



Frequently Asked Questions

About Mind Medicine Australia

What is Mind Medicine Australia?

Mind Medicine Australia is a registered charity working towards establishing regulatory-approved and evidence-based psychedelic-assisted therapies for mental illness in Australia.

Why was Mind Medicine Australia launched?

Mind Medicine Australia was established to support further investigation to enhance the effectiveness and safety of psychedelic-assisted therapies, and to reduce unnecessary delays in implementing this approach within Australia. One in five Australians are currently suffering from a mental illness. One in two Australians will be affected by a mental illness in their lifetime. Australia is experiencing a growing mental health crisis that current treatment options are unable to adequately address. While available mental health treatments can be effective, about half of all patients do not respond. Therefore, we need to support the most effective and innovative treatments to address this unmet need. Over the past decade, psilocybin- and MDMA-assisted psychotherapies have demonstrated remarkably promising clinical results in overseas trials. Mind Medicine Australia believes Australia should join the global effort to investigate and optimise these treatment approaches for mental illness.

Why psychedelic-assisted psychotherapy?

In major international trials, psychedelic-assisted psychotherapies have shown impressive outcomes in treating a range of mental illnesses with greater effectiveness than standard treatments, and with an excellent safety profile. Australia is currently behind the US, UK, Canada, Israel and Europe when it comes to research and regulatory support for these promising treatments.

What do you hope to achieve?

Mind Medicine Australia acts as a nexus between clinicians, academia, government, regulators, philanthropists, and patients, working in close consultation and partnership with relevant experts and organisations. Subject to the results from Phase 3 clinical trials currently underway overseas, we are preparing to assist the health care system for possible regulatory changes in Australia, by supporting clinical research, and developing a clinical implementation framework and therapist training protocols. We are also educating and engaging relevant stakeholder groups and the general public, to increase awareness, and to drive best-practice.

What is Mind Medicine Australia’s Therapist Training program?

Knowledge, training, and certification will be essential to ensure best practice for a novel therapeutic approach that is currently largely unfamiliar to the Australian mental health service sector.

Therefore, in partnership with leading organisations overseas and locally, we are establishing an evidence-based therapist training program.

What are MMA’s plans for research?

Mind Medicine Australia supports research that investigates the benefits, mechanisms, and risks of psychedelic-assisted psychotherapy. We are particularly interested in novel research protocols that expand on research conducted by major universities overseas, and that seek to answer key questions to enhance clinical effectiveness and safety.

What policy change is MMA advocating for?

We advocate for evidence-based policy that supports research into the therapeutic use of psychedelics alongside psychotherapy. We are not advocating for recreational or other non-clinical use of psychedelics. Nor do we advocate any changes to the law with respect to non-clinical uses. Subject to positive results from Phase 3 clinical trials (the final stage clinical trials before regulatory approval), which are commencing overseas, we will advocate for the development and availability of psychedelic-assisted psychotherapy within a limited number of designated clinical centres in Australia.

How can I assist MMA to achieve its goals?

We are a small organisation doing big things. We rely on support from our partners and the community. You can help to support research and the development of psychedelic-assisted psychotherapy by:

- donating money or skills;
- connecting us with people and organisations within the medical fraternity, academia, government, regulatory agencies, philanthropy, and other relevant sectors;
- sharing the evidence for this treatment approach and contributing to mature and open conversations about such matters.

About Psychedelics

What are psychedelics?

Psychedelics are chemical compounds which temporarily create changes in brain function including shifts in perception, thinking, and feeling, producing an ‘altered state of consciousness’. The ‘classical psychedelics’ include substances like psilocybin (found in a variety of mushrooms), ayahuasca, mescaline, lysergic acid diethylamide (LSD), and dimethyltryptamine (DMT). Although not a classical psychedelic, MDMA is often included in this category due to some similarities in its effects and clinical applications. Classical psychedelics appear to produce many of their effects through the activation of a specific Serotonin receptor (5HT_{2A}) in the brain. The word psychedelic, coined by British psychiatrist Humphry Osmond, means ‘mind revealing’.

What is psychedelic-assisted psychotherapy?

Psychedelic-assisted therapy involves certain approaches to ‘talk-therapy’ alongside the ingestion of a psychedelic compound such as psilocybin, or MDMA. Researchers and clinicians often describe three distinct therapy phases that take place over several days: preparation, the psychedelic experience, and integration. Importantly, the non-psychedelic elements of this approach are essential for both effectiveness and safety.

For how long have psychedelics been in use?

Historians and anthropologists have found that psychedelic agents have been utilised for thousands of years and in various contexts, from the medicinal to the ritualistic. The historical use of psychedelics in the West traces back to Ancient Greece’s Eleusinian Mysteries, a ritualised initiation rite involving what anthropologists believe was a psychedelic drink. MDMA was first synthesised in 1912 by the German pharmaceutical company Merck, and LSD was first synthesised in 1938 by the Swiss chemist Albert Hofmann at Sandoz Laboratories. Sandoz also isolated psilocybin for the first time in 1957. In the 1950s, psychedelic-assisted psychotherapy was regarded by a large proportion of psychiatry as the next big breakthrough for treating mental illness, and was used for a range of conditions in tens of thousands of patients. Thousands of research papers were published on psychedelic therapy between 1950-1972. These documented their application as treatments for depression, anxiety, post-traumatic stress disorder (PTSD), and alcohol dependence.

Why were these substances scheduled alongside drugs like heroin and crack cocaine? How did they get such a bad name?

Psychedelics were scheduled for predominantly political reasons. These centred on former US President Nixon’s ‘War on Drugs’, which was used to suppress the anti-Vietnam war movement. Classical psychedelics and MDMA are currently Schedule 9 drugs in Australia (Schedule 1 in the USA). This category is reserved for substances considered by regulators to be without medical value, and with high abuse potential. Extensive research has shown that psychedelics do not meet either of

these criteria. In addition to unjustified scheduling that has had a global impact through various international treaties, government funding and ethics committee support for research was completely stopped. Given that psychedelic-assisted psychotherapy was establishing itself through the 1950s and 1960s as the 'next big thing' in psychiatry, this censoring of inquiry into such a promising line of research is unprecedented in the modern world. Former US officials within the Nixon administration have since admitted that their scheduling of psychedelics and certain other compounds was an attempt to suppress parts of society that posed a challenge to their world-view and political agenda.

What is the evidence for their effectiveness?

Internationally, there has been a resurgence of research into psychedelics at universities such as Harvard, Johns Hopkins, New York University, Stanford, Imperial College London, and the University of Zurich. Several well-controlled clinical trials have yielded promising results. The new data show that psychedelic-assisted psychotherapy frequently leads to remission from certain mental illnesses within a few doses, when administered with proper psychotherapeutic support before, during and after treatments. The proportion of participants who show positive clinical improvements, and the degree to which they improve, are substantially higher than clinical outcomes associated with currently available treatments.

Are there advantages to psychedelic therapies over available treatments?

Research over the past decade shows that with psychedelic-assisted psychotherapy, patients frequently experience reductions in symptoms within a few sessions, with little in the way of side-effects. This is a striking difference from traditional pharmacotherapy, such as anti-depressants, where patients take medication daily for months, years, or indefinitely, and typically experience unpleasant or problematic side effects.

In terms of 'talk therapy', the time and financial commitment for ongoing mental health treatment can be a barrier for many. More critically, only about half of patients respond to common drug and talk therapies in use today, with a majority of responders continuing to experience sub-diagnostic symptoms during treatment, and high relapse rates.

Psychedelic-assisted therapies have achieved substantially better clinical outcomes than the available talk therapies and drug therapies, with far fewer 'therapeutic doses' required to achieve robust outcomes. Also, they are generally free from the unpleasant or problematic side effects. Further work is needed to investigate how and to what degree clinical outcomes can be sustained following psychedelic-assisted psychotherapy; yet the longer-term data from early studies suggest the outcomes might be sustained longer than available treatments, with avenues to explore further sustaining the change.

How effective are psychedelics compared with current treatments?

Current drug and talk therapies for depression and anxiety work in 40-60% of cases, with high rates of sub-diagnostic symptoms and relapse. In a trial involving participants who had failed to respond

to several different drug and talk therapies, psilocybin-assisted psychotherapy substantially reduced depressive symptoms in over 65% of these ‘treatment-resistant’ patients.

In a trial using psilocybin-assisted-therapy for smoking cessation, 80% of patients had quit smoking six months after the therapeutic sessions, and after one year, that figure was still at 67%. Typically, the current ‘gold-standard’ smoking cessation treatments with similarly addicted participants can hope to achieve around a 20% quit rate at follow-up.

PTSD is notoriously hard to treat, with current anti-depressant pharmacotherapy achieving relief from symptoms in about 20% of sufferers. In recent trials, MDMA-assisted psychotherapy led to remission from PTSD in over 75% of patients who had not previously responded to standard treatments. These trials have informed the current Phase 3 clinical trials, and the FDA’s decision to designate MDMA as a ‘Breakthrough Therapy’, expediting research and the transition to prescription medicine.

How do psychedelics work?

A number of theories have been put forward to account for the therapeutic effects of psychedelics. The most prominent theories are based on recent brain imaging data. One way in which classical psychedelics may help with issues like depressive, addictive, and obsessive disorders is by allowing the brain and mind to ‘break out’ of repetitive and rigid styles of thinking, feeling, and behaving. Psychedelics temporarily alter activity and increase connectivity between novel neural networks within the brain, potentially breaking patients out of pathological patterns of thought and habit.

What do psychedelics do?

In a therapeutic setting, psychedelics frequently produce profound personal or existential insights, feelings of empathy and self-compassion, and a sense of connection or unity with other people, things, and the world in general. Research shows that these characteristics are correlated to therapeutic outcomes and that patients regard these experiences among the most meaningful of their lives. In clinical settings, psychedelic-assisted-psychotherapy creates a fertile ground for change and for restoring patient agency.

What do brain imaging studies tell us about psychedelics?

Brain imaging studies have opened a window into the mechanisms of psychedelic-assisted therapy and the study of consciousness itself. Psychedelics reduce the activity of a ‘hub’ structure in the brain called the Default Mode Network (DMN). The DMN is associated with rumination about the past, daydreaming and autobiography - our ‘self-story’, which can become distorted and overactive in mental illness. By temporarily decreasing the activity of the DMN, psychedelics appear to enable communication among more diverse brain regions, and possibly facilitate an opportunity to break free from dysfunctional beliefs and mental ‘ruts’.

How does MDMA work?

MDMA is known for increasing feelings of trust and compassion whilst decreasing fear and defensiveness, which makes it easier for patients to be able to revisit their traumatic memories

without debilitating anxiety, and to address them in various ways. MDMA-assisted psychotherapy increases a sense of safety and self-compassion, allowing patients to revisit traumatic memories without producing re-traumatisation.

Is MDMA the same thing as the street drug Ecstasy?

MDMA is not the same as 'Ecstasy'. Substances sold on the street may contain MDMA, but frequently also contain unknown adulterants. In clinical studies, pure MDMA has been shown to be safe for human consumption when taken a limited number of times in moderate doses.

How safe are these medicines/therapies?

The risk profile of psychedelics is excellent, with negligible physiological toxicity or abuse potential, and little in the way of side-effects for eligible participants (e.g., people at risk of psychosis, or with cardiac issues, are typically not eligible). The psychological risks need to be better understood and mitigated. To date, modern research trials have done well to select appropriate participants and conduct trials in such a way as to produce impressive levels of safety. While the therapy can be challenging and bring up difficult experiences, these may be crucial to the therapeutic process, and the majority of participants rate the experience as among the top five most important of their lives.

I've heard that psychedelics can induce psychosis or can result in frightening experiences

While psychedelics are powerful substances, and can produce challenging experiences without appropriate support, there is no evidence that psychedelic use is linked to either mental illness or negative health outcomes. A meta-analysis published in the premier journal *Nature* found no link between psychedelic use (not within a clinical context) and psychosis across a cohort of 135,000 people. The researchers found that individuals who had taken psychedelics were not at increased risk of developing 11 indicators of mental-health problems, including: schizophrenia, psychosis, depression, anxiety disorders and suicide attempts. In addition, it was found that lifetime psychedelic use was associated with decreased suicide risk and improved wellbeing. For patients with psychosis risk or other unstable personality issues, psychedelic-assisted psychotherapy may be ineffective or involve complications, and is not recommended – although further research is needed to determine the degree to which safety concerns are warranted. As a matter of caution, patients with these conditions are typically excluded from clinical trials of psychedelic-assisted psychotherapy.

Which mental illnesses are helped by psychedelics - based on recent studies?

So far, psilocybin-assisted psychotherapy has shown great promise in the treatment of depression, anxiety, and addiction in well-controlled Phase 2 clinical trials, with some evidence for successfully treating Obsessive Compulsive Disorder. MDMA-assisted psychotherapy has been successfully used to treat PTSD; early clinical data also suggests application for social anxiety in autistic adults.

What other conditions could psychedelics assist with?

It has been suggested that psychedelics are most helpful in conditions characterised by rigid thoughts and behaviours such as depression, anxiety, addiction, OCD, and eating disorders. Recently, the Psychedelic Research Centre at Imperial College has suggested investigating psychedelics for use in ‘disorders of consciousness’ including acquired brain injury, vegetative states and minimally conscious states. MDMA was originally used in couples’ therapy and for conflict resolution, for which it offers great promise.

When will this therapy be available?

Psilocybin and MDMA have been granted ‘Breakthrough Therapy’ status by the US Food and Drug Administration (FDA), expediting their transition to prescription medicines subject to positive outcomes within current trials. Critical data are expected to be released within the next year from Phase 2b and Phase 3 trials for psilocybin and MDMA respectively. If these confirm the treatments to be effective, MDMA for the treatment of PTSD may become available as early as 2021 in the US and psilocybin for the treatment of depression within the next five years in some countries. MDMA has recently been approved for advanced access (Compassionate Use) in Israel for patients who do not have other treatment options. Likewise, MDMA is pending approval for a similar program (Expanded Access) in the USA.

What research is there still to do?

While psychedelic-assisted therapies have shown some strong clinical results, considerable research is still required to confirm the benefits, ensure best practice and optimise clinical effectiveness. Several large multi-site international ‘Phase 3’ trials of both psilocybin and MDMA will determine whether the promising results seen to date will hold up in larger and more realistic clinical settings.

While classical psychedelics pose negligible toxicity or dependence risks, psychological risks need to be better understood and mitigated. To date, research trials have done well to select appropriate participants and conduct trials in such a way as to produce impressive levels of safety. However, in order to offer these therapies to a much larger proportion of the population, more work is needed to understand psychological risks and how to maintain the currently low levels of adverse events.

More research into the ‘therapeutic mechanisms’ of this approach is essential in order to optimise the effective aspects of the therapy, to understand why some people do not respond clinically, to determine what works best for different mental health conditions, and to prolong the positive change.