MIND MEDICINE AUSTRALIA

Frequently Asked Questions

About Mind Medicine Australia

What is Mind Medicine Australia?
Mind Medicine Australia is a registered charity committed to alleviating the suffering caused by mental illness in Australia through expanding the treatment options available to medical practitioners and their patients.

Why was Mind Medicine Australia launched?
Mind Medicine Australia was established to support research into and enhance the effectiveness and safety of, medicine-assisted psychotherapies, while reducing 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, more than half of all patients do not respond. Therefore, we need to support the most effective and innovative treatments to address this these cases. Over the past decade, medicinal psilocybin and medicinal 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. Read more about the state of mental health here.

Why medicine-assisted psychotherapies?
In major international trials, medicine-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. Read a literature review by Dr. Martin Williams here.

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 Professional Development program?
Knowledge, training and certification will be essential to ensure best practice for medicine-assisted psychotherapies. In partnership with leading organisations overseas and locally, we are establishing a Certificate in Psychedelic-Assisted Therapies (CPAT) program to support the integration of this novel approach into the Australian mental health service sector. The Mind Medicine Australia CPAT will give qualified clinicians the additional skills and awareness they need in order to safely and successfully facilitate medicine-assisted psychotherapies. Instruction will focus on a standardized approach to medicine-assisted psychotherapies that can be integrated with clinicians' existing psychotherapeutic experience and training. The CPAT will include a mix of face-to-face and online learning components.

What are MMA's plans for research?
Mind Medicine Australia supports research that investigates the benefits, mechanisms and risks of medicine-assisted psychotherapies. 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 and appropriate service provision for the therapeutic use of psychedelics alongside psychotherapy. We are not advocating for recreational or other non-clinical use of psychedelics. Nor do we advocate for any changes to the law with respect to non-clinical use. Our primary focus is the support of policies that will result in substantial improvement in mental health treatment outcomes for Australians (remission & response rates). Subject to continued supporting results from clinical trials, Mind Medicine Australia advocates for policies that will enable access to evidence-based medicine-assisted psychotherapies in a manner that is accessible and affordable to all Australians in need.

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 medicine-assisted psychotherapies by:

- Donate **to Mind Medicine Australia** to support Psychedelic Research, Public Education, and Future Therapist Training
- Volunteer in-kind support, products and services
- Sharing our 1 page Mind Medicine Australia fact sheet with key facts and figures about the state of mental health in Australia and Mind Medicine Australia

- Sharing our 2-minute Animation about medicine-assisted psychotherapies far and wide!
- Attending our webinars, screenings and live events, and bringing others along
- Setting up and joining local Mind Medicine Australia Chapters
- Connecting us with people and organisations within the medical fraternity, academia, government, regulatory agencies, philanthropy, and other relevant sectors;
- Reaching out to your local politicians, GPs and other health professionals
- Spreading the word to your friends and networks and share our social media posts
- Sharing the evidence for this treatment approach and contributing to scientific and open conversations about this promising approach.
- Keeping up to date with the latest news about Psychedelic Medicine by accessing information from Mind Medicine's website and subscribing to our regular newsletter.

About Psychedelics

What are psychedelics?

Psychedelics are chemical compounds which temporarily create changes in brain function including shifts in perception, thinking and feeling, which produces an 'altered state of consciousness'. The word psychedelic was coined by British psychiatrist Humphry Osmond, and means 'mind revealing'. 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 related clinical applications. Classical psychedelics appear to produce many of their effects through the activation of a specific serotonin receptor ($5HT_{2A}$), a receptor which research from Imperial College London has linked to enhancing openness and promoting a form of "active coping" in the brain.

What are medicine-assisted psychotherapies?

Medicine-assisted psychotherapies involve 'talk-therapy' alongside the ingestion of a psychedelic compound such as medicinal psilocybin, or medicinal 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, 'kykeon'. 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. Hofmann also isolated psilocybin for the first time in 1957. In the 1950s, medicine-assisted psychotherapies were 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 medicine-assisted psychotherapies were establishing themselves 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 medicine-assisted psychotherapies frequently lead 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. Psilocybin-assisted therapy can lead to remission in 60-80% of cases of anxiety and depression, whereas current existing treatments lead to remission in a maximum of 35-42% of cases. Read a literature review by our Scientific Officer here.

Are there advantages to medicine-assisted psychotherapies over other treatments?

Research over the past decade shows that with medicine-assisted psychotherapies, patients frequently experience a reduction in symptoms within a few sessions, with little in the way of side-effects. This is a striking difference from traditional pharmacotherapy, such as with 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 treatment can be a barrier for many. More critically, only about half of patients respond to the drug and talk therapies in use today, with a majority of responders continuing to experience sub-diagnostic symptoms during and post-treatment, and high relapse rates.
Medicine-assisted psychotherapies have achieved substantially better clinical outcomes than the available talk and drug therapies, with far fewer 'therapeutic doses' required to achieve robust outcomes. Also, they are generally free from unpleasant or problematic side effects. Further work is needed to investigate how, and to what degree, clinical outcomes can be sustained following medicine-assisted psychotherapy; longer-term data from early studies suggest the outcomes might be sustained longer than available treatments, with avenues to explore to further sustain the change.

How effective are psychedelics compared with current treatments?
Current drug and talk therapies for depression and anxiety respond in 35-42% 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 therapy 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 therapy led to remission in 67% of PTSD patients who had not previously responded to standard treatments for an average of 18 years. These trials have informed the current Phase 3 clinical trials, and the FDA's decision to designate MDMA and psilocybin as "Breakthrough Therapies", 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, breaking patients out of pathological patterns of thought and habit. Psychedelics primarily activate the 5HT2a receptor in the brain. Recent research suggests that this receptor aids adaptivity through enhancing sensitivity to context, learning and unlearning, cognitive flexibility and synaptogenesis (new neuronal connections).

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, medicine-assisted-therapies create 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 medicine-assisted psychotherapies 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 therapy increases a sense of safety and self-compassion, whilst decreasing avoidance and defensiveness, allowing patients to revisit traumatic memories without producing re-traumatisation. MDMA has also been shown to decrease the reactivity of the amygdala, reducing the experience of fear associated with traumatic memory, allowing the processing of adverse events in psychotherapy.

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 at therapeutic doses.

How safe are these medicines/therapies?

Overall psychedelics have a good safety profile in both clinical trials and even in population use. There is negligible physiological toxicity or abuse potential, and little in the way of side-effects for eligible participants in trials. While the therapy can be challenging and bring up difficult experiences, these may be crucial to the therapeutic process; the majority of participants rate the experience as among the top five most significant of their lives. While the psychological risks are increasingly better understood and mitigated, fine attention to psychological support and a controlled clinical context is vital. Anxiety during the experience can be ameliorated with careful preparation by the individual and therapist as well as support during the active session. The use of medical monitoring

is also recommended, albeit in over 119 clinical trials thus far, there has been only one slight increase in heart rate as a physical side effect associated with MDMA.

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 contrast, it was found that lifetime psychedelic use was associated with decreased suicide risk and improved wellbeing. For patients with psychosis risk or complex personality disorders, medicine-assisted psychotherapies may involve complications, and is currently not recommended –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 medicine-assisted psychotherapies.

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. New trials are underway for Dementia and Anorexia Nervosa. MDMA-assisted psychotherapy has been successfully used to treat PTSD and addiction; early clinical data also suggests an application for social anxiety in autistic adults.

What does the future look like for medicine-assisted psychotherapies?

This is a hugely exciting field with research to date showing very encouraging outcomes for patients, especially for post-traumatic stress disorder in conjunction with medicinal MDMA and medicinal psilocybin-assisted psychotherapy for end-of-life depression and anxiety and treatment resistant depression. The safety profile and strong effect sizes to date suggest that this could become an extremely important addition to our options for the treatment of severe and enduing maladies of the mind. In partnership with academic and industry leaders, Mind Medicine Australia is working to establish a Centre of Excellence in medicine-assisted psychotherapies - a world leading research institution to innovate the delivery, practice and understanding of medicine-assisted psychotherapies.

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. They may also prove to be helpful with pain relief, immune function and learning 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 a couple of years in some countries. MDMA has recently been approved for advanced access (Compassionate Use) in Israel, Switzerland and the USA for patients who do not have other treatment options.

What research is there still to do?

While medicine-assisted psychotherapies 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.