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PSILOCYBIN IN THE TREATMENT OF DEPRESSIVE DISORDERS: CLINICAL EVIDENCE AND ITS POTENTIAL TO ADDRESS THE GLOBAL MENTAL HEALTH CRISIS - A REVIEW

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ABSTRACT

Introduction: Depressive disorders are one of the greatest public health challenges worldwide, affecting up to 16% of the population over a lifetime and significantly impacting quality of life, disability, and premature mortality. Major depressive disorder (MDD) is a leading cause of disability, despite the availability of numerous treatment options. In 20–50% of patients, traditional pharmacotherapy and psychotherapy become ineffective, leading to a diagnosis of treatment-resistant depression (TRD).
Objective: The objective of this study was to provide a thorough assessment of current research findings evaluating the efficacy and safety of psilocybin-assisted therapy (PAT) in patients with MDD and TRD, with particular emphasis on rapid antidepressant effects and long-term therapeutic potential.
Methods: A literature review was conducted in the PubMed and Google Scholar databases. Keywords related to psilocybin, depression, treatment-resistant depression, and psychedelic-assisted therapy were used.
Results: Psilocybin-assisted psychotherapy is a promising alternative for the treatment of MDD, TRD, and secondary depression. Compared to traditional antidepressants, PAT is characterized by a faster onset of action, symptom reduction often occurs as early as the first week after starting therapy, and the achieved results may persist long-term for up to 6–12 months. In addition, many patients showed improvement in anhedonia, anxiety, and overall psychosocial functioning.
Conclusions: Psilocybin represents a promising therapeutic alternative for patients with severe depression and TRD, offering rapid and lasting antidepressant effects. Its use could significantly change the approach to treating depression, particularly in cases resistant to standard therapies.

KEYWORDS

Psilocybin, Depression, Treatment-Resistant Depression, Major Depressive Disorder, Psychedelic-Assisted Psychotherapy, Psilocybin-Assisted Therapy

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Introduction:

Depressive disorders are among the greatest global public health challenges. In the general population, depressive disorders affect up to 16% of individuals over their lifetime, imposing a substantial burden on both individuals and society (Fiorillo et al., 2025). WHO projections predict that depressive disorders will be the leading cause of morbidity and mortality worldwide by 2030. These disorders will rank first in terms of the overall disease burden. (Malhi et al., 2018; Richardson et al., 2025). Depression is increasingly recognized as a major civilization-related disorder, shaped by rapid socioeconomic transformations and exerting profound consequences not only for individual well-being but also for healthcare systems, workforce productivity, and global public health. The scale and complexity of this burden highlight the urgent need for innovative diagnostic and therapeutic strategies, including the integration of advanced neurotechnologies and digital tools. Modern approaches such as functional magnetic resonance imaging (fMRI) and other neuroimaging techniques are increasingly being explored to improve diagnostic precision, monitor treatment response, and identify neurobiological markers that could guide personalized interventions. Despite the wide availability of numerous approved pharmacological treatments, major depressive disorder (MDD) remains a leading cause of disability and even reduced life expectancy. Clinicians generally recommend antidepressants and psychotherapy as first line treatments; however, they are ineffective in 20-50% of patients (Cleare et al., 2025). These patients are considered to have treatment-resistant depression (TRD). Current U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) guidelines define TRD as the absence of improvement after at least two consecutive, adequate antidepressant trials during a single depressive episode. Compared to the classic form of depression that responds to treatment, TRD is associated with a poorer prognosis, higher mortality

rates, worsening physical health and increased potential healthcare costs for the patient (Fiorillo et al., 2025; Sirés et al., 2025).

The rising prevalence of depressive disorders is also linked to broader social, demographic, and environmental changes, including urbanization, social isolation, and increased exposure to chronic stressors, all of which contribute to both the onset and persistence of depressive symptoms. Depression rarely occurs in isolation, it is often accompanied by anxiety disorders, substance use disorders, and chronic somatic conditions such as cardiovascular disease or diabetes, which further complicates both diagnosis and treatment (Malhi et al., 2018; Richardson et al., 2025). Co-morbid conditions not only worsen clinical outcomes but also place an additional burden on healthcare systems, as patients often require multidisciplinary care and long-term management strategies. Additionally, individuals with TRD often experience recurrent hospitalizations, functional impairment, and significant limitations in occupational and social functioning, underscoring the urgent need for more effective and accessible treatment options (Fiorillo et al., 2025).

The primary therapeutic goal in the treatment of depressive disorders is complete remission of symptoms, which is a fundamental prerequisite for improving the quality of daily life as well as for a favorable long-term prognosis (Rush et al., 2006). The traditional pharmacological model, based primarily on modulation of the monoaminergic system, is associated with the occurrence of the so-called therapeutic lag, that is, the need to wait even several weeks for treatment effects, which in individuals with TRD translates into a risk of further clinical deterioration (Harmer et al., 2017). Low remission rates, the need for repeated treatment and this phenomenon collectively highlight the need for novel therapies with distinct neurobiological mechanisms that enable faster clinical responses (Rush et al., 2006). Psilocybin, currently experiencing a scientific resurgence, offers a promising approach to these challenges by influencing neuronal plasticity and modulating the default mode network (DMN), thereby inducing rapid and sustained antidepressant effects (Vollenweider et al., 2020; Carhart-Harris et al., 2018).

In addition to its effects on neural circuits, psilocybin has been shown to induce profound psychological experiences, often described as “mystical” or “insightful,” which may contribute to its enhanced therapeutic potential by facilitating cognitive and emotional processing (Carhart-Harris et al., 2018; Vollenweider et al., 2020). This dual mechanism, combining neurobiological and experiential elements, distinguishes it from traditional antidepressants and aligns with new models of depression treatment that emphasize network-level dysfunction rather than solely neurotransmitter imbalances (Harmer et al., 2017). Furthermore, clinical studies suggest that psilocybin-assisted therapy may yield clinically significant improvements after just one or two sessions, potentially reducing the need for long-term daily medication and improving treatment adherence (Cleare et al., 2025; Fiorillo et al., 2025). This review discusses the latest clinical trials evaluating the efficacy and safety of psilocybin in patients with major depressive disorder and treatment-resistant depression.

Methods:

We conducted a literature search in late February and early March 2026 using major scientific databases, including PubMed and Google Scholar. The selected articles were carefully assessed and summarized in this review. The keywords used for review included: psilocybin, depression, treatment-resistant depression, depressive disorders, and psychedelic-assisted therapy. Our search covered publications from January 2017 to March 2026 and included relevant earlier studies. Our review included only full-text, peer-reviewed articles in English and Polish. The included studies comprised both original research and review articles. In total, we initially selected 259 publications. Duplicates were removed, followed by screening of titles and abstracts. This process identified 54 full-text articles for eligibility assessment. Ultimately, 38 of the most relevant studies were selected. A key limitation of this review is the heterogeneity of included studies, particularly regarding dosing protocols, control groups and models of psychological support, which may limit the comparability of results across studies.

To enhance the reliability of the selection process, each article was independently assessed by two authors, who compared their ratings and resolved any discrepancies through discussion. Particular attention was paid to methodological rigor, sample size, diagnostic criteria, and the transparency of outcome measures. Studies utilizing neuroimaging or biomarker analysis were also included, provided they made a significant contribution to understanding the mechanisms underlying therapeutic effects. Additionally, we considered the context in which interventions were carried out, such as the setting, the duration of preparatory sessions, and the qualifications of the practitioners, as these factors often influence treatment outcomes. Although the review aimed to include the most representative and methodologically sound studies, the rapid development of this field means that new findings may emerge shortly after the end of our article search period. This dynamic situation underscores the need for continuous updates and cautious interpretation of long-term implications.

Results and Discussion:

Psilocybin:

Psilocybin (4-phosphoxy-N,N-dimethyltryptamine) is a naturally occurring psychoactive alkaloid found in mushrooms of the genus Psilocybe, commonly known as "magic mushrooms" (Kalfas et al., 2023). Psilocybin is a prodrug, meaning it is biologically inactive in its original form. After ingestion, it is rapidly dephosphorylated by alkaline phosphatases and esterases, primarily in the gastrointestinal tract and blood, to its active metabolite psilocin (4-hydroxy-N,N-dimethyltryptamine) which produces psychotropic effects. The active metabolite crosses the blood-brain barrier and can be detected in the bloodstream as early as 30 minutes after administration. Peak plasma concentrations are typically reached within 2–3 hours and the elimination half-life is approximately 3 hours. Psilocin is metabolized in the liver to form O-glucuronide conjugates, which are subsequently excreted in the urine (Kinderlehrer, 2025). A distinguishing feature of psilocybin compared with other psychedelics is its relatively shorter half-life, allowing therapeutic sessions to be limited to 6–8 hours, which enables the entire intervention to be conducted within a single workday (Holze et al., 2021).

The predictability of pharmacokinetics is one of the most desirable and practical advantages of psilocybin-assisted therapy, allowing medical staff to closely monitor patients during the acute psychoactive phase, thereby reducing the logistical burden on both medical staff and patients. Compared to other substances, such as LSD, which may require observation periods exceeding 12 hours, psilocybin allows for greater feasibility of implementation in structured clinical settings (Holze et al. 2021). Additionally, clinical studies demonstrate that oral administration of psilocybin provides relatively consistent absorption profiles under controlled conditions, thereby facilitating dose standardization and ensuring reproducibility of results in subsequent clinical trials (Kalfas et al., 2023).

The Neurobiological Effects of Psilocybin:

The therapeutic effects of psilocybin in depression are primarily mediated through activation of serotonin receptors, particularly the 5-hydroxytryptamine 2A (5-HT2A) subtype. Cortical areas play a key role in mood regulation, perception and emotional processing. It also exhibits high expression of the aforementioned receptors. During the conversion of psilocybin to its active metabolite, psilocin, interactions occur across multiple serotonin receptor subtypes, influencing both its clinical effects and the complex phenomenology of the psychedelic experience. One reason for psilocybin's effectiveness, particularly in treatment-resistant patients, may be related to age-associated changes in the serotonergic system, which is subject to progressive decline. In postmortem studies using neuroimaging (PET), a reduction in the number of serotonin receptors within the prefrontal and temporal cortices has been documented, along with characteristic abnormalities in their expression in a group of elderly patients with depression, in whom an increased number of receptors correlates with reduced levels of serotonin in the extracellular space. In this context, psilocybin may have an advantage due to its direct agonism of 5-HT2A receptors, potentially bypassing impaired serotonin synthesis and transport mechanisms and enabling a therapeutic response in cases where conventional treatments have failed (Dorczok et al., 2025). Furthermore, this receptor-level mechanism differs fundamentally from selective serotonin reuptake inhibitors, whose action depends on the presence of endogenous serotonin. This key difference may explain why psilocybin exhibits high therapeutic potential even in individuals who have previously shown a poor response to many monoaminergic medications (Dorczok et al., 2025). Significant stimulation of 5-HT2A receptors also causes extensive desynchronization of the cerebral cortex, facilitating changes in sensory integration and emotional processing that may support therapeutic cognitive restructuring (Carhart-Harris et al., 2019).

Neural Plasticity:

At the molecular level, activation of serotonergic receptors is associated with increased glutamatergic signaling, thereby promoting neural plasticity. Psilocybin has been shown to activate brain-derived neurotrophic factor (BDNF)-related signaling pathways, which stimulate synaptogenesis and increase dendritic spine density, potentially supporting the restoration of neural circuits affected by atrophy in chronic depression (Jungwirth et al., 2025; Syed et al., 2026). This effect is particularly significant in the treatment of treatment-resistant depression, where prolonged exposure to stress and prolonged depressive episodes are associated with structural reductions in cortical thickness and hippocampal volume. Recent research findings suggest that psychedelic substances may act as psychoplastogens, compounds capable of rapidly enhancing structural and functional plasticity in cortical networks (Schmaal et al., 2017; MacQueen and Frodl, 2011; Ly et al., 2018). Compared to traditional antidepressants, which often require long-term use to induce noticeable neuroplastic changes, psilocybin is capable of initiating these processes within a few hours of administration (Jungwirth et al., 2025). The rapid induction of synaptic remodeling may underlie the rapid antidepressant

response observed in several clinical trials. Furthermore, increased neuroplasticity may create favorable conditions for psychotherapeutic integration, allowing newly formed cognitive and emotional associations to consolidate more effectively following an acute psychedelic experience (Carrhart-Haris et al., 2019).

The Default Mode Network:

Psilocybin influences the reorganization of the brain's functional connectivity, affecting particularly the Default Mode Network (DMN). This network is involved in self-referential thinking and rumination, and its hyperactivity and functional rigidity are associated with depressive symptoms. Psilocybin causes a temporary disruption of the DMN, which in clinical settings manifests with reduced cognitive rigidity and increased functional connectivity between brain regions that do not typically interact (Borgogna et al., 2025; Meshkat et al., 2025).

The process of increased brain entropy leads to a shift in the cognitive characteristics of treatment-resistant depression (Carhart-Harris et al., 2017). Magnetic resonance imaging studies show a transient decrease in network modularity and enhanced communication between separated cortical circuits, which could potentially enable the emergence of new patterns of information processing (Lord et al., 2023).

Such changes may break the recurring negative self-referential loops that are considered a hallmark of depressive thinking. Subjective correlates of these neural effects often include ego dissolution, an altered autobiographical perspective, and increased emotional openness, all of which may contribute to therapeutic outcomes when appropriately supported in clinical settings. Normalization of DMN connectivity has been observed following the resolution of acute medication effects, suggesting that temporary destabilization may facilitate more adaptive long-term network reorganization (Carhart-Harris et al., 2017).

The Window of Plasticity:

The above-mentioned combination of molecular activation of the serotonergic system and systemic reorganization of the DMN results in the creation of "a window of plasticity". It enables patients with TRD to undergo lasting neural and cognitive reconfiguration as well as provide immediate relief from depressive symptoms. Recent studies indicate that psilocybin-induced changes in brain connectivity may contribute to its sustained therapeutic effects, despite its relatively short plasma half-life, suggesting a potential advantage over traditional pharmacotherapies (Konstantinou et al., 2025; Hieronymus et al., 2025). The restoration of neural plasticity appears to play an important role in determining the significant efficacy in overcoming treatment resistance in TRD (Ross et al., 2025).

This concept has become a central element of contemporary theoretical models that explain how the combination of neurochemical effects and long-term psychological transformation influences the effectiveness of psychedelic-assisted therapy. During this transitional period of heightened adaptability, patients may be particularly receptive to therapeutic interventions aimed at changing maladaptive beliefs, patterns of emotional avoidance, and entrenched cognitive schemas (Hieronymus et al., 2025). The long-term persistence of treatment responses suggests that the induced neuroplastic changes may lead to a stable recalibration at the network level rather than merely a temporary reduction in symptoms. This stands in stark contrast to traditional antidepressants, whose effects often depend on consistent, daily dosing (Konstantinou et al., 2025).

Digital tools and neurotechnologies in psilocybin research:

In the latest clinical trials on psilocybin, advanced digital tools and modern neurotechnologies play a significant role, enabling multilevel and simultaneous analysis of brain changes. One such tool is Brain-MGF, a multimodal graph fusion network that analyzes EEG and fMRI data, capturing both electrophysiological and hemodynamic aspects of brain connectivity. This model utilizes adaptive modal fusion, allowing for better differentiation between the effects of psilocybin on the patient's state and control states such as meditation or rest. The results suggest that such approaches, integrating artificial intelligence and graph analysis, can significantly improve the interpretation and precision of studies of psychedelic-induced neural changes (Yap et al., 2025).

Despite the growing importance of biomarkers in medicine, their use in psychiatry remains limited, primarily due to a mismatch between diagnostic categories and their neurobiological foundations. One particular example of this heterogeneity is depression, which encompasses diverse symptom profiles and variable treatment response. Functional magnetic resonance imaging (fMRI) studies in large, multicenter trials suggest that it is possible to distinguish distinct biotypes of depression based on patterns of brain connectivity, primarily within limbic and fronto-striatal networks. These tools enable the development of biomarkers with high sensitivity and specificity, transcending classical clinical classifications, and can also predict response to specific interventions, such as neurostimulation, enabling the development of personalized psychiatry (Drysdale et al., 2017).

Digital tools and various imaging methods play a significant role in characterizing psilocybin's mechanisms of action and predicting therapeutic response in patients with treatment-resistant depression. The use of resting-state fMRI enables a thorough analysis of global brain functional connectivity prior to intervention, leading to the identification of biomarkers of treatment response. Furthermore, the application of machine learning algorithms to neuroimaging data allows for the differentiation of patients who respond to psilocybin treatment and non-responders and the identification of the most predictive connectivity patterns. The use of such tools enhances the potential of personalized medicine in psilocybin-assisted therapy, also providing insight into the neurobiological basis of depression heterogeneity (Copa et al., 2024).

Telepsychiatry:

Telepsychiatry is an effective and comparable method of providing mental health services compared to traditional inpatient care, considering both the quality of clinical assessment and therapeutic outcomes. Considering subtle differences in physician and patient perceptions of teletherapy, overall satisfaction levels are high, and any concerns about a deterioration of the therapeutic relationship are not clearly supported by clinical research. Furthermore, economic analyses indicate that telepsychiatry may be an even more beneficial solution without compromising treatment outcomes. Therefore, it is safe to say that it has the potential to remain a permanent element of modern models of psychiatric care (Hubley et al., 2016).

At the same time, models based on passive monitoring of data from electronic devices are developing, opening up new possibilities for continuous assessment of patient mental state and well-being. Using mobile phones to collect behavioral and environmental data allows for early detection of clinical changes and the implementation of personalized interventions. Current research on this topic suggests significant methodological limitations, insufficient consideration of privacy and data security issues, and a lack of complete integration into clinical practice. Future implementation and further development of these technologies requires interdisciplinary collaboration and the development of standards that can ensure reliability, usability, and clinical acceptability (Cornet et al., 2017).

The importance of integrating psilocybin therapy into broader public health strategies:

Psilocybin may potentially have a beneficial impact on reducing the burden on healthcare systems, as demonstrated by clinical trials and economic analyses of psilocybin-assisted therapy for treatment-resistant depression. Recent results suggest that PAT has proven therapeutic efficacy while demonstrating a favorable cost-effectiveness profile compared to traditional treatments such as pharmacotherapy, psychotherapy, or electroconvulsive therapy. Simulation models using QALY and ICER scales indicate that this therapy can demonstrate real economic value with a high probability of cost-effectiveness and a lower expected social loss than traditional models. Furthermore, more advanced models encompassing various clinical states, such as remission or relapse, demonstrate that, in addition to achieving clinical outcomes, it generates cost savings while simultaneously improving the patient's quality of life. These advantages persist under various analytical scenarios and accumulate over the long term. These results suggest that psilocybin-assisted therapy, when properly implemented, could offer both innovative and cost-effective justification for its introduction into public health strategies. However, its true systemic value depends on further research and cost optimization, as well as effective integration into daily clinical practice (Ziadi et al., 2026; Avaceña et al., 2025).

Discussion:

The findings of recent clinical trials continue to confirm the efficacy of psilocybin-assisted psychotherapy for various types of depression. In a systematic review, Dawood, Hristova, and Péter-Jover showed that psilocybin exhibits a rapid onset of action compared with traditional antidepressants. It produced a marked improvement in symptoms as early as the first day or week after administration, and sustained long-term effects for 6 to 12 months (Dawood et al., 2023). The rapid and effective nature of this mechanism was confirmed by Raison and colleagues in their Phase 2 clinical trial, who showed that administration of a single 25mg dose of psilocybin in combination with psychological support led to a significant drop in MADRS scores from day 8, maintained to day 43, with a sustained response to treatment observed significantly more often in the experimental group - 42% vs. 11% (Raison et al., 2023). The long-lasting effect, especially in the population suffering from treatment-resistant depression, is highlighted by Carhart-Harris and colleagues, who showed the peak therapeutic effect at week 5, where 31% of participants achieved full remission for up to six months without the need for further pharmacotherapy (Carhart-Harris et al., 2018). Goodwin and colleagues demonstrated that psilocybin’s therapeutic effects are dose-dependent. They demonstrated that a 25 mg dose of psilocybin was optimal compared with 10 mg and 1 mg, producing significantly better outcomes after three weeks, including reduced severity of depression and anxiety, as well as improvements in social functioning

and quality of life (Goodwin et al., 2023). In a subsequent study, Goodwin and colleagues demonstrated that psilocybin therapy at a 25 mg dose is safe and effective even in patients concurrently taking SSRIs. After 3 weeks, participants showed a mean reduction of 14.9 points on the MADRS scale and 42.1% achieved full remission, without an increased risk of suicidal behavior. These findings suggest that psilocybin may be safely administered without discontinuation of existing pharmacotherapy (Goodwin et al., 2023). In a randomized clinical trial, Ross and colleagues also confirmed the efficacy of the intervention in studies of secondary depression, where patients with life-threatening illnesses demonstrated that a single 25 mg dose of psilocybin generates high effect sizes compared to placebo and the effects obtained persist for up to 26 weeks (Ross et al., 2025). The results obtained by Rosenblat and colleagues in groups of patients with high clinical complexity appear particularly promising, indicating that psilocybin therapy is effective and safe in individuals with ultra-resistant depression -resistant depression (an average of 11 failed treatment attempts) and comorbid personality disorders, bipolar disorder, or active suicidal ideation. The study demonstrated a large effect size (Hedges' g = 1.07) and a positive association between repeated psilocybin administration and improved antidepressant effect (Rosenblat et al., 2024). However, individual variability in patient response arises, as discussed in the study by Meikle and colleagues in patients with TRD, which showed that despite high efficacy of the treatment, patients' trajectories were varied, from long-term remission (20 weeks) to a symptom relapse or no improvement at all (Meikle et al., 2025). An important context for the observed discrepancies is provided by the meta-analyses by Metaxa and Clarke involving 436 participants, showing that the efficacy of psilocybin is greater in secondary depression compared to primary depression, and that older age and the patient's prior experience with psychedelics are predictors of a better response to treatment (Metaxa and Clarke, 2024). Syed and colleagues, on the other hand, highlight the importance of methodological factors, emphasizing the need to adjust psilocybin dosing according to body weight and to provide sufficiently long-term psychological support. The authors suggest the advantage of non-manualized psychotherapy, which allows the therapist greater flexibility in treatment and also achieves better treatment outcomes in patients with MDD without full-blown treatment-resistant features compared to the TRD group (Syed et al., 2026). Despite promising results, the scientific community recognizes clear limitations in the existing studies referenced by Syed and colleagues, who highlight the standardization of protocols - a critical condition for increasing the likelihood of regulatory approval of the therapy, while also noting that the main shortcoming of the current state of knowledge remains insufficient demographic diversity, as approximately 91% of participants in previous studies were white, limiting the possibility of fully generalizing the study results (Syed et al., 2026). Erritzoe and colleagues addressed the question of whether psilocybin therapy is superior to traditional pharmacological methods in a 6-month observational study. Outcomes following two 25 mg doses of psilocybin were compared with a 6-week treatment regimen of escitalopram (10–20 mg/day) in patients with moderate to severe major depressive disorder (MDD). After six months, both groups showed similar reductions in depressive symptoms; however, psilocybin was associated with significantly better results in terms of social functioning, psychological connectedness and perceived meaning in life. These results suggest that psilocybin therapy may offer additional value beyond the standard effects of treatment with classic antidepressants (Erritzoe et al., 2024). Agrawala and colleagues raised an important organizational aspect in the debate on optimizing care by introducing a model of psilocybin-assisted group therapy for cancer patients with MDD. Studies have demonstrated that 25 mg psilocybin in small groups is safe, effective and potentially feasible in oncology ward settings. The researchers observed a sharp decline in depression scores, with an average reduction of 19.1 points and found that up to half of participants achieved sustained remission within the first week following the session. The results not only provide evidence of psilocybin's efficacy but also demonstrate financial benefits and therapeutic gains through the reduction of existential isolation using a group therapy format. The basis for these clinical successes is psilocybin's high safety profile and good tolerability (Agrawal et al., 2024). As demonstrated by Goodwin et al. and Raison et al., reported adverse effects are generally mild and transient, including headache, nausea and temporary increases in blood pressure (Goodwin et al., 2023; Raison et al., 2023). A key finding from the study by Syed and colleagues is the absence of serious adverse events (SAEs), such as prolonged psychosis (Syed et al., 2026). Contrary to common beliefs regarding high-risk populations, Rosenblat et al. reported no cases of mania induction in patients with bipolar II disorder. In addition, Goodwin et al. found no evidence of serotonin syndrome in patients receiving psilocybin with SSRI medications (Rosenblat et al., 2024; Goodwin et al., 2023). Psilocybin is not associated with addictive potential or withdrawal symptoms, making it favorable compared with traditional pharmacotherapies, which are often linked to adverse effects such as sexual dysfunction or weight gain (Dawood and Pérez-Jovera, 2023). In a randomized clinical trial by Martens et al. involving patients with treatment-resistant depression, the efficacy

of psilocybin at doses of 5 mg and 25 mg was compared with nicotinamide. The 25 mg dose achieved the highest clinical response rate (17.0%), compared with 12.5% for 5mg and 10.6% for nicotinamide. Although the primary endpoint did not reach statistical significance, secondary endpoint analyses suggested a significant reduction in depressive symptom severity, indicating potentially higher efficacy of the 25 mg dose. The authors noted observed adverse effects, such as suicidal thoughts, suggesting the need for further monitoring of the safety of the therapy (Mertens et al., 2026). The analysis by Kaczmarek and colleagues provides evidence that PAP may significantly reduce the severity of anhedonia in the treatment of treatment-resistant depression. They demonstrated a decrease in SHAPS scores as early as 2 weeks after the start of therapy, and these effects persisted for 3–6 months (Kaczmarek et al., 2026). The study by Carhart-Harris et al. also confirmed the therapeutic efficacy of psilocybin in the treatment of depression. The authors demonstrated that the use of psilocybin in patients with moderate to severe treatment-resistant depression, without concomitant cancer was associated with a reduction in symptoms as early as 2 weeks after the start of therapy and the persistence of the effect for at least three months. Eight of the twelve participants achieved complete remission of symptoms after the first week of therapy. After three months, 42% of patients remained in remission, suggesting a lasting therapeutic effect (Carhart-Harris et al., 2016). An economic analysis by Ziadi et al. found that PAT is effective in treating treatment-resistant depression and is approximately $7,000 less expensive than traditional treatment approaches. The analysis estimated a gain of 0.10 QALYs per patient, which could translate over 30 years into 9.87 QALYs and an estimated economic benefit of $215,900. These results may suggest favorable economic value and positive clinical outcomes, although further long-term studies are needed to confirm this hypothesis (Ziadi et al., 2026). Although these findings are promising, the implementation of PAT into routine clinical practice will require standardized protocols, cost optimization and greater demographic diversity in Phase 3 trials, which are required for approval by regulatory institutions like the U.S. FDA and the EMA (Syed et al., 2026).

Table 1. Summary of selected clinical studies on the therapeutic application of psilocybin in psychiatric disorders.

Author (Year)	Population / Study Type	Psilocybin Dose	Efficacy / Clinical Outcomes
Dawood et al. (2023)	Systematic review	Not specified	Rapid onset (1 day–1 week), effects sustained for 6–12 months
Raison et al. (2023)	Phase 2 trial, TRD	25 mg (single dose)	MADRS reduction from day 8 to 43; response rate 42% vs. 11% (placebo)
Carhart-Harris et al. (2018)	TRD	Not specified	Peak effect at week 5; 31% remission up to 6 months
Goodwin et al. (2023)	RCT, MDD/TRD	25 mg vs. 10 mg vs. 1 mg	25 mg most effective; improved depression, anxiety, functioning
Goodwin et al. (2023)	Patients on SSRIs	25 mg	MADRS ↓ 14.9 points; 42.1% remission; no ↑ suicidal risk
Ross et al. (2025)	Secondary depression (terminal illness)	25 mg	Large effect vs. placebo; sustained up to 26 weeks
Rosenblat et al. (2024)	Ultra-TRD + comorbidities	Not specified (repeated dosing)	Large effect size (Hedges' g = 1.07); better outcomes with repeated dosing
Meikle et al. (2025)	TRD	Not specified	Variable response: remission up to 20 weeks, relapse, or no improvement
Metaxa & Clarke (2024)	Meta-analysis (n=436)	Not specified	Greater efficacy in secondary depression; better response in older patients and those with prior psychedelic experience

Author (Year)	Population / Study Type	Psilocybin Dose	Efficacy / Clinical Outcomes
Syed et al. (2026)	Methodological analysis	Weight-adjusted dosing	Better outcomes with flexible psychotherapy; more effective in MDD vs. TRD
Erritzoe et al. (2024)	6-month observational study	2 × 25 mg	Similar symptom reduction vs. escitalopram; better social functioning and meaning in life
Agrawal et al. (2024)	Group therapy (oncology patients)	25 mg	Depression ↓ 19.1 points; ~50% remission within 1 week
Goodwin et al. (2023); Raison et al. (2023)	Safety data	25 mg	Mild AEs: headache, nausea, transient ↑ blood pressure
Syed et al. (2026)	Safety	—	No serious adverse events (SAEs)
Rosenblat et al. (2024)	Bipolar II	—	No induction of mania
Goodwin et al. (2023)	SSRI + psilocybin	25 mg	No serotonin syndrome observed
Martens et al. (2026)	RCT, TRD	25 mg vs. 5 mg	Response: 17.0% (25 mg), 12.5% (5 mg), 10.6% (control)
Kaczmarek et al. (2026)	TRD (anhedonia)	Not specified	SHAPS reduction after 2 weeks; sustained 3–6 months
Carhart-Harris et al. (2016)	TRD	Not specified	8/12 remission after 1 week; 42% remission at 3 months
Ziadi et al. (2026)	Economic analysis	—	~$7,000 cheaper; +0.10 QALYs per patient

Conclusions:

Psilocybin-assisted psychotherapy is emerging as a promising alternative to traditional treatments for major depressive disorder, treatment-resistant depression, and secondary depression. An undeniable advantage of PAT compared to standard methods is its rapid onset of action, reducing symptoms as early as the first week of treatment, with long-term effects lasting up to 6–12 months. This high efficacy is due to a distinct neurobiological mechanism based on the direct activation of 5-HT2A receptors, which allows bypassing the dysfunctional serotonergic system; furthermore, the induction of neuroplasticity and the temporary disintegration of the default mode network enable patients to break free from rigid cognitive patterns and rumination. The observed effects suggest that psilocybin not only suppresses symptoms but may also facilitate a deeper reorganization of cognitive and emotional processes, allowing patients to reassess maladaptive patterns and develop more flexible ways of thinking. An important aspect of this therapeutic approach is the duality of combining pharmacological action with psychological support. Subjective experiences that occur during the acute phase of psilocybin's action appear to play a significant role in treatment outcomes, indicating that the effectiveness of the intervention depends not only on biological mechanisms but also on the context in which it is implemented. Structured preparation, guided sessions, and post-session integration may therefore be essential elements in achieving lasting benefits from psilocybin in reducing the burden on mental health systems. From a clinical perspective, the safety profile observed under controlled conditions appears favorable, and most side effects are transient and manageable. The lack of addiction potential and the limited number of doses required further support the potential usefulness of this method as an alternative to conventional treatments. Despite its promising profile, psilocybin-assisted psychotherapy is not effective in all cases, and variability in patient response remains a significant factor to consider. Some individuals experience long-term remission, while others experience only partial improvement or even relapse over time. This heterogeneity in the effects of psilocybin in psychotherapy suggests that further refinement of patient selection criteria and treatment protocols will be necessary to maximize treatment outcomes and reduce the burden on mental health systems.

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