring compound found in a variety of psychedelic fungi often referred to as 'magic mushrooms'. There is 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 is sub-hallucinogenic and participants are not expected to notice any marked alterations in their conscious state. In other words, the doses we are investigating will not lead to typical psychedelic effects. There will be an option for those in the placebo group to also receive the treatment if clinical efficacy is demonstrated.

What is involved?

Once you have completed a screening procedure, you will commit to a 10-week intervention, comprised of 6 weeks of drug treatment (dosing twice each week), and then additional follow-up visits after 1 week and 1 month. During these visits you will complete various assessments to monitor your progress. We are unable to provide monetary reimbursement for participation in this trial, but we are able to cover all travel expenses and provide some meals. Moreover, you will be making a valuable contribution to the development of effective treatment for depression.

What are the risks?

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 I get involved?

If you believe you are eligible for this trial and would like to participate, please email us. We will send you a survey asking for your medical history. You will also need to provide details of your regular treating GP or psychiatrist.

Who can participate?

Key Inclusion Criteria:

- Major depressive disorder of moderate severity
- Aged 18+
- Fluent in English
- Must not drive yourself to the trial site. We can organise rideshare transport for you if you live within 20km of Macquarie University or can reimburse you $100 per visit if you are 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

For more information, please contact:

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