

Through the looking glass: Translating clinical trial experience with MDMA and psilocybin-assisted psychotherapies to real world applications

Authors:

Stephen J. Bright^{1,2}, Petra Skeffington³, Anisha Balchand⁴, Sean Hood⁴

¹School of Medical and Health Sciences, Edith Cowan University, Perth, Australia,

²Psychedelic Research In Science & Medicine Ltd., Melbourne, Australia, ³School of Psychology, Murdoch University, Perth, Australia, ⁴School of Medicine, University of Western Australia, Perth, Australia.

Presenter's email: s.bright@ecu.edu.au

Background: In 2023, Australia became the first country in the world to legislate MDMA and psilocybin as medicines. Prior to this, we commenced Australia's first clinical trial of MDMA-assisted psychotherapy, and Western Australia's first clinical trial of psilocybin-assisted psychotherapy.

Description of Model of Care/Intervention: MDMA- and psilocybin-assisted are each distinct psychotherapies with separate indications and contraindications. They are more time intense than traditional psychotherapies and typically involve two psychotherapists working together as a co-therapy team. Unlike traditional psychotherapies, because the treatments involve the concurrent administration of Schedule 8 medicines, they require seamless collaboration between psychological and medical services. This additional medical governance and hours of therapist time make the treatment very expensive for consumers to access outside of clinical research.

Effectiveness/Acceptability/Implementation: The effectiveness of these treatments has likely been overestimated due to methodological issues, including expectancy effects, difficulties maintaining blinding, highly selected trial samples, and the confounding contribution of intensive psychotherapy. Our participants identified a number of barriers to real-world implementation including the intensity of the psychotherapy, weaning off contraindicated medications, unrealistic expectations and the rigidity of the protocol.

Conclusion and Next Steps: Translation of psychedelic-assisted psychotherapy into routine care requires adaptation of trial protocols to improve scalability while maintaining safety and therapeutic integrity. Future work should focus on developing sustainable service delivery models, refining patient selection processes, and evaluating alternative workforce and governance structures to improve accessibility.

Implications on communities, practice, policy and/or First Nations communities: Our research highlight the need for cautious implementation of psychedelic-assisted psychotherapy within Australia's emerging regulatory framework. Policy and practice should prioritise equitable access, clinician training standards, robust governance structures, and realistic communication regarding treatment efficacy to avoid hype.

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