

# MINI-BRIEF | The Future of the Field: Psychedelic-Assisted Therapy

## PSYCHEDELIC-ASSISTED THERAPY TODAY

In recent years, rigorously-designed research studies have demonstrated substantial potential for certain psychedelic compounds to treat a wide range of mental health and substance use disorders. It is likely that the FDA will approve 3,4-methylenedioxy-methamphetamine (MDMA) for posttraumatic stress disorder (PTSD) and psilocybin for major depression/treatment-resistant depression and/or alcohol use disorder in the coming years, while ketamine is already legally available in off-label use.<sup>1</sup>

The psychedelic compound itself is only one part of the equation, however. Many experts believe that it is the combination of psychotherapeutic support and psychedelic medication that allows patients to heal or experience reduced symptomatology. Notably, many ketamine providers do not offer psychotherapy alongside ketamine treatments, and the importance of psychotherapeutic support in ketamine treatment is a topic of debate among researchers and practitioners.

Most modern clinical studies on psychedelics measure the effects of the medication compared to a placebo while keeping psychotherapeutic protocols constant across study groups. These studies do not evaluate the role that psychotherapy has in shaping patients' experience, outcomes, and safety. As a result, knowledge of "what works" in psychedelic-assisted therapy is based almost exclusively on the experiences and opinions of experts rather than on experimental data. BrainFutures introduces readers to the emerging consensus approach to this treatment modality in our report, [\*An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy\*](#).

As BrainFutures explains in the full report, clinical studies of psychedelics (other than ketamine) typically follow a similar structure. Specifically, the stages of this treatment paradigm are: intake screening and assessment, a series of preparation therapy sessions, one medication session (when psychedelic drugs are administered), and a follow-up series of integration sessions after the psychedelic experience. In many trials, the preparation, medication, and integration series is repeated multiple times over the course of treatment. The patient's mindset (set) as well as the social and physical environment (setting) have a significant impact on the patient's experience during the medication session. Creating a safe environment for the patient throughout the process is also paramount.

In this mini-brief, BrainFutures explores how future research and innovation in psychedelic-assisted therapy can build on this promising model in four key areas: precision and customization, cost reduction, access, and safety.

## PRECISION AND CUSTOMIZATION

At present, psychedelic-assisted therapy is legally available almost exclusively in research settings. Since clinical studies are currently focused on building evidence for the efficacy of psychedelic compounds, psychotherapeutic practices must maintain consistency between patients to avoid introducing extraneous variables. Post FDA-approval, psychedelic-assisted therapy could be customized for each individual patient. Unfortunately, at present there is little research evidence that would help the therapist individualize a treatment plan.

Clinicians need new tools to customize approaches to nearly every element of psychedelic-assisted therapy. Below are factors that could be assessed for each element of the process.

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|--------------------------|--|
| Screening and Assessment | <ul style="list-style-type: none"><li>• The level of risk, both psychological and physiological. Patients could be assigned to evidence-based risk pools based on validated criteria that would ensure comprehensive screening for those at highest risk for harm while removing the burden of unnecessary examinations for those at lowest risk.</li><li>• The best psychedelic medication and/or combination of medications for the patient's symptoms and health profile (assuming future approval of multiple psychedelic compounds)</li></ul> |
| Preparation              | <ul style="list-style-type: none"><li>• Psychological readiness for the medication session</li></ul>   |
| Set & Setting            | <ul style="list-style-type: none"><li>• Optimal patient mindset</li><li>• Aspects of the physical setting that are likely to enhance or inhibit a patient's experience</li></ul>   |
| Integration              | <ul style="list-style-type: none"><li>• Patient's level of "experienced integration," as proposed by Frymann and colleagues (2022),<sup>2</sup> including feeling settled, harmonized, and improved compared to before treatment</li></ul>   |

## COST REDUCTION

BrainFutures estimates that the cost of psychotherapy alone for psychedelic-assisted therapy could be **\$5,300 to \$7,500 per patient**. While the long-term costs associated with psychedelic-assisted therapy may be lower compared to treatment as usual (such as SSRIs and long-term psychotherapy),<sup>3</sup> cost will undeniably be a barrier for many prospective patients, especially in the early years after approval when it is unlikely that most major insurers will immediately offer coverage.

As a result, it is imperative that clinicians and researchers explore methods to reduce costs without sacrificing outcomes. These could include:

- Offering online learning modules or group classes as part of the preparation process instead of relying on one-on-one therapy sessions with licensed mental health care providers
- Reducing the therapist-to-patient ratio from two therapists per patient (as is standard in many clinical trials) either through one-on-one therapy or group therapy during one or more phases of treatment
- Transferring some of the burden of psychedelic integration therapy to community support group contexts instead of clinical settings

## EXPANDING ACCESS

While cost is widely considered to be one of the most important barriers to accessing psychedelic-assisted therapy, there are other issues that also limit patient populations. One major concern is the lack of trained therapists who are qualified to do this work. Additionally, study populations are not representative of the general population, or even the likely patient population. To expand access, researchers must better understand:

- The level of risk relative to potential benefit for patients with comorbidities such as bipolar disorder, borderline personality disorder, or histories of psychosis (family or individual)—all of whom are typically excluded from psychedelic-assisted therapy studies
- Benefits and risks in populations that are underrepresented in current studies, especially nonwhite and non-college educated patients
- The safety and effectiveness of remote preparation and integration psychotherapy for patients who do not live near treatment facilities

## PROMOTING SAFETY

While most psychedelics are generally physically well-tolerated, there are still physical and, more commonly, psychological risks. Safety underlies, and overlaps with, every other element of psychedelic-assisted therapy, so it can be difficult to name specific research needs that are purely related to safety. Many of the topics discussed above, including risk-to-benefit calculations, assessing readiness for the medication session, and risk assessment, are fundamentally about safety.

Additionally, the risk of suicidality came up several times in BrainFutures' research. There is evidence that psychedelic treatment may rapidly reduce suicidality in many patients, yet the association with suicidality appears to be complex. Some experts are concerned that psychedelic-assisted therapy can exacerbate suicidality in some patients. Further research could assess markers or risk factors that would help predict which patients might experience increased or decreased suicidality.

This mini-brief is derived from BrainFutures 2022 report, *[An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy](#)*. Throughout the paper, BrainFutures discusses the need for further research and innovation that will move the field forward toward our vision of equitable access to safe, high-quality psychedelic-assisted therapy.

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<sup>1</sup> Although ketamine is a non-classic psychedelic, it is often referred to as a psychedelic due to similar subjective effects.

<sup>2</sup> Frymann, T., Whitney, S., Yaden, D. B., & Lipson, J. (2022). The psychedelic integration scales: Tools for measuring psychedelic integration behaviors and experiences. *Frontiers in Psychology*, 13. <https://doi.org/10.3389/fpsyg.2022.863247>

<sup>3</sup> Marseille E., Mitchell, J. M., Kahn, J. G. (2022) Updated cost-effectiveness of MDMA-assisted therapy for the treatment of posttraumatic stress disorder in the United States: Findings from a phase 3 trial. *PLoS ONE* 17(2): e0263252. <https://doi.org/10.1371/journal.pone.0263252>