<u>Psilocybin-assisted Psychotherapy for Methamphetamine use disorder: A novel</u> safety and feasibility trial

<u>ELIZABETH KNOCK</u>^{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 / Issues:

Treatments for Methamphetamine Use Disorder (MAUD) demonstrate modest effectiveness, leaving a requirement for novel, efficacious treatment approaches. Psilocybin-assisted psychotherapy (PAT) has shown promising initial results in treating a number of substance use disorders (SUD), but has yet to be trialled for MAUD. This pilot study aimed to determine if such treatment was safe and feasible for delivery within this population.

Method / Approach:

This was an open-label, single-arm study consisting of three preparatory psychotherapy sessions, one dose day using 25mg of psilocybin, and two integration psychotherapy sessions. Participants met criteria for MAUD and were otherwise healthy with no history of psychotic disorders. Feasibility was measured by number recruited and completing the intervention. Safety was the number of Adverse Events (AE's) by system organ class. Follow up was completed at 7,14, 28 and 90 days post psilocybin dose.

Results:

56 participants were pre-screened, 16 progressed to screening and 15 were eligible following all screening visits. 15 participants were enrolled in the study (12 male [80%] Median age 42 [Interquartile range 50-40] years) and began the intervention protocol and 14(93%) participants completed the intervention. Of those completing the intervention, 13(93%) completed follow up to 90 days. There were no treatment related serious adverse events (SAE) recorded. Of 27 AE's reported, 7 (26%) were potentially or probably related, all mild and all resolved.

Discussions and Conclusions:

The study adds to research exploring the use of Psilocybin-assisted psychotherapy in treatment of SUD. It is the first trial of PAT within MAUD and provides safety and feasibility data for its use within this population. Future research will need to further explore growing understanding of safety profiles. Randomised controlled trials are indicated to examine efficacy of this potential treatment.

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