

A study protocol for the PsiMA trial: Psilocybin assisted Psychotherapy for Methamphetamine use disorder.

ELIZABETH KNOCK^{1,2}, NADINE EZARD^{1,2,3}, RIC DAY^{1,3}, KRISTA J SIEFRIED^{1,2,4}, PAUL LIKNAITZKY^{5,6}, MARG ROSS⁶, STEVE ALBERT³, JONATHAN BRETT¹

¹St Vincent's Hospital Sydney, ²National Centre for Clinical Research on Emerging Drugs (NCCRED), ³University of NSW, ⁴The National Drug and Alcohol Research Centre (NDARC) ⁵Deakin University, ⁶St Vincent's Hospital Melbourne

Presenter's email: <Elizabeth.knock@svha.org.au>

Introduction and Aims:

Treatments for Methamphetamine use disorder (MAUD) demonstrate only 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, but has not yet been trialled for MAUD. The study aims to determine if such treatment is safe and feasible for delivery within this population.

Design and Methods:

Fifteen participants will be recruited from the Stimulant Treatment Program at St. Vincent's Hospital Sydney for this open-label, single-arm pilot study. Participants must be ≥ 25 years old, meet criteria for MAUD and consume methamphetamine less than 16 days per month. There are three preparatory psychotherapy sessions, one psilocybin 25mg oral dose day, and two integration psychotherapy sessions. The primary outcome of safety and feasibility will be measured through clinical observation, monitoring of vital signs and mental health and wellbeing at screening, during psychotherapy, throughout dose day and at all follow up points up to 3 months following psilocybin dosing. Measures include the Depression Anxiety and Stress Scale, Brief Psychiatric Rating Scale, suicidality screening, and measures of methamphetamine use. Semi-structured interviews will be completed pre and post PP.

Results: A team of counsellors have been trained in PP and recruitment is expected to begin in June 2022.

Discussions and Conclusions:

The PsiMA study will add to research exploring the use of PP in treatment of substance use disorders and inform future directions and approach to PP research. If found to be safe, the PsiMA study protocol will form a model for further studies investigating the efficacy of PP in treating MAUD.

Disclosure of Interest Statement: This research is funded through the National Centre for Clinical Research on Emerging Drugs (NCCRED). EK was the recipient of an NCCRED Clinical Research Scholarship 2020/21. No pharmaceutical grants were received in the development of this study.