# SAS-B Application

## Patient Information and Consent Form

**Medicinal Psilocybin-Assisted Psychotherapy for the Treatment of Depression**

**What is Depression?**

The DSM-5 describes depression as “the presence of sad, empty, or irritable mood, accompanied by somatic and cognitive changes that significantly affect the individual’s capacity to function.”.[[1]](#endnote-1) According to Beyond Blue, depression is, if, “for more than two weeks, you’ve felt sad, down or miserable most of the time, or have lost interest or pleasure in usual activities” and have experienced several signs or symptoms such as:[[2]](#endnote-2)

1. Feeling frustrated, overwhelmed or irritable;
2. Withdrawing from close friends and family, relying on alcohol and other sedatives or not going out as much;
3. Having self-critical and harsh internal thoughts;
4. Often being physically run down, tired, sick or have a loss or gain in appetite.

**What are the current treatment options?**

There are a variety of treatment options for depression including pharmacotherapy, psychotherapy and ECT, however, while some patients experience clinical improvement in their symptoms, many still retain their diagnoses, and continue to experience long-term and debilitating symptoms.

Recent studies show that only 35% of sufferers experience remission from pharmacotherapy (primarily anti-depressants) or psychotherapy. 40 - 60% show some response but most experience some continuing symptoms - and between 50 - 80% relapse after treatment stops.[[3]](#footnote-1) Common side-effects of anti-depressants include insomnia, blurred vision, dry mouth, fatigue, GI distress, weight gain, nausea and sexual dysfunction.

**What is medicinal psilocybin-assisted psychotherapy and why could it be helpful?**

Medicinal psilocybin-assisted psychotherapy combines the traditional psychotherapeutic approach with the ingestion of psilocybin within a clinical setting. Psilocybin is a compound that appears to produce many of its effects through the activation of a specific serotonin receptor (5HT2A); a receptor which research from Imperial College London has linked to enhancing openness and promoting a form of “active coping” in the brain. Medicinal Psilocybin alters communication between the brain networks, such as the Default Mode Network (DMN), which are associated with various mental illnesses, enabling patients to ‘break out’ of repetitive and rigid styles of thinking, feeling and behaving.[[4]](#footnote-2)

**What is the current research around medicinal psilocybin-assisted psychotherapy for the treatment of depression?**

Some recent trials have found that the treatment effects of medicinal psilocybin-assisted psychotherapy for the treatment of depression can be sustained at least 6 months. For example, in a recent well-controlled study using psilocybin-assisted psychotherapy, 51 terminally ill patients suffering with depression and anxiety symptoms received two high-dose sessions: following the first psilocybin session, 60% reported a drop in depression symptoms into the normal range, with sustained and improved outcomes 6-months later with 71% of patients reporting remission into normal range.[[5]](#footnote-3)

**What does medicinal psilocybin-assisted psychotherapy for the treatment of depression look and feel like?**

Medicinal psilocybin-assisted psychotherapy occurs within a safe, private space, that’s free from interruption and with minimal external stimuli. During the therapeutic process, two trained specialists will support you throughout the therapy. After consuming the medicinal psilocybin containing capsule, you will be offered music, played through headphones, and are encouraged to wear a facemask. The two therapists are always present and available to support and encourage your healing process. As the medicinal psilocybin begins to take effect, you may experience dizziness and nausea, and may begin to see unusual colours or patterns. You are encouraged to close your eyes, relax and welcome whatever experiences come to you. Trust that you are in safe hands and that any powerful emotions, memories or other experiences are part of the therapeutic process.

You will also be offered the option of your session being recorded. For some people this becomes a valuable record of what happened and can be used for further therapeutic work.

As the dosed therapy session can extend over 6-8 hours, patients are provided with pre-planned meals and private access to a toilet. Plans around accommodation will be discussed with you in advance. The spaces are well-designed and aesthetically pleasing. You will is made aware of all safety measures and equipment put in place to ensure your safety in the unlikely event of a medical complication.

**What are the risks and are there any side effects?**

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. While the therapy can be challenging, and bring up difficult experiences, these may be crucial to the therapeutic process. 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.

According to current research, there is no evidence to suggest that psychedelic use is linked to either mental illness or negative health outcomes. A meta-analysis published in the premier journal Nature 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. 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.

**If you have any further questions or concerns, please raise these with your treatment team.**

Patient name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DOB: \_\_\_\_\_\_\_\_\_

I have been specifically advised of the following:

1. Trauma related memories may surface through the process of medicinal psilocybin-assisted therapy
2. Some clients have experienced reactions during the treatment sessions that neither

they, nor the administering clinician, have anticipated including but not limited to

strong emotional or physical sensations, disorientation, anxiety, nausea, muscle tension.

1. Subsequent to the treatment session, the processing of incidents and/or material

may continue, and dreams, memories, feelings, etc. may surface.

I have considered all the above and I have obtained whatever additional input and/or professional advice I deemed necessary or appropriate.

By my signature below I hereby consent to receiving medicinal psilocybin-assisted therapy as treatment for depression. My signature on this Information and Consent form is free from pressure or influence from any person or entity. I understand I may stop treatment at any time before or after a session and that more than one medicinal psilocybin-assisted therapy session is usually necessary for successful treatment.

Patient Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_

1. https://www.beyondblue.org.au/the-facts/anxiety/types-of-anxiety/ptsd [↑](#endnote-ref-1)
2. https://maps.org/research-archive/mdma/MDMA-Assisted-Psychotherapy-Treatment-Manual-Version7-19Aug15-FINAL.pdf [↑](#endnote-ref-2)
3. Holmes et al (2018) and Cuijpers (2017)

   De Maat et al (2006) Relative efficacy of psychotherapy and pharmacotherapy in the treatment of depression: A meta analysis 16(5): 566-578

   Judd, L. L. (1997). The clinical course of unipolar major depressive disorders. Archives of General Psychiatry, 54(11), 989. [↑](#footnote-ref-1)
4. Schenberg, E. E. S. (2018). Psychedelic-assisted psychotherapy… *Frontiers in pharmacology*, *9*, 733.

   Petri, G., et al(2014). Homological scaffolds of brain functional networks. *Journal of The Royal Society Interface*, 11(101), 20140873. [↑](#footnote-ref-2)
5. Griffiths, R. R. et al. (2016). Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. Journal of psychopharmacology, 30(12), 1181-1197. [↑](#footnote-ref-3)