Clinical Trials Unit
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Dear Mental Health Provider,

We are currently recruiting participants diagnosed with major depressive disorder to take part in the MicroDep Trial, **a randomised, placebo controlled and double-blind study assessing the safety, feasibility and efficacy of low-dose psilocybin**. We seek your assistance in identifying potential participants.

Psilocybin is a naturally occurring compound found in a variety of psychedelic fungi often referred to as 'magic mushrooms'. Emerging evidence suggests that psilocybin can be an effective and long-lasting treatment for depression. Microdosing refers to the practice of regularly consuming sub-hallucinogenic doses of psychedelic substances (for psilocybin, typically 1.5 – 5mg). **At this dose individuals do experience significant alterations to their state of consciousness. Some individuals do not notice any subjective effects at all**. Some notice minor changes in emotions, attention and perception. Individuals typically report being able to continue with their regular day to day activities following a microdose. **Studies show compelling evidence that administration of psychedelics in the microdose range can impact cognition in ways that are likely to have clinical benefits, in particular improved mood and reductions in depressive symptoms**. With the MicroDep Trial we hope to add to this scientific literature by investigating the safety, feasibility and efficacy of low-dose psilocybin in treating moderate depression.

All participants in the trial will undergo thorough screening by a psychiatrist, and if deemed eligible, will be enrolled in a six week intervention, consisting of 11 dosing sessions. Participants in the active drug condition will receive 4mg of synthetic psilocybin and will be monitored following each dose by a psychiatrist. There is the option to titrate the dose down if necessary. After the main intervention phase of the project is complete, participants in the placebo condition will be given the option to access the active drug intervention in an open-label extension if is there evidence of clinical efficacy.

To be eligible for the study, participants must meet the following criteria:

- Participant has a clinician's diagnosis of major depressive disorder and depression is of moderate severity.
- Depression must be the primary diagnosis. Participants with other, more severe, co-morbid mental illnesses will not be eligible.
- Participant must not have used any psychotropic medication in the prior 3 months, or plans to start new medication in the upcoming 2 months.
- Participant is aged 18+.
- Participant is fluent in English.
- Participant has not experienced moderate or severe suicidal ideation in the previous 12 months.
- Participant must not have a history of psychosis, bipolar disorder, stroke or epilepsy.
- Participant must not have a first degree relative with psychotic disorder.
- Participant must live within 40 minutes drive of Macquarie University (we will provide transport for all trial visits).

If you believe you have a patient that might be suitable for such a trial, please either refer them to us via the contact details below or inform them of the trial for them to contact us if they wish. While a doctor's referral is not necessary to participate in the trial, we will ask potential participants for the details of their regular treating medical doctor.

We would like to emphasise that we can only accept **unmedicated individuals with moderate levels of depression, without any more severe comorbid diagnoses**. If you have any questions, please get in touch, we are very happy to provide additional information to health practitioners. Thank you for your consideration of this trial.

To make a referral or enquiry, or to request trial information, background research or literature, contact:

Email: microdep@mq.edu.au

Phone: (02) 9812 2958

Fax: (02) 9850 5747

We look forward to working with you and thank you for your assistance.

Sincerely,

Dr Vince Polito
Principal Investigator, MicroDep Trial
Clinical Trials Unit, Macquarie University