

THIS MATERIAL IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY AND NOT FOR DISTRIBUTION TO THE GENERAL PUBLIC

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| <p>HOW TO REFER A PATIENT</p> <p>We welcome referrals to our service. When preparing the referral, please take note of the eligibility criteria listed on page 4 and include the client's diagnosis, medications, treatment history and a brief health history. Referrals can be submitted via email or fax.</p> | <p>Contact Empax: T: 1300 539 006 F: (08) 9455 1370 E: info@empaxcentre.com</p> |
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1. INTRODUCTION

MDMA-AT (MDMA-AT) is an emerging treatment for people living with PTSD. MDMA-AT is a structured care program that combines MDMA with specialised psychotherapy to help people process trauma in a safe, supportive environment and is now legally available for patients who haven't found relief through traditional therapies like psychotherapy or medication.

2. HOW MDMA-AT WORKS

MDMA is a psychoactive medicine that, when used in a carefully structured therapeutic setting, can help people feel safer and more emotionally open during therapy. Many people find it reduces fear and emotional defensiveness, which can make it easier to reflect on difficult experiences and engage more fully in the therapeutic process.

Research suggests that MDMA may also support changes in how the brain processes emotions, including temporarily reducing fear responses and supporting emotional regulation. This can allow people to revisit challenging memories with greater emotional safety and flexibility. These effects may help support insight, learning, and ongoing therapeutic work beyond the dosing session, though experiences and outcomes vary from person to person.

3. THE EVIDENCE BEHIND MDMA-AT

MDMA-AT (MDMA-AT) has been tested in several randomised clinical trials, including two large studies of more than 190 adults with PTSD in total.

Across these trials, MDMA-AT consistently produced bigger reductions in PTSD symptoms than therapy with a placebo. In the two largest studies 67% and 71% of people who received MDMA-AT no longer met the criteria for a PTSD diagnosis after treatment, compared with around 32% and 48% of those who received therapy with a placebo (Mitchell et al., 2021; 2023).

The benefits have been strongest for people with long-standing, treatment-resistant PTSD, including military veterans and first responders (Mithoefer et al., 2018).

In Australia, MDMA is not an approved medicine and can only be prescribed through the TGA's Authorised Prescriber Scheme, in approved clinical settings like Empax Centre.

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Our real-world clinical experience at Empax Centre supports these research findings, with similar improvements observed across the wider, more diverse range of patients we see in everyday practice.

4. PROGRAM STRUCTURE AND THERAPEUTIC EXPERIENCE

MDMA-AT is delivered as a staged protocol for the treatment of PTSD, combining pharmacological dosing with structured psychotherapeutic support and oversight by an Authorised Prescriber psychiatrist.

- **Screening and assessment:** Eligibility is established through comprehensive medical and psychological evaluation covering PTSD history and current symptomatology, prior treatment response, cardiovascular status, current medications (with attention to interactions), and mental health history and risk profile. Baseline investigations include routine bloods (with pregnancy testing for those of childbearing potential), urine drug screen, and vital signs (BP, temperature, pulse). Clients deemed unsuitable are offered alternative trauma-informed options and onward referral.
- **Preparation:** Suitable clients are allocated a fixed therapy dyad (two trained therapists). Sessions establish therapeutic rapport, set expectations and boundaries, clarify intentions, build coping tools, and complete safety planning.
- **Dosing:** MDMA is administered in a controlled clinical setting designed to support sustained inward focus. The dyad remains with the client throughout; the Authorised Prescriber psychiatrist provides onsite oversight. Pre-dose safety checks comprise a urine pregnancy dipstick and urine drug screen. The client is monitored until acute effects have substantially subsided and the team confirms psychological stability and physical safety.
- **Integration:** Post-dosing sessions support processing of the dosing experience, translation into behavioural change, and management of any difficult reactions.
- **Follow-up:** Scheduled check-ins at defined intervals support sustained recovery and identify any need for further intervention.

Typical Schedule

Clinical research suggests three dosing sessions, with preparation and integration is associated with the durable outcomes for many people with PTSD.

A typical program includes:

- 2 preparation sessions
- 3 MDMA dosing sessions (each spaced 2 weeks apart)
- 9 integration therapy sessions (i.e. 3 after each dosing session)
- Follow-up check-ins, usually at 3, 6, 9 and 12 months after treatment

A typical MDMA-AT treatment program is shown in Figure 1.

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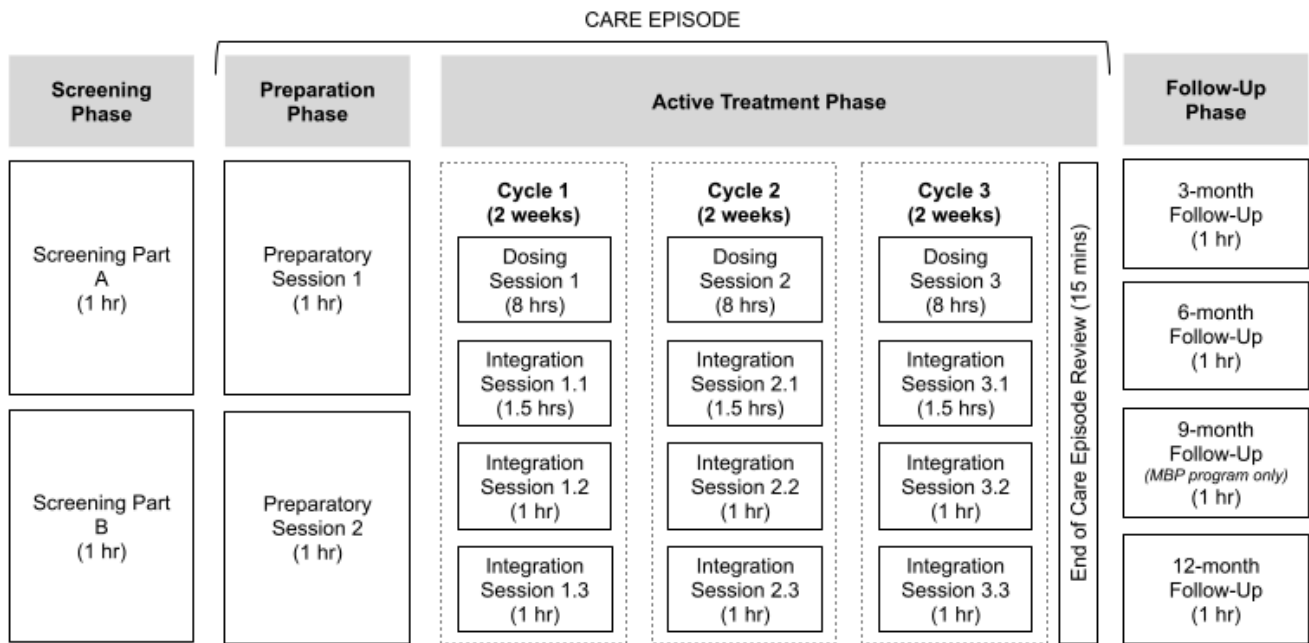


Figure 1: Typical MDMA-AT treatment program

5. COST OF TREATMENT

MDMA is not listed on the Pharmaceutical Benefits Scheme (PBS). The total cost of MDMA-AT typically ranges from \$25,000 to \$35,000. The final fee is determined by the client's personalised treatment plan, which is tailored to their clinical needs and response to care, as well as the specific program requirements set by their individual funder. Current funding options include:

- **Medibank:** Medibank has partnered with Empax Centre and our hospital site partners to fund all costs associated with our PTSD program for eligible Medibank customers (existing and new). Before accessing Medibank funding support, all potential Empax clients must complete two out-of-pocket screening assessments.
- **Medicare:** A Medicare rebate is available for the Eligibility Review and Care Plan with a rebate ranging from ~\$250 to ~\$755. Our team can apply for this benefit on the client's behalf once we have been provided with a valid referral and details of their Medicare card.
- **Mind Medicine Australia (MMA) Patient Support Fund:** The MMA Patient Support Fund subsidises treatment costs for Psychedelic-Assisted Therapy in Australia to support equitable access. The fund can provide up to 50% of treatment to a maximum of ~\$10,000 towards treatment and is available to those with limited assets and income.
- **The Department of Veterans' Affairs (DVA):** DVA has announced funding coverage for eligible veterans, a significant step toward improving access for those with service-related trauma. Coverage has been confirmed for eligible Gold Card and White Card holders with an appropriate diagnosis (e.g., TRD).
- **WorkCover:** Case-by-case funding remains available for patients with treatment-resistant workplace trauma (PTSD/TRD), assessed on clinical need. This includes licensed private insurers (e.g., QBE, GIO) and government insurance schemes.

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6. ELIGIBILITY CRITERIA

MDMA-AT is designed for people who:

- Have a diagnosis of PTSD
- Haven't found relief with traditional treatments like psychotherapy or medication
- Are in generally good physical health, including stable heart function and blood pressure
- Are willing to engage in therapy before, during, and after their MDMA sessions
- Are not currently pregnant or breastfeeding
- Are open to adjusting medications that may interact with MDMA (under medical supervision).

MDMA-AT may not be suitable for people who:

- Have a history of schizophrenia, psychosis, or bipolar disorder type 1
- Have a serious heart condition or uncontrolled hypertension
- Are experiencing a current mental health crisis or severe suicidal thoughts
- Are taking medications that can't be safely adjusted before treatment.

These guidelines exist to ensure client safety. Some medical or psychiatric conditions may increase the risk of adverse effects, while others may interfere with how the medicine works.

7. SIDE EFFECTS & SAFETY MEASURES

MDMA-AT is conducted in a carefully monitored medical setting with a trained clinical and therapeutic team. While most people tolerate the treatment well, it's important to understand that, like all medical interventions, it may come with side effects.

| Timeframe | Possible risks and side effects |
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| Before treatment | <ul style="list-style-type: none"> • Temporary discomfort from blood tests • Mild anxiety or emotional discomfort during medical or psychological assessments. |
| During or soon after dosing | <ul style="list-style-type: none"> • During dosing session: Temporary increased body temperature, heart rate and blood pressure during dosing. Less common: Nausea, tight jaw, dizziness, fatigue, thirst, impaired balance, sensitivity to cold and irritability. • After dosing session: Low appetite, dry mouth, difficulty concentrating, sweating, teeth grinding, and headache. |
| Later the same day or next day | <ul style="list-style-type: none"> • Fatigue, headaches, head pressure or face pain, difficulty concentrating, heavy or tired legs, lack of energy, lack of appetite, changes in mood. • Rare: Body aches/heaviness, irritability, dark thoughts, insomnia, anxiety. |
| Weeks and months post-dosing | <ul style="list-style-type: none"> • While there is no evidence of MDMA abuse and dependence in clinical settings to date, we cannot rule out the possibility of addiction. There is no evidence to suggest clinical MDMA poses a risk of dependency / abuse or addiction potential based upon research outcomes to date. • Some people have difficult psychological material emerge during MDMA |

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| Timeframe | Possible risks and side effects |
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| | <p>dosing, which may take months or longer to resolve. This is less likely with the appropriate screening, preparation and integration therapy offered within this program, however it is possible to have upsetting or confusing experiences that require ongoing counselling to resolve.</p> <ul style="list-style-type: none"> • Side effects associated with anxiety and irritability can include confusion, violent behaviour, suicidal thoughts, and temporary experiences of delusion. There could be associated legal risks, should aggressive or violent behaviour occur in the context of these side effects. • There has only been one serious adverse event in trials of MDMA which resolved, with all other side effects reducing after 24 hours and resolving completely within a week. |
| Rare but serious risks | In rare cases, significant agitation, confusion, suicidal thoughts or unsafe behaviour could occur. This is one reason dosing is delivered in a controlled setting with close monitoring and clear discharge rules. |
| Unknown risks | Pregnancy risks are not well-established. Clients are advised that they must not become pregnant during treatment. |

How We Keep Our Clients Safe

Client safety is our top priority. We have multiple safeguards in place, including:

- Thorough medical and psychological screening before treatment
- Real-time monitoring of heart rate, blood pressure, and overall well-being during sessions
- Video recording of all sessions, for safety and quality purposes
- Post-session care, including requiring the client to nominate a support person to stay with them overnight after each dosing session
- Integration therapy to help clients make sense of their experience and manage any emotional after-effects
- Immediate access to medical care if needed, including medication adjustments or hospital referral in rare cases.

Most side effects are short-lived and resolve within 24–48 hours, but in rare cases, some symptoms can last up to a week. Everyone’s experience is unique; some individuals may have minimal side effects, while others may find certain symptoms more intense.

REGULATORY DISCLAIMER

MDMA is an unapproved product, which is why MDMA-AT is only available under the TGA’s Authorised Prescriber scheme in Australia. Individual results may vary, and participation is based on an eligibility screening. This fact sheet does not replace medical advice; individuals should always consult their healthcare provider for personal guidance.

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