

Psychedelic medicine and cultural responsiveness: A call for Aboriginal and Torres Strait Islander engagement in Australian clinical trials and practice

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Since the mid-2000s, there has been a resurgence of interest in psychedelics for treatment of mental health conditions.¹ Whilst often described as ‘new and innovative,’ psychedelics have been a part of Indigenous cultural practices globally since time immemorial.^{2,3} Indigenous plant medicine use is often not restricted to mental health treatment, but typically has a far broader application, such as for hunting and divination.^{4–6} The interest in psychedelics in Western medicine and research raises concerns for Indigenous Peoples globally, including the endangerment of plant species through psychedelic tourism, cultural appropriation of spiritual practices and the lack of inclusion of Indigenous Peoples in clinical research and new legal prescribing pathways.^{3,4,7}

Celidwen and colleagues³ have developed ethical principles to guide Western psychedelic research and practice, highlighting the importance of reparation, consultation and inclusion, and Indigenous knowledge systems. To date, there has been a lack of consultation and diversity in both therapists and participants, as the majority of

psychedelic clinical trials do not involve Indigenous Peoples or have protocols that are designed with cultural safety at the forefront.⁸ Therefore, as psychedelic medicine enters the Western medical system in Australia via the numerous clinical trials with various psychedelic compounds, and the re-scheduling of 3,4-methylenedioxymethamphetamine (MDMA) and psilocybin by the Therapeutic Goods Administration, it is imperative that Aboriginal and Torres Strait Islander Peoples are included in the ethical development and clinical use of psychedelic medicines in Western clinical practice.

Whilst the guidelines by Celidwen et al.³ focus on Indigenous Peoples of the Americas, there is limited literature in the Australian context. The Victorian government strategic consultation paper⁹ explores a broad set of principles and strategic priorities to facilitate greater self-determination for Traditional Owners in the Native Foods and Botanicals Industry. Aboriginal and Torres Strait Islander Peoples have over 65,000 years of knowledge as the experts in being in ‘right relationship’ with the land, waters, ancestral wisdom and their plant

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kin due to their long-established connection to these plants and fungi. This relationship is perceived as sacred, via their working with plant medicines within a spiritual context. We regard that, where possible and appropriate, there is collaboration with Aboriginal and Torres Strait Islander Elders and community members prior to engaging in clinical psychedelic use to establish appropriate acknowledgement of traditional knowledge keepers and legal safeguards protecting intellectual property and misappropriation of traditional practices and substances. Further, from an Indigenous perspective, the unsafe use of psychedelic medicine can have a detrimental impact on the land or 'Country', including the species of flora, when psychedelic medicine is practiced in the absence of a 'sacred space' and appropriate protective energy clearing practices. Aboriginal and Torres Strait Islander Peoples have a right and responsibility to respond to what is happening on their traditional lands, especially where there is the potential for harm. This collaborative paradigm shift is recommended as a source of positive overlap of the Western medical model and Aboriginal and Torres Strait Islander cultures to benefit all participants in clinical trials.

The emergence of psychedelic-assisted psychotherapy brings awareness to the need to decolonise health care and promote health equity for Aboriginal and Torres Strait Islander Peoples in Australia. Despite significant research highlighting institutional and interpersonal racism as a barrier to healthcare access, the systemic issues created by Western healthcare system remain and are embedded within a eurocentric, biomedical model that does not consider the cultural and historical contexts that impact the social determinants of health and perpetuate culturally unsafe practices.¹⁰ Assumptions and implicit bias of non-Indigenous practitioners can impact their understandings of the ongoing impact of colonisation, intergenerational trauma and systemic racism impacting the wellbeing of Aboriginal and Torres Strait Islander Peoples. The majority of current psychedelic-assisted therapy protocols reflect the colonial individualism of Western psychiatry, with preparation, dosing and integration sessions happening on an individual basis between the participant and the therapist dyad.¹¹ In contrast, Indigenous worldviews generally consider the wellbeing of the collective as the wellbeing of the individual. Aboriginal and Torres Strait Islander health refers to the social, emotional and cultural wellbeing of the community where every individual can thrive and contribute to the wellbeing of their communities.¹² Therefore, healing happens within the context of community health and wellbeing, rather than the onus being solely on the individual. The Western individualistic approach risks pathologising the ongoing impact of colonisation experienced by Aboriginal and Torres Strait Islander Peoples and defining these impacts as individual deficits.¹³

To address the health disparities between Indigenous and non-Indigenous Australians, the Closing the Gap initiative recognises the importance of cultural safety in service delivery to improve social and emotional wellbeing of Aboriginal and Torres Strait Islander Peoples.¹⁴ Cultural safety is an essential component of mental health service delivery, and protocols for psychedelic-assisted therapy must adopt safer practices that are culturally responsive to the diverse Aboriginal and Torres Strait Islander communities. Recommendations from the Ways Forward: National Aboriginal and Torres Strait Islander Mental Health Policy Report¹⁵ recognises Indigenous perspectives on mental health as holistic and the importance of culturally valid understandings of health and mental health care, including access to

traditional healers and culturally informed healing practices, where spiritual beliefs and worldviews may be misinterpreted or inappropriately supported by non-Indigenous clinicians. The Transforming Indigenous Mental Health and Wellbeing (TIMHWB) program¹⁶ is an initiative working to increase cultural safety in mental health support through increased service access, cultural competency and improving cultural safety in mainstream clinical services through employment of cultural healers. The Psychotherapy and Counselling Association (PACFA) also has the College of Aboriginal and Torres Strait Islander Healing Practices that aims to support, develop and accredit Indigenous healing practice.¹⁷ The psychedelic-assisted therapy space is advised to make appropriate provisions for culturally responsive mental health care as psychedelics are integrated into the mental health treatment paradigm.

In Australia, there are three pathways by which psychedelics can presently be used: drug development clinical trials; investigator initiated clinical trials and clinical use when prescribed via an authorised prescriber. The approach to psychedelic-assisted therapy in all three pathways generally require a specific diagnosed condition, such as treatment-resistant depression, and for participants to complete screening surveys or clinical interviews that have not been standardised on Aboriginal and Torres Strait Islander populations and do not consider differences in Indigenous perspectives on mental health and culture-bound syndromes that may present as mental health disorders and require cultural support.¹⁸ Therefore, Aboriginal and Torres Strait Islander Peoples who have not received a clinical diagnosis under the Western medical paradigm and wish to access psychedelic-assisted psychotherapy through the Authorised Prescriber pathway are currently excluded. Further, participation in clinical trials where specific diagnostic criteria are applied during screening may not allow for cultural deviations in eligibility criteria. This condition-based focus is a function of the global drug development paradigm and regulatory framework typified by the Food and Drug Administration (FDA) requirements. Clinical studies that focus on drug development will be constrained by this system; however, investigator-initiated clinical trials and clinical use have much more flexibility in developing alternative protocols that are culturally responsive.

Presently, clinical research with psychedelics generally focuses on establishing optimal protocols regarding drug dosage, number of required administrations and accompanying psychotherapy sessions. The majority of protocols focus on the individual's history and intentions, rather than establishing a relationship with the medicine itself.¹¹ From an Indigenous perspective, preparation and building right-relationships with the psychedelic medicine may be of greater importance than the dosing session itself, with a lesser emphasis on establishing the 'right dose' and a greater emphasis on creating a relationship with the plant or fungi spirit, where the relationship with the spirit is the agent to facilitate healing.¹⁹ To enable greater participation in research and prescribed medical use, protocols should be established that are in line with Indigenous worldviews and perspectives on wellbeing, with Aboriginal and Torres Strait Islander Peoples forming part of expert reference groups for protocol and treatment model design, as all participants, both Indigenous and non-Indigenous may benefit from Indigenous perspectives across all phases of psychedelic-assisted therapy.

Therapist training is another prohibitive factor. Currently, most training programs and protocols require therapists to have specific

qualifications, such as in psychology, and registration with a governing body. Likewise, the FDA guidelines for clinical investigations with psychedelics drugs recommend that therapists be licensed in credentialed areas such as psychologists and psychiatrists.²⁰ This excludes Indigenous Peoples who may be trained in culturally-informed healing practices and have expertise in creating safe, contained spaces when working with botanical medicines, from participating in treating teams. This is despite Indigenous therapists being better positioned to serve the cultural needs of their communities, with histories of colonial violence and intergenerational trauma, than non-Indigenous therapists. This is particularly important if cultural themes emerge during the psychedelic journey that requires cultural support and integration. However, the eligibility requirements to enter psychedelic-assisted therapy trainings, such as registration with a regulatory body, and a minimum number of years of professional practice, may prevent Indigenous therapists from being trained and therefore gaining approval by Human Research Ethics Committees (HREC) to work as therapists on psychedelic-assisted therapy trials.

As part of improving cultural safety and accessibility of psychedelic-assisted psychotherapy, an alternative model could have a basis in the social and emotional wellbeing (SEWB) framework where the wellbeing is comprised of seven interconnected domains: mind and emotion, body, family, community, culture, Country and spirituality.¹² The SEWB framework was developed by Indigenous psychologists through collaboration and community-based knowledge transfer with Indigenous Elders and community members and addresses the intergenerational impacts of genocidal colonialism that undermine the wellbeing of communities.²⁰ A model such as this could inform a protocol for psychedelic-assisted therapy based on the SEWB model that incorporates Indigenous ways of knowing, being and doing, connection to Country, culture and community interwoven in the wellbeing journey of the individual for collective wellbeing. It would ensure community connection and support are integral parts of the model, and as integration can take many months, even years, ongoing access to community-based integration support could be a central feature of the model.

In the context of new legal prescribing pathways for psychedelics and increasing drug development and investigator-initiated clinical trials, substantial caution is required in Australia to ensure that the mistakes of previous decades are not repeated and client wellbeing is at the forefront of all decision-making. Aboriginal and Torres Strait Islander Peoples must be able to access psychedelic-assisted therapy in ways that are culturally responsive. Collaborative models of care that include Western and Aboriginal and Torres Strait Islander knowledge have the potential to benefit all people. Thus, we recommend a) Aboriginal and Torres Strait Islander Peoples form expert reference groups for clinical protocol and treatment model design, b) consultation with Traditional Owners to ensure appropriate acknowledgement, establishing legal protections of cultural knowledge and care of Country, c) support for diversity in therapist teams, including Indigenous healers for culturally responsive care, d) consideration of decentralised and group-based models of care for participants in clinical trials conducted in naturalistic settings where community connection and support are incorporated, e) HRECs, regulatory authorities and study sponsors supporting Aboriginal and Torres Strait Islander therapist participation and in study and protocol design. Other prohibitive factors, such as cost, should also be

addressed to enable greater access to these treatments. Decolonising Australia's healthcare system is a complex and multifaceted process, yet Australia is still in the early stages of designing the psychedelic-assisted therapy landscape, and thereby now is an opportune time to prioritise Aboriginal and Torres Strait Islander Peoples's health equity and wisdom through inclusion at all stages of this developing and evolving process.

Author contributions

B Sebben wrote the initial draft of the manuscript in consultation with J Stone. All authors contributed in the conceptualisation of the work and/or narrative of the paper and critically reviewed the manuscript and approved the final version. This included J Stone, K Mallie, S Barnett, individuals of Aboriginal and Torres Strait Islander descent, who played an integral role in the consultation process.

Ethics approval

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Conflicts of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: B Sebben, J Stone, K Mallie and S Barnett are cofounders of IPAT (Indigenous Psychedelic Assisted Therapies), a private company that has developed a model of psychedelic-assisted therapy based on Indigenous ways of knowing, being and doing and offers cultural consultation services. J Sarris and D Perkins helped fund IPAT and are also co-CEOs of Psychae Therapeutics, a commercial company developing psychedelic therapies. SGD Ruffell works for the not-for-profit arm of the aforementioned company. He is also the co-founder of a not-for-profit organisation conducting research into traditional plant medicines. VL Beesley has received unrelated funding from Woke Pharmaceuticals for a psilocybin-assisted therapy trial.

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