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HOW TO REFER A PATIENT

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.

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1. INTRODUCTION

PSIL-AT (PSIL-AT) is an emerging treatment for people living with treatment resistant depression (TRD). PSIL-AT is a structured care program that combines psilocybin with supportive psychotherapy in a safe environment and is now legally available for patients who have failed to respond to at least two different antidepressant medications.

2. HOW PSIL-AT WORKS

Psilocybin is a naturally occurring psychedelic compound that has shown promise in helping individuals explore deeply rooted emotional patterns, often related to depression, anxiety, or trauma. When paired with therapy, and in an appropriate clinical setting, psilocybin can promote a sense of expanded awareness, emotional release, and connection to a larger sense of meaning or self. This state often allows individuals to access insights that feel both profound and healing, creating the potential for lasting shifts in perspective and behaviour.

Scientific studies suggest that psilocybin also enhances neuroplasticity, which is also believed to aid in the brain's capacity to break free from rigid thought patterns. During PSIL-AT, activity in the brain's default mode network (associated with rumination and self-criticism) tends to quiet down, while connectivity across different brain regions increases. These temporary changes can open a window of opportunity for new ways of thinking and feeling, which, along with supportive therapy, can help build healthier emotional patterns and lift mood over time.

3. THE EVIDENCE BEHIND PSIL-AT

PSIL-AT has been tested in multiple randomised clinical trials of more than 300 adults with depression. Across these studies, just one or two psilocybin sessions, combined with therapy, produced rapid and meaningful improvements in depression symptoms including in people whose depression had not responded to previous treatments.

In one trial, around 71% of participants had their depression symptoms reduced by more than half within four weeks of treatment (Davis et al., 2021). In a larger trial, a single 25 mg dose of psilocybin produced clearly greater improvements in depression than a very low control dose (Goodwin et al., 2022). In a separate trial that compared psilocybin directly with a commonly prescribed antidepressant (escitalopram), the two treatments produced similar improvements on the main

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measure of depression, with psilocybin tending to do better on measures of well-being and the ability to feel pleasure (Carhart-Harris et al., 2021).

Benefits have generally been strongest in the first weeks after treatment, which is why ongoing therapy and integration support remain important.

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

PSIL-AT is delivered as a staged protocol for the treatment of TRD, 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 MDD 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:** Psilocybin 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.

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Typical Schedule

Clinical research typically involves one to three dosing sessions, with preparation and integration is associated with the durable outcomes for many people with TRD.

A typical program includes:

- 2 preparation sessions
- 3 psilocybin 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

Flexible Options

Some patients may benefit from a shorter course (e.g. a single dosing session). The therapy team will discuss the most appropriate plan with the client based on their needs, goals and safety considerations.

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

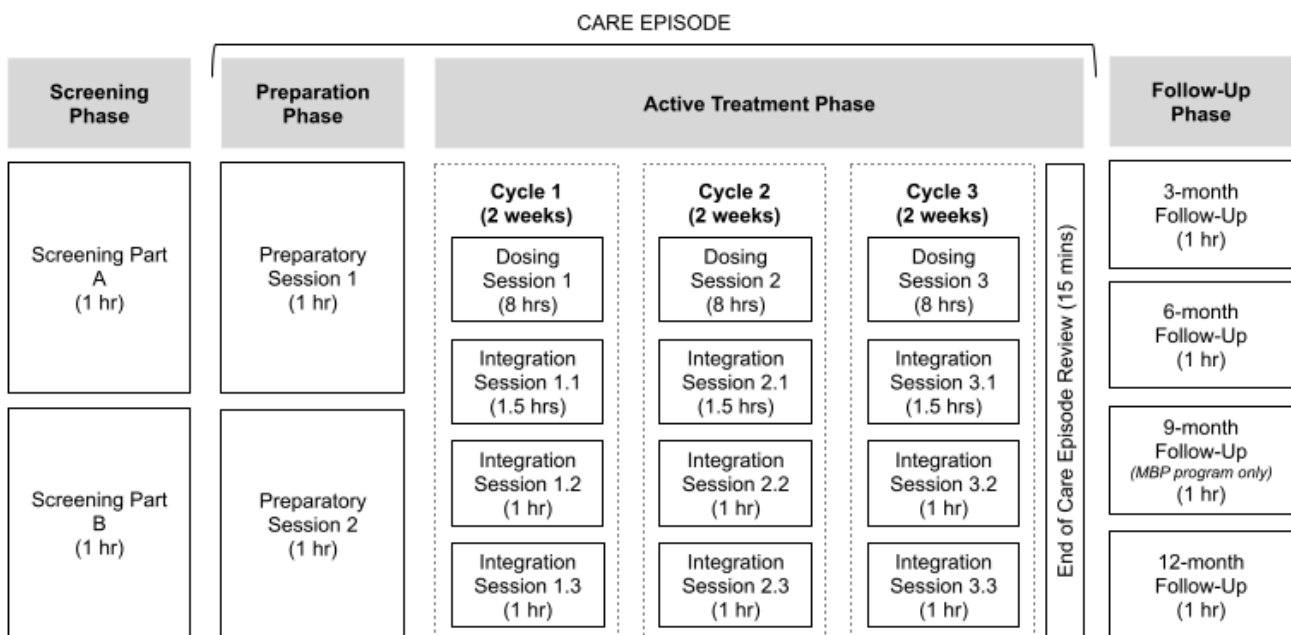


Figure 1: Typical PSIL-AT treatment program

5. COST AND FUNDING OPTIONS

Psilocybin is not listed on the Pharmaceutical Benefits Scheme (PBS). The total cost of PSIL-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:

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- **Medibank:** Medibank has partnered with Empax Centre and our hospital site partners to fund all costs associated with our TRD 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 \$255.90 to \$755.90. Our team can apply for this benefit on your behalf once we have been provided with a valid referral and details of your Medicare card.
- **Mind Medicine Australia Patient Support Fund:** The Mind Medicine Australia Patient Support Fund is a charitable fund which 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 \$10,500 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.

Since each client's financial situation is unique, clients are invited to discuss their treatment options and funding pathways with our team, who are happy to answer any questions and assist with any supporting documentation.

6. ELIGIBILITY CRITERIA

PSIL-AT is designed for people who:

- Have a diagnosis of major depressive disorder
- Have tried and failed to respond to at least two different antidepressant medications
- Are in generally good physical health, including stable heart function and blood pressure
- Are willing to engage in therapy before, during, and after their psilocybin sessions
- Are not currently pregnant or breastfeeding
- Are open to adjusting medications that may interact with psilocybin (under medical supervision)

PSIL-AT is not suitable for people who:

- Have a history of schizophrenia, psychosis, or bipolar disorder type 1
- 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.

If PSIL-AT isn't the right fit, we can support clients with referrals to other trauma-informed treatment options that may better suit their needs and circumstances.

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7. SIDE EFFECTS & SAFETY MEASURES

PSIL-AT is delivered with structured safeguards. Even so, side effects and risks can occur. Most effects are temporary, but some people may experience challenging psychological material that takes time to resolve.

Timeframe	Possible risks and side effects
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"> • Common side effects include nausea, dizziness, headache, fatigue, sweating, mild increase in body temperature, and physical discomfort. Temporary changes in perception, thinking, or emotions are expected. • Psychological side effects include anxiety, panic, fear, or low mood may occur during the session. These experiences are usually short-lived and managed with reassurance and clinical support. • Other possible side effects include temporary increases in heart rate and blood pressure. These are usually within safe limits for healthy individuals but are monitored closely. Rarely, chest pain, shortness of breath, confusion, or neurological symptoms may occur and would require immediate medical review. • People with a personal or strong family history of psychotic or bipolar disorders may be at risk of prolonged psychotic or manic episodes triggered by psilocybin. For this reason, such individuals are excluded from treatment.
Later the same day or next day	<ul style="list-style-type: none"> • Headache, nausea, tiredness, mood fluctuations, or emotional sensitivity may persist into the following day but typically resolve within 24 hours. • Sleep disturbance may occur.
Weeks and months post-dosing	<ul style="list-style-type: none"> • Emotional processing may continue, which can include temporary emotional vulnerability, low mood, or increased sensitivity as insights are integrated in therapy. • Ongoing or worsening psychological symptoms are uncommon and would be managed by the treating team or the patient's usual care providers.
Rare or longer term risks	<ul style="list-style-type: none"> • Mild increases in body temperature can occur; significant overheating is uncommon and managed clinically. • People with certain pre-existing heart conditions may be at risk of abnormal heart rhythms and are excluded through screening. • Psilocybin has a low risk of dependence when used in a controlled therapeutic setting.
Unknown risks	Pregnancy risks are not well-established. Clients are advised that they must not become pregnant during treatment.

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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 for 24 hours 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

Psilocybin is an unapproved product, which is why PSIL-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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