

Position statement

Psychologists and psychedelic-assisted therapy

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Executive summary

Psychedelic substances are a group of drugs which are known for their hallmark induction of non-ordinary states of consciousness. Used by Indigenous and First Nations peoples for thousands of years, psychedelics only piqued the interest of western psycho-medico research in the mid-20th Century. Early systematic research was halted in the 1970s until the recent 'renaissance' in the past 15-20 years. Until recently, psychedelic substances have been strictly controlled outside designated clinical research trials. Psychedelics are typically separated into four groups (1) classic psychedelics, (2) empathogens or entactogens, (3) dissociative anaesthetics and, (4) other hallucinogens. Focussing on the first two classes, this position statement describes the current understanding of the cognitive, perceptual, social, and emotional effects of psychedelics, and importantly, evidence for their effect on symptoms of mental health disorders. It is well accepted that psychedelics are not treatments in and of themselves, they are an adjunct tool for (psycho)therapy.

Research is evolving quickly in this field and emerging results are promising. This, combined with global media and public interest has resulted in the regulations regarding psychedelic substances shifting. Since 1 July 2023, approved psychiatrists under the Authorised Prescriber Scheme are able to prescribe (1) MDMA for the treatment of post-traumatic stress disorder (PTSD) and (2) psilocybin for the treatment of treatment-resistant depression in combination with psychotherapy. However, more robust research is still needed to determine the longer-term effects of these treatments.

Typically, it appears that psilocybin and MDMA are well tolerated in clinical settings and result in few adverse events. Strict screening, monitoring and dose control is required which limits the settings in which psychedelic-assisted therapy should be undertaken. Cost, availability, and training also still limit the provision of psychedelic-assisted therapy to the public. The limitations of current research include, *inter alia*, (1) knowledge of appropriate dosing protocols, (2) selection bias, (3) screening and generalisability, (4) small sample sizes, (5) inadequate blinding and controls, (6) relatively short follow-ups, and the (7) unknown different effects of psychotherapy.

The APS is interested in all emerging evidence-based treatment options, particularly for patients who do not respond to current evidence-based treatments. Given this, the APS acknowledges the therapeutic potential of psychedelic-assisted therapy and supports ongoing research in this field. Until there is sufficient compelling phase 3 clinical evidence, and systematic research to overcome the current limitations, however, the APS would not, at this stage, endorse the widespread use of psychedelic-assisted therapy. Critically, as psychedelic-assisted psychotherapies become more widely available, data regarding the safety, tolerability and efficacy should be systematically recorded and evaluated. As regulated practitioners, psychologists should play a lead role in providing psychedelic-assisted therapy to vulnerable patient populations. Training and professional development should be provided in collaboration with health professional associations. This is to ensure evidence-based approaches are taken and propagated and to ensure that the strict treatment protocols are followed and necessary patient screening is undertaken.

1. Introduction

- 1.1** An estimated one in five Australians reported having a mental disorder in the previous 12 months, and almost half of all Australians have been affected at some point in their lifetime¹. It is estimated that in 2018-19, mental ill-health and suicide cost the Australian economy up to \$70 billion and up to an additional \$150 billion when disability and premature death due to mental illness are also considered². Despite the availability of evidence-based treatments, it appears that many patients (possibly up to 30%) remain 'treatment resistant' and still suffer significant burden which can have staggering quality of life and economic consequences³⁻⁵.
- 1.2** Psychedelics are substances which can be divided into four types of drug: (1) classic psychedelics (e.g. 'magic mushrooms' (psilocybin) or Lysergic acid diethylamide (LSD)), (2) empathogens or entactogens (e.g. 3,4-methylenedioxymethamphetamine (MDMA)), (3) dissociative anaesthetics (e.g. ketamine) and, (4) other hallucinogens^{6,7}. The current position statement will focus on the first two classes as they tend to be separated in the literature ^{e.g. 7} and clinical memoranda ^{e.g. 8}. It is important to note that MDMA is technically not a psychedelic but is similar in terms of subjective effects, potential therapeutic effects, and current Therapeutic Goods Administration (TGA)⁹ and international drug scheduling¹⁰ (the current status of psychedelic substances will be described in more detail in Section 3). A, and possibly the, defining feature of psychedelic substances is their effect in inducing a non-ordinary state of consciousness¹¹.
- 1.3** There are significant numbers of Australians already taking psychedelic substances to 'self-medicate' to treat symptoms of mental health disorders¹².
- 1.4** In a 2020 Global Drug Survey¹³, 6,500 of 110,000 respondents stated that they were using psychedelic substances as a self-treatment of psychiatric illness or emotional distress: most commonly depression, anxiety, or relationship issues. The report suggests that the most used substances were LSD (34% of reported psychedelic use), MDMA (25.3%), psilocybin ('magic mushrooms') (20.4%), and ketamine (13%). Such underground use precludes the appropriate pharmacological, medical, and psychological safeguards which may explain the relatively high number of emergency visits of psychedelic users¹³. A 2022 survey of US citizens suggested that 28% of adults have used at least one psychedelic substance in their lifetime¹⁴.

2. Background

- 2.1 Psychedelic substances have been used in spiritual and therapeutic practices by Indigenous and First Nations peoples for thousands of years¹⁵⁻¹⁸. Some argue that psychedelics may be the oldest psychoactive substances used by humans¹⁸.
- 2.2 It is only in the second half of the 20th Century, that psychedelic substances piqued the interest of western psycho-medico research. LSD was first synthesised in 1938 but was largely forgotten due to it being “physiologically unremarkable”^{16 (p. 2)}. In the mid-1940s the archetypical psychological effects of psychedelics were documented in western contexts¹⁷. Research investigating the potential therapeutic benefits of psychedelic substances steadily gained popularity in the 1950-60s. In that time, the experiences of over 40,000 patients were documented in 1,000 papers¹⁹.
- 2.3 Despite emerging evidence, clinical research investigating the therapeutic potential of psychedelics was stopped due to the world-wide classification of psychedelic substances in Schedule I of the 1967 United Nations Convention on Drugs²⁰. This almost eliminated clinical research into their therapeutic potential until the recent renewed interest spurred by the need to consider alternative treatment options. Termed the ‘renaissance’ of psychedelic research, interest in the field has been increasing steadily for the past 15-20 years. Until recently, MDMA and psilocybin were classified as Schedule 9 (prohibited) substances by the TGA as listed in the *Poisons Standard June 2023*⁹ and were only administered legally in the context of clinical research trials.

3. Current status of psychedelic substances

- 3.1** In February 2023, the TGA announced that, from 1 July 2023, approved psychiatrists under the Authorised Prescriber Scheme can prescribe psilocybin to address treatment resistant depression and MDMA to treat PTSD in Australia²¹. In part, this decision was based on the 2021 final report from independent experts who considered current evidence regarding the safety and clinical utility of MDMA and psilocybin²². They concluded that “MDMA and psilocybin may show promise in highly selected populations but only where these medicines are administered in closely clinically supervised settings and intensive professional support”^{22(p. 5)}. Under all other circumstances, these substances are classified as Schedule 9 poisons⁹ due to having a “high propensity for dependency and abuse” and are not available for clinical use outside State or Territory approved clinical research trials²³.
- 3.2** To prescribe psilocybin or MDMA, psychiatrists must first be approved by a registered Human Research Ethics Committee (HREC) before seeking authorisation from the TGA. This pathway is designed to ensure robust protocols are followed including, for example, patient selection and monitoring, administration setting, and reporting²⁴.
- 3.3** The USA Food and Drug Administration (FDA) has classified psychedelics as illegal Schedule 1 substances which have “no currently accepted medical use and a high potential for abuse”¹⁰. Psychedelic treatments in the USA are not permitted outside an Institutional Review Board approved clinical trial²⁵. However, there appears to be rapid and decentralised movement towards decriminalisation as US cities and states have begun to loosen restrictions and/or legalise psychedelic-assisted therapy in certain circumstances²⁶.
- 3.4** MDMA-assisted psychotherapy for the treatment of PTSD^{27,28} and Psilocybin-assisted psychotherapy for the treatment of treatment-resistant depression^{7,29} have been given ‘breakthrough’ designation by the FDA, suggesting they have the potential to be safer and more effective than current treatments^{27,29}: Breakthrough designation expedites the approval and distribution of treatments once clear evidence from controlled clinical trials is available^{30,31}.
- 3.5** In the UK, psychedelics are classified as Class A drugs which strictly prohibits their sale and possession^{32,33}. Similarly, psychedelics are currently Class A controlled drugs in New Zealand³⁴ except ibogaine which is a prescription medicine^{35,36}.

4. Current evidence of psychological and therapeutic effects

- 4.1** Table 1 provides a detailed overview of the effects of psychedelics on psychological processes and effects on mental health disorders.
- 4.2** Psilocybin exerts a number of effects on cognitive and perceptual processes^{37,38}, has been associated with blissful feelings and a greater sense of well-being^{38,39}, and anxiety and confusion or thought disorder^{38,40}. There have been multiple studies providing emerging evidence that psilocybin-assisted therapy had some, albeit statistically limited benefits (in some cases) in reducing symptoms of depression and/or anxiety in patients with **treatment-resistant depression**⁴⁰⁻⁴² and **cancer patients**^{39,43,44}.
- 4.3** Similarly, MDMA has been shown to affect a number of positive cognitive and emotional processes⁴⁵⁻⁵¹ including reported increased access to emotional material^{46,52}. Unfortunately, MDMA may also induce anxiety and mild cognitive or psychomotor impairments^{45,46,49,52-55}. Some of the hallmark effects of MDMA are the subjective social relatedness effects such as enhanced sociality and closeness to others^{45,56} and a blunting of an ability to decode negative expressions⁵⁶.
- 4.4** Patients with **treatment resistant PTSD** experienced a **decrease in PTSD symptoms** after MDMA-assisted therapy^{53,57-59} and the **reduction in PTSD symptoms** appear to be **sustained**⁶⁰. In a randomised, double-blind placebo-controlled phase 3 study, MDMA-assisted therapy was found to **reduce PTSD symptoms** and **reduced functional impairment** compared to placebo with therapy in patients with **severe, including co-morbid PTSD**⁶¹.
- 4.5** The evidence supporting the therapeutic applications of LSD, ayahuasca and ibogaine is less convincing although may emerge with additional research. Some early evidence is listed in Table 1.

5. Psychedelic-assisted therapy

- 5.1** Critically, the current evidence suggesting promising effects of psychedelics are almost solely in conjunction with psychotherapy which has led to the largely accepted view that psychedelics are not a viable treatment in and of themselves⁶². It is thought that psychedelics enable the surfacing of previously unavailable emotional material which can then be processed and integrated⁴⁰. The precise mechanisms of each component of psychedelic-assisted therapy are still not well understood and require additional research⁷.
- 5.2** Central to the psychedelic-assisted psychotherapeutic approach is the importance of set (i.e., psychological expectations), setting (i.e., physical environment) and having a trust-based therapeutic clinician-patient relationship. Effects of psychedelic substances, do appear to be context dependent, which is consistent with the traditional religious and spiritual uses⁶³. Studies which have deemphasised the importance of context setting, have typically not reproduced the strength of positive effects, which has made it difficult for psychedelic research to demonstrate 'pure' pharmacological effects in efficacy testing⁶⁴⁻⁶⁶. For example, one study cited the strength of their results in affecting trait-based measures could have been due to the importance of the research context, which encouraged the integration of spiritual values into daily life (e.g. prosocial values, cultivating a sense of wonder)³⁸.
- 5.3** Typically, psychedelic-assisted therapy paradigms include very few doses of psychedelic substances and the following therapy sessions⁷:
- a. **Preparatory session(s)** – which involves understanding the patient's history and intentions and educating the patient on the likely experience during the active session.
 - b. **Psychedelic active session(s)** – Typically, patients are accompanied by a male-female therapist dyad⁶⁷ which is unfortunately deemed necessary due to previous reports of sexual abuse during MDMA-assisted therapy⁶⁸. Although potentially profound and leading to long-term positive effects, it is important to acknowledge that this session could be very challenging due to the emotional material that may surface.
 - c. **Integration session(s)** – arguably the most important step, this includes the interpretation of the material raised during the active session and the integration of this experience into long-term positive change.
- 5.4** The typical psychotherapeutic approach has been non-directive, supportive psychedelic or psycholytic therapy which is seen as facilitating the experience rather than directing it. Many believe in the importance of therapists undertaking the experience themselves as a personal practice⁶⁹ to fully appreciate the profundity of the psychedelic-assisted therapeutic approach⁷⁰.
- 5.5** Both the FDA⁶⁷ and TGA²² acknowledge the importance of close professional involvement as being a critical component of successful psychedelic-assisted therapy. Specifically, the FDA requires that the two therapists:
- "Are mental health care practitioners and (have) a professional licence in good standing"^{62 (p.4)}
 - Have demonstrable clinical psychotherapy or mental health counselling experience
 - Have a Masters' level qualification.

As recommended by Tai et al⁶⁷, it is not necessary that a psychiatrist is a member of the therapist dyad, but one must be present during an active psychedelic session in case of a psychiatric or medical adverse event.

6. Known risks and side effects

- 6.1** When considering the side effects of psychedelic substances, it is important to distinguish between use in clinical and research settings compared to street use. Research on the street use of psychedelics is fundamentally uncontrolled and the drugs are often contaminated by other substances⁷¹.
- 6.2** Given the emerging nature of the field, research in clinical settings must adequately screen for high-risk individuals, including patients with:
- a. **Personal or family history** of psychosis^{17,72}
 - b. **Personal history** of mania, violence towards others, acute suicidality, current substance abuse (unless this is the target of the intervention), serious cardiovascular (including uncontrolled hypertension), liver, renal, or neurological comorbidity, current or expected pregnancy¹⁷
- 6.3** The similarity of some effects of psychedelic substances with some symptoms of psychosis⁷² has been concerning for researchers and so long-term perceptual disturbances are of particular interest (e.g. hallucinogen persisting perception disorder) when evaluating their safety.

Classic Psychedelics

- 6.4** In clinical settings, psilocybin appears to be well tolerated^{22,40,42,43}, apart from transient headaches^{39,40,42,73}. Importantly, adverse events with participants taking psilocybin appear to be rare^{22,38,40,43,74}. An analysis of 110 healthy participants found no evidence of hallucinogen persisting perception disorder, prolonged psychosis or other long-term impairment⁷⁵. However, psychedelic effects on personality and mood appear to be dose-dependent which suggests that care must be taken to ensure the dose is controlled³⁸.
- 6.5** Similarly, LSD appears to be well tolerated in controlled settings with healthy participants^{74,76} and participants with life-threatening diseases⁷⁷.
- 6.6** Apart from inducing vomiting in approximately 50% of participants, ayahuasca was well tolerated in research settings^{78,79}. It is important to note, however, that clinical research involving ayahuasca is still limited by the precise understanding of the ingredients and concentrations of compounds of the decoction⁷.
- 6.7** In contrast to other psychedelics, ibogaine has the potential to generate life-threatening cardiac arrhythmias⁸⁰ and so more research is required to understand its therapeutic potential, particularly in patients with pre-existing cardiovascular comorbidities⁸¹.

MDMA

- 6.8** There have been many reported psychological side effects of street use of 'ecstasy' (MDMA) in the literature⁸² and importantly, it appears that some of these effects are sustained after periods of abstinence⁸³. Other serious physical side effects have also been observed⁸⁴. The observed cardiovascular effects of MDMA, however, may be toxic in crowded and/or hot places or when combined with physical activity^{85,86}. Other research, however, suggests that acute complications caused by ecstasy intake are epidemiologically rare, and results are often confounded by users taking multiple illicit drugs⁸⁴. Specific dose-response relationships for individuals may also vary, according to genetic differences, and previous exposure to the drug – meaning that it is difficult to predict toxic reactions of individuals⁸⁴.

- 6.9** Using a field study design, Halpern et al.⁸⁷ found little evidence of neurocognitive differences of users versus non-users of ecstasy who have had minimal exposure to other drugs. Apart from differences in poorer strategic self-regulation, ecstasy users did not appear to demonstrate residual neuro-toxic cognitive effects.
- 6.10** Studies of MDMA in animals have indicated that controlled high doses of MDMA which lead to deficits in serotonin neurons can have lingering effects on behaviour but that change is not necessarily neurotoxic (i.e. leading to cell death)⁸⁸. Importantly, MDMA administered in controlled clinical research settings appears to be well-tolerated^{22,53,59,61,89} and have few harmful side effects^{22,41,48,53,54,57,61,86}. Recent phase 3 results did not indicate an increase in suicidality in patients with PTSD undergoing MDMA-assisted therapy⁶¹.

7. Limitations of current research

Apart from the lack of detailed understanding of the psychological mechanisms underpinning psychedelic-assisted therapy, there are a number of limitations with the current research which need to be addressed:

- 7.1 Knowledge of appropriate dosing protocols** – animal models have often been used as the rationale or background to studies involving psychedelic substances. Animal studies often use very high doses (per kg weight) and the results may not generalise to human populations. Although there is significant volume of literature describing the effects within the ‘therapeutic window’, there is still limited knowledge of the effects above and below that range. Recent research is, for example, investigating the effects of microdosing on wellbeing or creativity^{90–93} and still requires further investigation^{94,95}.
- 7.2 Selection bias** – in the limited number of active research trials, participants often volunteer or ‘self-refer’⁴⁰ and contact study co-ordinators directly. Such a bias may mean that results are limited to participants who are open to psychedelic experiences ^{see 17} or other homogenous factors may play a role.
- 7.3 Screening and generalisability** – for safety reasons, patients who have a family history of psychosis⁹⁶, may be pregnant, breastfeeding, have hypertension or heart disorders are typically excluded from clinical trials¹⁷. Ultimately, it means that the generalisability of results may be limited in those populations²². This has important implications as psychedelic treatments are becoming more widely available.
- 7.4 Small sample sizes** – due to the preliminary nature of much of the research conducted to date, there are typically very small sample sizes^{35,41}. If anything, however, this may under-power the ability to detect experimental effects, but is also less likely to produce robust data regarding safety and tolerability.
- 7.5 Inadequate blinding and controls** – due to the often visibly evident effects of psychedelic medications, it is difficult to blind study administrators from experimental groups, which may introduce expectancy effects^{17,77,97}. Similarly, it is difficult for participants to be blind to their experimental condition, as they may not experience any psychedelic effects in the control conditions. The increased use of ‘active placebo’ conditions may assist, as will true placebo-dose conditions to ensure that low doses of substances are psychopharmacologically active³⁸.
- 7.6 Relatively short follow-ups** – due to the preliminary nature of the majority of the research, there are still limited longitudinal clinical studies to assess the effects of psychedelics in the long-term⁹⁷.
- 7.7 Unknown differential effects of types of psychotherapy** – most psychedelic-assisted therapy research utilises non-directive, supportive psychotherapy. Future research should elucidate the utility of other guideline recommended psychotherapeutic approaches in combination with psychedelic substances^{22,41,98} and investigate the mechanisms by which therapeutic effects of psychedelics are realised.

8. The future of psychedelics in Australia

- 8.1** There is an increasing investment in the therapeutic potential of psychedelics and a number of charities and other organisations forming in Australia which are promoting the research, and widespread adoption of psychedelic substances into mainstream healthcare.
- 8.2** The Australian Medical Research Future Fund - Clinical Trials Activity Initiative - 2021 Innovative Therapies for Mental Illness - Grant Opportunity released an additional \$15M in March 2021 to “assess the safety and efficacy of innovative therapies using hallucinogens and stimulant drugs supported by psychological/ psychiatric care for treatment resistant mental illness, compared to standard therapies clinical trial research being undertaken in Australia”⁹⁹. It is anticipated that additional funding will be released to support new research in this field.
- 8.3** Despite MDMA and psilocybin being available in Australia, a number of barriers remain which limit their widespread use:
- a. **Cost** – similarly to medicinal cannabis, the manufacturing of pharmaceutical grade psychedelic substances remains highly regulated and expensive ^{see also 17,100}.
 - b. **Training** – the emerging evidence suggests that the therapeutic benefits of psychedelic substances work in conjunction with psychiatric and psychological treatment to help prepare, guide, and integrate participants’ psychedelic experiences⁶⁷. As described in Sections 5 and 9, psychologists can play a crucial role in psychedelic-assisted therapy. Adequate training and professional development to prepare the psychology workforce is required to ensure that the strict treatment protocols are followed, and necessary patient screening is undertaken.
 - c. **Availability of appropriate settings** – at least initially, it will be important that psychedelic-assisted therapy will be conducted in hospitals and other controlled settings to enable appropriate monitoring and ensure access to medical and acute psychiatric/clinical psychological assistance if adverse effects occur.
- 8.4** The worldwide advancement of personalised medicine is also starting to influence healthcare in Australia. It is foreseeable that the development of individual mental health treatment plans will consider genetic information, medical and psychological history, success of previous treatments, personal preferences, and individualised risk profiles to determine the optimal treatment approach. As psychedelic-assisted therapy becomes more accessible in Australia, it is important to consider these factors in determining the suitability of the treatment for individuals.

9. The APS position

- 9.1** The APS welcomes the emergence of safe, evidence-based treatment options to address the shortcomings of currently available medication options for individuals with mental health disorders. Psychologists are ethically bound by the principle of beneficence¹⁰¹. The APS has a duty to support the development of emerging evidence-based treatments and clinical trial research into promising therapeutic options, provided they are conducted with patient well-being and safety being paramount.
- 9.2** The APS is encouraged by the emerging evidence which has led to the TGA's down scheduling of MDMA-assisted psychotherapy to treat PTSD, and psilocybin-assisted psychotherapy to manage treatment-resistant depression. Both offer many advantages over other alternate treatment options for refractory mental health conditions (e.g. electroconvulsive therapy or ketamine infusion therapy)⁷.
- 9.3** Despite the promising early evidence from the recent 'renaissance' of scientific research into psychedelics, understanding of the psychological processes of change underlying the observed benefits is limited. Until robust and longer-term evidence is available from Phase 3 clinical randomised control trials, there is insufficient evidence for the APS to endorse the widespread adoption of psychedelic-assisted therapy, or other therapeutic options involving psychedelic substances.
- 9.4** It would be premature for the APS to support the widespread use of psychedelic substances without data regarding the efficacy, safety, potential for abuse, and tolerability of these substances in vulnerable patient populations. As psilocybin- and MDMA-assisted therapy become more available in Australia, data collected by the TGA and states and territories authorities must be regularly evaluated to elucidate the effects of these treatments in the broader population. The APS anticipates that it may reconsider its position on a regular basis as additional evidence becomes available.
- 9.5** Every therapeutic intervention carries some element of risk, however, not intervening or using ineffective treatments also carries its own risk ^{see} ¹⁰². Rates of suffering, relapse, and even suicide, for individuals with treatment resistant psychological disorders are still unacceptably high. It is for this reason that the APS supports ongoing systematic research investigating the therapeutic applications of psychedelics. Given the inhomogeneity of different psychedelics' effects and safety and efficacy profiles, it is not appropriate to treat them the same¹⁰³. Specific research is required to determine each substance's therapeutic potential.
- 9.6** It is important to consider, however, that throughout the decades, there have been a number of 'waves' of public excitement and expectation that new treatment options will be the mental illness panacea. There are valid arguments to suggest that there is a current overreliance on medications to 'fix' mental health disorders¹⁰⁴. Not only do all psychoactive medications carry their own risks and side effects¹⁰⁵, improvements that occur as a result of taking medication can help fuel an external attribution of change (i.e. symptoms improved due to an external factor – a drug) rather than an internal one¹⁰⁶. Such an attribution can help perpetuate a dependence on medications and/or result in relapse¹⁰⁶. This can be further exacerbated by the anticipation of any discontinuation (e.g., withdrawal) effects or tolerance to effects with sustained use¹⁰⁷.

- 9.7** Psychedelic-assisted therapy has the potential to mitigate some issues related to tolerance and attribution as manualised protocols suggest low numbers of doses of psychedelic substances (typically 1-3 doses) and the therapy component of the treatment is emphasised^{27,108}. In addition, current evidence suggests that psychedelics typically do not induce physical dependence^{27,60}, although tolerance to effects may be problematic in sustained use¹⁰⁹. It is important that future research rigorously investigates the issues of tolerance, physical and psychological dependences when studying psychedelic-assisted therapy to treat mental health conditions.
- 9.8** As the interest in the therapeutic potential of psychedelic substances and their availability continues to increase in Australia, the specific role of psychologists will also evolve. As described in Section 5, only highly trained, experienced, and regulated mental health professionals should be providing psychedelic-assisted therapy. Therefore, psychologists should play a crucial, lead role due in delivering psychedelic-assisted therapy. This is due to the profundity of the experience in addressing and accessing highly emotional, and often traumatic material⁶⁷. An in-depth understanding of psycho-emotional processes and their interaction in mental-health treatment, while undertaking a trauma-informed approach will be necessary to ensure patient safety and treatment efficacy.
- 9.9** As Australian psychologists' peak body, the APS aligns with the Royal Australian New Zealand College of Psychiatrists (RANZCP) and other health professionals' peak bodies to be a collaborative voice to determine how treatment is developed and regulated in Australia and what role psychologists have in providing these services. Given our evidence base, experience, and training in working with vulnerable patient populations, it is imperative that psychological expertise is utilised in the development of this emerging field. In addition to undertaking a lead role in the delivery of psychedelic-assisted therapy, we would also consider the role of psychologists would be to participate in inter-disciplinary relationships with a view to establishing joint educational opportunities and knowledge sharing. As the RANZCP⁸ and other professional bodies' positions continue to evolve, we endeavour to work collaboratively to ensure the best health outcomes for Australians.
- 9.10** Currently, most of the training of psychedelic-assisted psychotherapists is conducted in the context of clinical trials. This has the advantage of being informed by the latest evidence-base. As psychedelic-assisted therapy becomes more accessible, training and professional development will be required to adequately prepare the workforce on a larger scale⁶⁷. This must be undertaken in collaboration with regulated professional organisations, to ensure the best-practice, evidence- standards are maintained and propagated throughout the professions. Professional guidelines and stringent screening protocols would also need to be developed.
- 9.11** The cost and practical constraints related to the delivery of psychedelic-assisted therapy suggest that, currently, such treatment is unlikely to become a 'frontline' option and is more suitable for patients with treatment-resistant mental health disorders.

Table 1- The effects of psychedelics on psychological processes and effects on mental health disorders

Classic psychedelics (5-HT_{2A} receptor agonists^{18,110–112})					
Psilocybin – present in the Psilocybe mushroom species¹¹³	Effects on psychological processes				
	Cognition	Perception	Positive emotional effects	Negative emotional effects	Social relatedness
	<ul style="list-style-type: none"> • Mystical experience³⁷ • Transcendence of time and space³⁷ • Sense of meaning and insight³⁸ • Increased spirituality³⁸ 	<ul style="list-style-type: none"> • Changes in perception e.g. synesthesia³⁸ • Visual pseudo-hallucinations and illusions³⁸ 	<ul style="list-style-type: none"> • Labile mood (e.g. blissful or joyful feeling)³⁸ • Greater well-being or life satisfaction^{38,39} 	<ul style="list-style-type: none"> • Labile mood (e.g. anxiety)^{38,40} • Confusion or thought disorder⁴⁰ 	<ul style="list-style-type: none"> • Increases in prosocial attitudes and behaviours³⁸
Effects on mental health disorders					
<ul style="list-style-type: none"> • In an open-label feasibility study, psilocybin assisted therapy had benefits in reducing depressive symptoms in patients with treatment-resistant depression⁴⁰ • Compared to escitalopram, participants who took psilocybin showed no difference in depression score after six weeks in a phase 2 randomised trial⁴². However, this study only involved 12 participants and statistical comparisons may be underpowered. • Similarly, other feasibility studies with minimal psychotherapy suggested that anxiety and mood were significantly improved in cancer patients after taking psilocybin^{39,43} • Using a randomised controlled crossover design, psilocybin-assisted therapy (preparation, medication dosing and postdosing integration sessions) resulted in decreased anxiety and depression in cancer patients⁴⁴. • Combined with nondirective interpersonal support, psilocybin has been shown in an open-label pilot study to aid smoking cessation¹¹⁴ and additional research is underway¹¹⁵. • In an open label proof of concept study using psilocybin-assisted therapy (motivational enhancement therapy, preparation sessions, psilocybin-assisted therapy sessions, and debriefing sessions), alcohol-dependent participants reported increased abstinence¹¹⁶ sparking phase two research¹¹⁷. • Preliminary evidence suggests that psilocybin can relieve symptoms of obsessive-compulsive disorder¹¹⁸. Current research to explore this is underway^{119,120}. • Additional research is investigating the use of psilocybin to treat substance use disorders¹²¹, anorexia nervosa¹²², depression in Alzheimer's disease¹²³ <i>inter alia</i>. • Current research in Australia is focussing on the potential of psilocybin-assisted therapy in reducing anxiety in end-of-life patients¹²⁴ and the psychological and neural effects of microdosing with psilocybin⁹⁰. 					
Lysergic acid diethylamide (LSD)	Effects on psychological processes				
	Cognition	Perception	Positive emotional effects	Negative emotional effects	Social relatedness
	<ul style="list-style-type: none"> • Increased cognitive flexibility⁹⁷ • Increased openness^{96,97,125} • 'Loosened' cognition^{97,126} • Insightfulness¹²⁷ • Increased suggestibility¹²⁸ 	<ul style="list-style-type: none"> • Psychosis type symptoms^{96,97,112} • Disembodiment¹¹² • Visual hallucinations⁹⁶ • Audio-visual synesthesia⁹⁶ 	<ul style="list-style-type: none"> • Positive mood^{66,97} • Increased optimism⁹⁷ • Blissful state^{96,112} • Impaired acute fear recognition^{76,129} • Enhanced wellbeing^{66,96} 	<ul style="list-style-type: none"> • Paranoia*⁹⁷ • Delusion*⁹⁷ • Acute anxiety*⁹⁶ <p>*Minor effects compared to group results</p>	<ul style="list-style-type: none"> • Increased closeness to others^{76,96} • Enhance emotional empathy⁷⁶ • Enhance sociality⁷⁶ • Feelings of trust⁹⁶

Table 1- The effects of psychedelics on psychological processes and effects on mental health disorders continued

	Effects on mental health disorders in conjunction with psychotherapy				
	<ul style="list-style-type: none"> • A pilot study suggested that LSD-assisted therapy can significantly reduce anxiety in patients with life-threatening diseases⁷⁷. • Positive and sustained effects on mood and attitudes of LSD may open possibilities for the treatment of mental health disorders⁶⁶. • LSD may influence the processing of negative stimuli which play a role in mood and anxiety disorders¹²⁹. • Future research will focus on LSD effects on anxiety¹³⁰ and the effects of microdosing of LSD⁹¹ 				
Ayahuasca – botanical brew containing dimethyltryptamine and harmine ⁷	Effects on psychological processes				
	Cognition	Perception	Positive emotional effects	Negative emotional effects	Social relatedness
	<ul style="list-style-type: none"> • Mystical and noetic experiences⁷ • Increased mindfulness¹³¹ 	<ul style="list-style-type: none"> • Auditory and visual hallucinations^{63,132} • Altered spatial perceptions⁶³ 	<ul style="list-style-type: none"> • Positive mood¹³² • Increased quality of life meaning and outlook¹³¹ • Hopefulness and empowerment¹³¹ 	<ul style="list-style-type: none"> • Acute psychotic episodes^{132*} 	<ul style="list-style-type: none"> • Qualitative reports of increased openness to others¹³¹
	Effects on mental health disorders				
	<ul style="list-style-type: none"> • In open-label trials, patients with recurrent depression showed significantly reduced depressive symptoms after one ayahuasca dose^{78,79}. • Self-reported cocaine use reduced after participation in an ayahuasca-assisted treatment program for people with problematic substance use¹³¹. 				
Ibogaine – psychoactive plant alkaloid ⁸¹	Effects on mental health disorders				
	<ul style="list-style-type: none"> • Preliminary studies investigating ibogaine treatment found reduced sustained opioid use and withdrawal symptoms^{35,133} and depressive symptoms³⁵ in substance dependent participants. 				

Table 1- The effects of psychedelics on psychological processes and effects on mental health disorders continued

Entactogens ⁶					
3,4-methylenedi oxymethamp hetamine (MDMA)	Effects on psychological processes				
	Cognition	Perception	Positive emotional effects	Negative emotional effects	Social relatedness
	<ul style="list-style-type: none"> • Stimulant effects^{45,46} • Increased openness⁴⁷ • Decreases in neuroticism⁴⁷ • Feelings of authenticity⁴⁶ • Increased access to emotional material^{46,52} • Spatial memory deficits⁵⁵ • Mild psychomotor impairment⁴⁹ • Feelings of being insightful⁴⁸ • Difficulty concentrating⁵⁴ 	<ul style="list-style-type: none"> • Body perceptual changes⁴⁹ • Slight perceptual alterations (not hallucinations)^{48,49} 	<ul style="list-style-type: none"> • Euphoria⁴⁸⁻⁵⁰ • Enhanced well-being⁴⁹ • Sense of a greater meaning in life⁵¹ • Confidence⁴⁸ 	<ul style="list-style-type: none"> • Anxiety^{45,46,52-54} • Confusion or 'drunken' feeling^{46,49} 	<ul style="list-style-type: none"> • Closeness to others^{45,56} • Enhanced sociability⁵⁶ • Decreased social anxiety⁴⁶ • Increased emotional empathy¹³⁴ • Enhanced ratings of affective touch¹³⁵ • Gregariousness⁴⁶ • Increased ratings of face trustworthiness⁵⁰ • Cooperative behaviour⁵⁰ • Blunting of ability to decode negative expressions⁵⁶
Effects on mental health disorders					
<ul style="list-style-type: none"> • In two pilot randomised-controlled trials, patients with treatment resistant PTSD experienced a decrease in PTSD symptoms after MDMA-assisted therapy^{57,58} • Importantly, the reduction in PTSD symptoms appeared to be sustained more than a year after the MDMA session⁶⁰. • In a phase 2 double-blind randomised-controlled trial, military veterans, firefighters, and police officers with treatment-resistant PTSD reported a reduction in PTSD symptoms and were more likely to be in remission after undergoing manualised¹⁰⁸ MDMA-assisted therapy⁵³. The high MDMA dose group also exhibited a reduction in depression symptoms and the moderate and high dose groups reported improved sleep quality, dissociative symptoms and gains in psychological, occupational and social functioning⁵³. Similar reduction in symptoms and remission rates were found in another phase 2 study⁵⁹. • In a randomised, double-blind placebo-controlled phase 3 study, MDMA-assisted therapy was found to reduce PTSD symptoms and reduced functional impairment compared to placebo with therapy in patients with severe, including co-morbid PTSD⁵¹. • In another study, increased openness facilitated by MDMA-assisted therapy predicted reduction in PTSD symptoms⁴⁷ • Results from a pilot randomised double-blind study suggest that MDMA-assisted therapy reduced social anxiety symptoms in adults with autism spectrum disorder⁵⁴ • In a randomised pilot study, MDMA-assisted therapy trended towards reducing trait anxiety in patients with a life-threatening illness, as well as decreasing depression symptoms and improving sleep quality⁸⁹. 					

Table 1: The effects of psychedelics on psychological processes and effects on mental health disorders. This is not intended to be an exhaustive literature review. The results included have been selected to provide a sense of the effects of the substances and the current state of research investigating their impacts on mental health disorders. Layout adapted from Reiff et al.⁷

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