

**YOUR CLINICIAN HAS PROVIDED YOU WITH THIS INFORMATION SHEET TO SUPPORT YOUR DISCUSSIONS ABOUT THE PSILOCYBIN-ASSISTED THERAPY PROGRAM AT EMPAX CENTRE.**

*Please read it at your own pace and bring questions to your appointments.*

## **1. WHAT IS PSILOCYBIN-ASSISTED THERAPY?**

Psilocybin-Assisted Therapy (PSIL-AT) is a structured treatment program for Treatment Resistant Depression (TRD), that combines Psilocybin (a naturally occurring psychedelic compound) with specialised psychotherapy. The goal is to support insight, emotional processing, and therapeutic change in a controlled clinical setting.

During a dosing session, Psilocybin may temporarily alter perception, emotional awareness, and patterns of thinking. This can allow for new perspectives on thoughts, emotions, or experiences, and may help you engage more openly with meaningful or challenging material while supported by a trained therapy team.

Participation is **voluntary** and **requires informed consent**.

### **PSILOCYBIN IS AN UNAPPROVED PRODUCT**

Psilocybin is not registered for use in Australia. At Empax Centre it is provided under the *Therapeutic Goods Act 1989, section 19(5)* through the TGA Authorised Prescriber scheme. This means:

- It can only be provided by an Authorised Prescriber
- It can only be used for approved clinical purposes (e.g. TRD) in a controlled setting
- Because it is unapproved, the TGA and the prescribing doctor can give no guarantee as to the quality, safety and efficacy of the product.

Your clinician will discuss what this means for you, including uncertainties and alternatives. This treatment may still be the best option for you in your particular circumstances.

### **Has this product been approved in other countries?**

Psilocybin is not registered in any jurisdiction at this time. However, it has been the subject of multiple phase 2 clinical trials for TRD (see FAQ section).

## **2. PROGRAM STRUCTURE AND THERAPEUTIC EXPERIENCE**

PSIL-AT at Empax Centre is delivered in stages:

### **A) Screening and Assessment**

Before starting, you will have a comprehensive medical and psychological assessment to determine whether PSIL-AT is appropriate and safe for you. This includes reviewing your:

- depression history and current symptoms
- past treatments and responses
- physical health (including heart and blood pressure)
- current medications (including interactions)
- mental health history and current risks

The following health checks will be performed during the screening phase:

- A sample of your blood will be taken for routine testing, including a test for pregnancy if you are able to get pregnant
- A urine sample will be taken to check for any drugs of abuse
- Your blood pressure, temperature and pulse will be recorded

If PSIL-AT is not suitable, we will discuss other treatment options and referrals.

### **B) Preparation sessions**

If you choose to proceed, you will meet with a designated therapy team of two trained therapists (a “therapy dyad”). Preparation focuses on:

- building trust and therapeutic rapport
- setting expectations and boundaries
- discussing intentions and exploring tools and techniques to support readiness
- safety planning

### **C) Dosing session(s)**

Psilocybin dosing occurs in a private, calm clinical environment. The session is designed to support sustained inward focus and sustained therapeutic engagement.

- Your therapy dyad stays with you throughout the day
- Your Authorised Prescriber psychiatrist is onsite to oversee dosing and ensure safety
- You will remain with the therapy team until the acute effects have substantially reduced and the team is satisfied you are psychologically stable and physically safe

The following health checks will be performed during dosing sessions:

- Urine pregnancy dip stick to confirm you are not pregnant prior to dose administration
- Urine drug screen to confirm you are not under the influence of any prohibited drugs

### **D) Integration session(s)**

Integration sessions help you process what happened during dosing and support changes in daily life. They also help address any difficult reactions that may arise after dosing.

### **E) Follow-up check-ins**

Follow-up sessions are scheduled at set intervals after the program to support ongoing recovery and identity if additional support is needed.

### Typical Schedule (and flexible options)

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

A typical program includes:

- 2 preparation sessions
- 2 Psilocybin dosing sessions (each spaced 2 weeks apart)
- 6 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). Your therapy team will discuss the most appropriate plan with you based on your needs, goals and safety considerations.

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

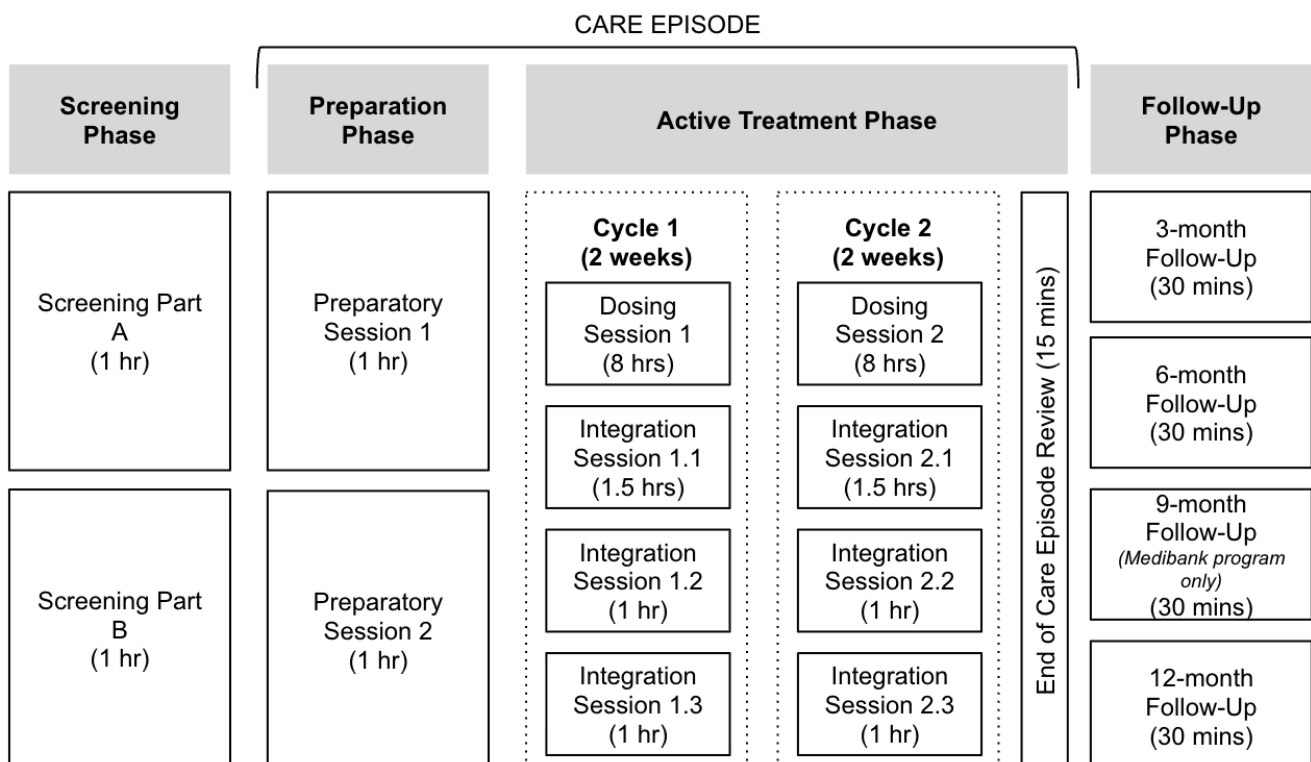


Figure 1: Typical PSIL-AT treatment program

### What Happens on a Dosing Session?

*Times below are indicative and may vary. A dosing session typically lasts 6-8 hours.*

<b>Time</b>	<b>What to Expect</b>
<b>~8 - 9 AM</b>	<p><b>Arrival and settling in</b> This time is spent settling into the room. The team checks in with you emotionally and physically by reviewing and confirming consent plans. Baseline observations may be taken (eg. blood pressure)</p>
<b>~9 AM - 3 PM</b>	<p><b>Administration of Psilocybin</b> Psilocybin is taken orally in capsule form. Effects usually begin within 30 to 60 minutes. Sometimes, a smaller supplemental dose may be offered around 1.5 to 2 hours after the first dose, based on clinical assessment.</p> <p><b>Therapeutic support and monitoring</b> As the effects of Psilocybin develop, you may experience changes in emotional state, bodily sensations, thoughts, or memories. You will be encouraged to attend to your internal experience at your own pace. Your therapy team remains present throughout the session to provide psychological support and ensure safety. This may include verbal guidance or periods of quiet observation depending on your needs and preferences.</p> <p><b>Use of music and sensory supports</b> Music is used during the session using a curated playlist. Some people choose to use an eye mask to reduce external stimulation and support inward focus.</p>
<b>4 - 5 PM</b>	<p><b>Closing the session</b> Around 5-6 hours after dosing, the effects of Psilocybin usually subside. Your therapy team will help you transition out of the dosing experience. You will only leave when the team is confident you are safe to go home with your support person.</p>
<b>Post-session</b>	<p><b>After the session</b> You must go home with a nominated support person and are advised to rest for the remainder of the day. Your first integration session is the following day. <i>You must not drive for 48 hours after Psilocybin administration.</i></p>

### 3. POSSIBLE RISKS AND SIDE EFFECTS

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.

<b>Timeframe</b>	<b>Possible risks and side effects</b>
Before treatment (screening and assessments)	Temporary discomfort from blood tests (e.g. bruising, soreness, or inflammation at the needle site). Some people may experience mild anxiety or emotional discomfort during medical or psychological assessments.
During or soon	<ul style="list-style-type: none"> <li>Common side effects include nausea, dizziness, headache, fatigue,</li> </ul>

<b>Timeframe</b>	<b>Possible risks and side effects</b>
after dosing	<p>sweating, mild increase in body temperature, and physical discomfort. Temporary changes in perception, thinking, or emotions are expected.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> </ul>
Later the same day or next day	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	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"> <li>• Mild increases in body temperature can occur; significant overheating is uncommon and managed clinically.</li> <li>• People with certain pre-existing heart conditions may be at risk of abnormal heart rhythms and are excluded through screening.</li> <li>• Psilocybin has a low risk of dependence when used in a controlled therapeutic setting.</li> </ul>

### **Pregnancy and Breastfeeding**

Pregnancy risks are not well-established. **You must not become pregnant during treatment.**

Tell the team immediately if pregnancy occurs. PSIL-AT is not provided during pregnancy or breastfeeding.

### **4. SAFETY MEASURES AT EMPAX CENTRE**

PSIL-AT at Empax Centre includes multiple measures to reduce risk and support your safety:

- **Thorough medical and psychological screening** prior to treatment, to assess eligibility and identify factors that may increase risk
- **Continuous monitoring** during dosing sessions, including assessment of heart rate, blood pressure, and overall physical and psychological wellbeing
- **Post-session safety requirements**, including the need for a nominated support person to stay with you overnight for approximately 24 hours following each dosing session

- **Scheduled integration therapy sessions**, which provide an opportunity to discuss the experience, address emotional responses, and support ongoing psychological processing
- **Access to medical care** if required, including review by your Authorised Prescriber, medication adjustments, or referral for hospital assessment in rare circumstances

## 5. RULES & RESTRICTIONS WHILST UNDERGOING TREATMENT

To support safety and treatment effectiveness, we ask that you:

- Attend all scheduled sessions and complete required questionnaires
- Nominate a support person to accompany you overnight after each dosing session
- Not start any new psychological therapies during the active treatment phase unless approved by your Authorised Prescriber
- Follow all medication and safety guidance provided by the treatment team.

**Before each dosing day**, the following temporary adjustments are required:

- **Alcohol:** Alcohol is not permitted from midnight the night before dosing
- **Food:** A light breakfast only (for example, a piece of toast) to provide energy but reduce nausea.
- **Caffeine and nicotine:** Avoid for at least 2 hours before and 6 hours after dosing.
- **Medications and supplements:**
  - Do not take non-approved prescription, non-prescription, or herbal medications in the week before dosing.
  - Some regular medications may need to be paused or adjusted. This will be planned with your Authorised Prescriber (and your usual prescriber if needed)
  - If you use opioid pain relief, you may be asked to reduce or pause around dosing with support from the team.

**After each dosing day**, it is important that you:

- Avoid driving, cycling, or operating machinery for at least 48 hours.
- Hold off on making big life decisions or sending emotionally charged messages for a few days.

An **After-Dose Care form** containing further information about how to care for yourself after dosing sessions will be provided to you at your first dosing session.

## 6. COMMUNICATION WITH YOUR USUAL CARE TEAM

PSIL-AT is intended to sit alongside, not replace, other healthcare supports you may be receiving. With your consent, we communicate with your referrer and relevant healthcare providers at key points before, during, and after the program to support continuity of care.

## 7. SUPPORT AFTER YOUR FINAL SESSION

At the conclusion of your treatment and with your consent, your Authorised Prescriber psychiatrist will share appropriate information about the treatment received with your referrer / usual care team. Where helpful, we may recommend next steps such as follow-up therapy, self-care strategies, or referrals.

## 8. WHO TO CONTACT

Contact details will depend on the nature of your inquiry and are summarised below. Please note, your Authorised Prescriber psychiatrist is ultimately responsible for your medical and psychiatric care during the program.

Contact reason	Contact details
For general inquiries, or questions or concerns between sessions that can be managed safely in a timely and coordinated manner	Empax Centre Phone: 1300 539 006 Email: <a href="mailto:clientsupport@empaxcentre.com">clientsupport@empaxcentre.com</a> <i>Please note, Empax Centre is not a crisis service</i>
For mental health emergencies	<ul style="list-style-type: none"> <li>• Western Australia – Mental Health Emergency Response Line (24/7): 1300 555 788</li> <li>• Queensland – Mental Health Acute Response Service (24/7): 1300 642 255</li> </ul>
For medical or psychiatric emergencies	Call 000 or present to your closest Emergency Department.
For concerns about the way treatment was conducted	ACT Health Human Research Ethics Committee Secretariat Phone: 02 5124 5659 Email: <a href="mailto:ethics@act.gov.au">ethics@act.gov.au</a>

## 9. REGULATORY DISCLAIMER

Psilocybin is an unapproved product and is only available through the TGA Authorised Prescriber scheme in approved clinical settings. Any prescribed medicine is for your use only. **Psilocybin must not be shared, sold, or used outside the therapeutic setting.** Misuse or diversion is against the law and may result in serious consequences.

This information sheet does not replace medical advice; please consult your healthcare provider for personal guidance.

## FREQUENTLY ASKED QUESTIONS

**FOLLOWING ARE SOME FREQUENTLY ASKED QUESTIONS ABOUT PSIL-AT. IF YOU HAVE FURTHER QUESTIONS, PLEASE EMAIL [CLIENTSUPPORT@EMPAXCENTRE.COM](mailto:CLIENTSUPPORT@EMPAXCENTRE.COM) OR BRING THEM TO YOUR NEXT APPOINTMENT.**

### 1. HOW DOES PSIL-AT WORK?

Psilocybin is a psychoactive medicine that, when used in a carefully structured therapeutic setting, can temporarily alter perception, thinking, and emotional awareness during therapy. Many people experience a shift in perspective or a sense of increased openness, which can support reflection on thoughts, emotions, and experiences and help people engage more fully in the therapeutic process.

Research suggests that Psilocybin may also support changes in how the brain processes thoughts and emotions, including increasing cognitive and emotional flexibility and reducing rigid or repetitive patterns of thinking. This can allow people to approach challenging experiences or long-held beliefs from a new perspective. These effects may help support insight, learning, and ongoing therapeutic work beyond the dosing session, though experiences and outcomes vary from person to person.

### 2. WHAT IS THE EVIDENCE BEHIND PSIL-AT?

A randomised, double-blind, and placebo-controlled gold-standard [clinical trial](#) tested PSIL-AT on 24 individuals with Major Depressive Disorder (MDD), many of whom had not improved with traditional treatments.

- 71% showed a >50% reduction in depressive symptoms after 4 weeks.
- Just two medication-assisted therapy sessions led to lasting improvements.

Another randomised, dose-ranging, multicentre [clinical trial](#) tested PSIL-AT on 233 individuals with treatment-resistant depression.

- A single 25 mg dose of psilocybin significantly reduced depression symptoms in treatment-resistant patients.

These results prompted the FDA to grant PSIL-AT “Breakthrough Therapy” status in 2018 for treatment-resistant depression (TRD) and in 2019 for MDD, fast-tracking its development.

A subsequent [trial](#) comparing Psilocybin with a commonly prescribed SSRI for depression, escitalopram, found:

- A single dose of Psilocybin was at least as effective as a course of escitalopram in treating depression.
- Greater improvements in well-being and anhedonia (the inability to experience joy or pleasure) in the Psilocybin group.

### **3. WHO IS PSIL-AT FOR?**

PSIL-AT is designed for people who:

- Have a diagnosis of major depressive disorder
- Haven't found relief with traditional treatments like talk therapy 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 Psilocybin sessions
- Are not currently pregnant or breastfeeding
- Are open to adjusting medications that may interact with Psilocybin (your doctor will guide you through this).

PSIL-AT may not be suitable if you:

- 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 your safety. Some medical or psychiatric conditions may increase the risk of adverse effects, while others may interfere with how the medicine works.

### **4. WHO WILL BE WITH ME ON DOSING DAYS?**

On dosing days, you will be supported by two trained therapists who work together as a team (known as a dyad). At least one therapist will remain with you at all times, including during breaks, to ensure you feel supported and safe throughout the day.

An Authorised Prescriber psychiatrist will also be onsite to oversee the medical aspects of treatment and monitor your physical wellbeing. In addition, operational and administrative staff are present to help ensure the day runs smoothly and comfortably.

### **5. WHY DO I NEED A SUPPORT PERSON TO ACCOMPANY ME OVERNIGHT?**

After each dosing session, you are required to have a support person stay with you overnight. Their role is to help provide a calm, safe environment, offer emotional reassurance if needed, and assist with practical tasks such as transport home and attending your next-day integration session.

Having a support person in place helps reduce risks and supports your wellbeing following dosing. The clinical team will discuss these requirements with you in advance and can help you plan for this safely and confidently.

### **6. HOW DO I KNOW IF PSIL-AT WILL WORK FOR ME?**

Every person's experience is unique. Many people with TRD experience significant benefit from PSIL-AT, but outcomes vary. Factors such as your trauma history, psychological readiness, your preparation, and personal circumstances all play a role.

While no one can promise a specific result, our team will offer you every therapeutic tool, safeguard, and support to give you the strongest possible foundation for healing.

**7. I'M WORRIED BECAUSE I DON'T KNOW THE THERAPISTS - WHAT IF I DON'T FEEL CONNECTED?**

This is a completely natural concern. Our experienced therapists are skilled at establishing warmth and trust quickly. Clients often report feeling surprisingly safe and understood within the first session:

*"I was nervous at first but felt at ease within the first session. The therapists understood my worries and made me feel supported right away."* — Empax Patient.

**8. HOW MUCH TIME SHOULD I PLAN TO TAKE OFF WORK?**

The amount of time you'll need to take off work varies depending on your individual circumstances and will be discussed with you during the screening process. As a general guide, most people are ready to return to work within a week of each dosing session. This allows for adequate rest, recovery, and integration, which are key components in maximising the benefits of the treatment.

**9. I'M SUBJECT TO DRUG TESTING AT WORK. WHAT DO I TELL MY EMPLOYER?**

If you choose to disclose your participation, we can provide an explanatory document outlining the clinical context and medical supervision involved in PSIL-AT. This can help prevent misunderstandings around routine workplace drug testing.

**10. WHAT IF I "FREAK OUT" DURING THE SESSION**

Many people worry about becoming overwhelmed, but strong emotions and physical sensations can be a normal part of the therapeutic process. Psilocybin can bring emotions to the surface, and expressing them in a supported setting is often part of how therapy works. Your therapists are trained to help you navigate intense feelings safely and at your own pace, using grounding and reassurance when needed. You will be closely supported and monitored throughout the day, and you will not be left alone at any point.

**11. WHAT HAPPENS AT INTEGRATION SESSIONS?**

Integration sessions help you reflect on your dosing experience and how it connects to your everyday life. Early sessions focus on grounding, emotional support, and settling back into normal routines, with no pressure to find meaning or insights. Over time, integration may explore how changes continue to unfold, support emotional preparation for future dosing (if planned), and help you reflect on what feels helpful or challenging. Integration is a flexible, supportive process that moves at your pace.

**12. WHAT IF I DON'T FEEL THE CHANGE I WAS HOPING FOR?**

Everyone's experience is different, and change can unfold gradually. If things don't feel as expected, you're encouraged to talk openly with your therapists or Authorised Prescriber so the approach can be adjusted if needed. For many people, insights and shifts continue to emerge weeks or months after dosing, especially through integration. You are always free to pause or stop treatment, and there is no obligation to continue if it no longer feels right for you.

**13. HOW MUCH DOES IT COST AND IS FUNDING AVAILABLE?**

Please note that Psilocybin is not listed on the Pharmaceutical Benefits Scheme (PBS). The total cost of PSIL-AT typically ranges from \$12,000 to \$25,000. The final fee is determined by your personalised treatment plan, which is tailored to your clinical needs and response to care, as well as the specific program requirements set by your individual funder, including Medibank or your workers' compensation insurer for example.

Current funding options include:

- **Medibank:** Medibank has partnered with Empax Centre and our hospital site partner, Perth Clinic 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.

If you would like to access additional funding options that are available to you, whether that be through your workers compensation insurer, accessing insurance through your superannuation fund or another option, the team at Empax Centre are happy to assist. We can provide written quotes, complete medical documentation or provide a letter from your Authorised Prescriber.