

## **Psilocybin-assisted Psychotherapy for Methamphetamine use disorder: Recruitment to a novel safety and feasibility trial**

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**Introduction / Issues:** Treatments for Methamphetamine Use Disorder (MAUD) demonstrate modest effectiveness, leaving a requirement for novel, efficacious treatment approaches. Psilocybin-assisted psychotherapy (PP) has shown promising initial results in treating a number of substance use disorders (SUD), but has yet to be trialed for MAUD. This pilot study ("PsiMA") aims to determine if such treatment is safe and feasible for delivery within this population.

**Method / Approach:** Participants (n=15) will be recruited for this open-label, single-arm study consisting of three preparatory psychotherapy sessions, one dose day using 25mg of psilocybin, and two integration psychotherapy sessions. Participants must meet criteria for MAUD, consume methamphetamine less than 16 days per month and be otherwise healthy with no history of psychotic disorders. The primary outcomes of safety and feasibility will be measured through clinical observation, monitoring of vital signs, and mental health and wellbeing throughout screening, intervention delivery, and 3-months of follow up assessments.

**Results:** As at May 2023, 26 individuals have been pre-screened, five of whom met eligibility criteria and were enrolled in the study. Four participants have completed the intervention protocol and two have completed the study to 90-day follow up. All those who began the intervention completed it, with no serious adverse events recorded or withdrawals due to adverse events.

**Discussions and Conclusions:** The PsiMA study will add to the research exploring the use of PP in treatment of SUD, and provide safety and feasibility data for its use within MAUD. Future research will need to consider recruitment issues alongside growing understanding of safety profiles within this population.

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