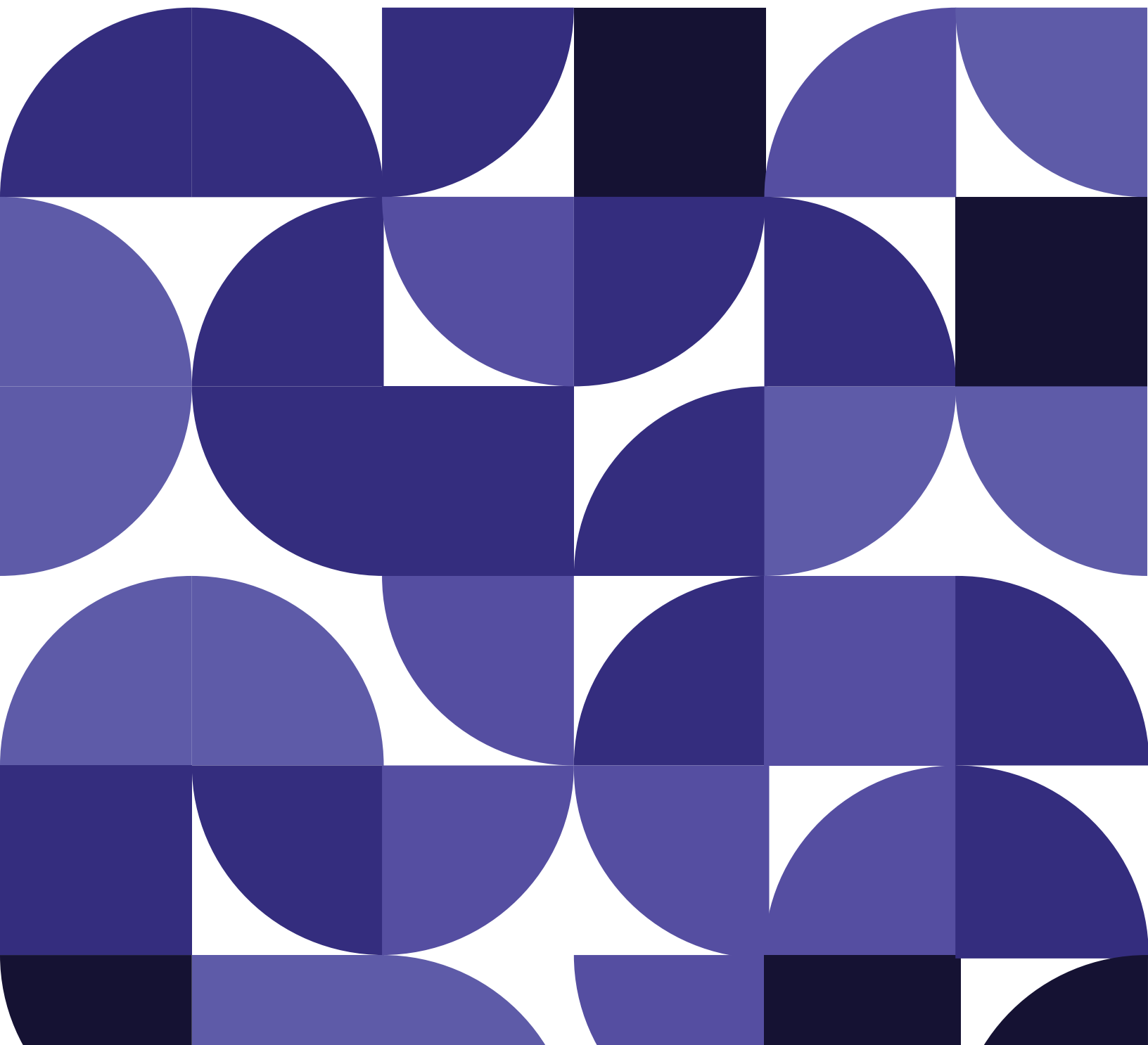


BRAINFUTURES

An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy



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Introduction

It is expected that in the next few years, psychedelic-assisted therapy will become a legal treatment for a variety of behavioral conditions in the United States (Busby, 2022). In anticipation of legal access in clinical settings, in early 2022 BrainFutures released [Psychedelic Medicine](#), a comprehensive review of the clinical literature on psychedelics, which demonstrated notable levels of efficacy in the treatment of conditions as diverse as tobacco addiction and major depression. Following, in [Expediting Psychedelic-Assisted Therapy Adoption in Clinical Settings](#), BrainFutures outlined several major obstacles to bringing this treatment into the United States' medical system, as well as potential solutions. In this final paper in the series, BrainFutures focuses on the psychotherapeutic aspect of psychedelic-assisted therapy.¹

An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy provides an overview of the psychedelic-assisted therapy model that is usually employed in clinical research trials of psychedelic medications. BrainFutures presents the emerging consensus around best practices for psychedelic-assisted therapy in a clinical context as of fall 2022. These conclusions are informed primarily by interviews and input from 22 experts, including academic researchers, clinical trial investigators, and practitioners. We begin by providing a brief overview of treatment designs that have shown efficacy in academic research including studies associated with FDA-approved clinical trials. In the following chapters, we explore the core elements of psychedelic-assisted therapy: screening and assessment, preparation, set and setting, the medication session, and integration. The paper concludes by addressing safety considerations.

Each chapter includes a section entitled “The Future of the Field,” which raises questions about how the current model of psychedelic-assisted therapy might be adapted to increase access and/or improve patient outcomes.

BACKGROUND

Although most psychedelics are currently illegal under federal law, rigorously-designed research studies have demonstrated substantial potential for certain compounds to treat a wide range of mental health and substance use disorders (MH/SUDs). It is likely that the FDA will approve 3,4-methylenedioxy-methamphetamine (MDMA) for posttraumatic stress disorder (PTSD) and psilocybin for major depression and/or alcohol use disorder in the coming years, while ketamine is already legally available in off-label use.² Despite widespread need, with approximately one in five US adults living with mental illness, a new class of psychiatric drugs has not been developed in decades (Mental Health America, 2022; Friedman, 2013). Additionally, psychiatric drugs are the most difficult to develop and get approved by the FDA among any class of non-oncology drugs, so FDA approval for any new psychedelic medication would be a momentous event (Zhu, 2021).

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 patients³ to heal or experience reduced symptomatology. If certain psychedelics become available as medications, BrainFutures anticipates that a large demand for psychedelic-assisted therapy services will follow.

Psychedelic-assisted therapy is distinct from other types of psychotherapy in large part due to the intense experiential effects of psychedelic compounds and often abrupt, life-changing outcomes. As such, psychedelic-assisted therapy requires intensive, *highly-skilled* therapeutic support.

FOCUSING ON PSYCHOTHERAPY

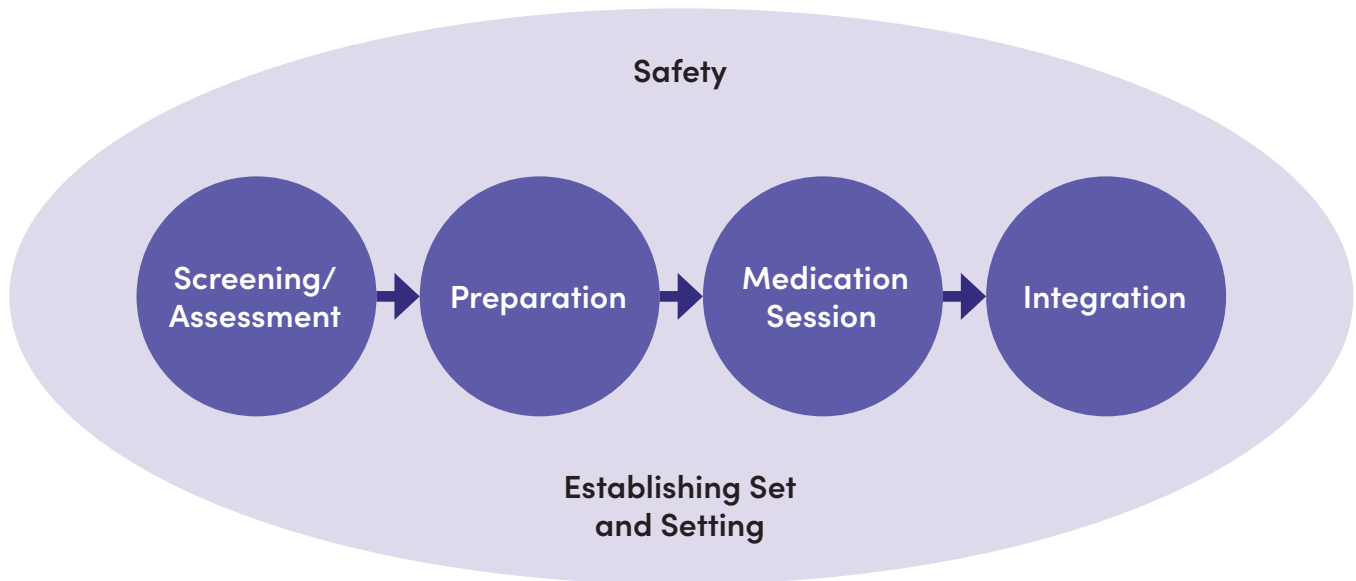
Media attention, research, and capital investment are often focused on the psychedelic medication rather than the extensive therapy accompanying it. In this paper, BrainFutures seeks to focus attention on the critical importance of psychotherapy in psychedelic-assisted therapy.

In clinical studies of psychedelic-assisted therapy for the treatment of conditions such as depression, alcohol use disorder, and PTSD, the psychedelic compound itself is the main variable of interest. Studies typically divide patients into two groups: those who receive therapy and a psychedelic medication, and those who receive the same therapy with a placebo or existing drug for the condition being studied. In many cases, results for the control group (those who do not receive the psychedelic drug) often show improvement, though usually to a lesser degree than patients in the treatment group. For example, after four pre-medication psychotherapy sessions in a recent trial of psilocybin-assisted therapy for alcohol use disorder, both the treatment and control groups reduced their heavy drinking days by about 30 percent (Bogenschutz et al., 2022). At 32-week follow-up, those in the control group maintained these improvements, while those who received psilocybin continued to improve significantly. This phenomenon is a testament to the power of the psychotherapy model that psychedelic therapists practice, while also underscoring the importance of the psychedelic medication for treatment outcomes.

BrainFutures has two main goals for this report. First, we aim to describe the model of psychedelic-assisted therapy that is commonly used in research trials which have shown efficacy for the treatment of MH/SUDs. BrainFutures anticipates that the demand for psychedelic-assisted therapy—and therapists—will increase sharply in the coming years, and many therapists may already be exploring the possibility of incorporating psychedelic-assisted therapy into their practice. Understanding that high-quality therapeutic support is fundamental to the success of psychedelic treatment, we envision this report as a resource for therapists who are considering taking on this new modality (and are therefore weighing additional training) as well as providers who may one day refer patients for psychedelic treatment.

Our second goal is to identify areas where this model of psychedelic-assisted therapy can be improved and expanded. Research on therapeutic methods in psychedelic-assisted therapy is scant, and to our knowledge there have not been any published experimental psychedelic-assisted therapy trials testing one therapeutic method against another, though several researchers have informally shared with BrainFutures that they have plans to design such studies. BrainFutures recognizes that the current model reflects the constraints of clinical research settings and is costly in terms of both time and money. We identify areas where innovation and new research could help customize treatments, expand access, reduce cost, and enhance safety in a series of sections called “The Future of the Field.”

Bringing psychedelic-assisted therapy to scale as it is currently practiced and described in this paper will be extraordinarily challenging. With this report, BrainFutures elevates the emerging consensus around the fundamentals of psychedelic-assisted therapy and calls for new research that will make psychedelic-assisted therapy a realistic option for all patients who could benefit from it.

FIGURE 1: ELEMENTS OF PSYCHEDELIC-ASSISTED THERAPY

Note: Set and setting are established beginning as soon as screening and are a part of the entire psychedelic-assisted therapy process. Similarly, safety is an overarching component that requires consideration at every phase of the process.

CORE ELEMENTS OF PSYCHEDELIC-ASSISTED THERAPY

The *Yale Manual for Psilocybin-Assisted Therapy of Depression* refers to “psychedelic-assisted therapy” as a particular mode of using psychedelic substances in which the effects of the drug, both biological and psychological, play a significant role in facilitating a psychotherapeutic intervention (Guss, Krause, & Slosower, 2020). Clinical studies of psychedelics showing efficacy for treating MH/SUDs typically combine ongoing or targeted psychotherapy with psychedelic medicines. The stages of this evidenced-based

treatment paradigm are intake screening and assessment, a series of preparation sessions, one medication session (when psychedelic drugs are administered), and a follow-up series of integration sessions after the psychedelic experience (Davis & Lampert, 2022). In many trials, the preparation, medication, and integration series is repeated multiple times over the course of treatment. Set and setting (the patient’s state of mind and the physical and social context of the psychedelic medication session) are vital considerations that significantly impact each stage of this process. Creating a safe environment for the patient (both physically and psychologically) throughout the process is also paramount.

METHODOLOGY

BrainFutures conducted interviews with 17 leaders who are influential in the field of psychedelic-assisted therapy. Interviewee credentials include researchers, veteran psychiatrists and psychologists, psychedelic-assisted therapy trainers, and key figures at some of the companies and organizations driving innovation and adoption.⁴ The content below is derived from a synthesis of these interviews and supplemented by published material and comments from five additional expert reviewers. Where direct quotes or ideas from individual experts are included, we reference specific interviewees accordingly. Some quotes are lightly edited for clarity. 🌱

Screening and Assessment

Key Takeaway: In modern research trials, patients are rigorously screened for both psychological and physiological conditions which could complicate treatment or result in exclusion due to safety concerns. After FDA approval, screening procedures may change to broaden access to a larger patient population.

Screening and assessment are essential to determining whether psychedelic-assisted therapy is appropriate for a patient. The process includes a combination of physiological and psychological assessment tools to determine whether a psychedelic compound is indicated for treatment. Screening also determines whether a patient's medical history or use of other drugs are contraindicated with a particular psychedelic medication or psychedelics in general.⁵ Reasons for exclusion during screening may include underlying health conditions that could complicate treatment, including cardiac conditions, co-occurring psychological conditions, and prescription or illicit drug use (Thomas & Malcolm, 2021). Notably, many therapists require patients to be off of antidepressants for six to eight weeks prior to the medication session (A. Getty, personal communication, August 16, 2022).

“Screening and assessment [are] incredibly important,” said Emma Knighton, MA, LMHC.⁶ “A psychedelic-assisted therapy practitioner must have the ability to screen for what's actually important: what kind of medicine, are they ready [for a psychedelic experience], trauma assessment, assess for personality disorders if the referring person doesn't have that expertise, and hopefully an MD will [assess] potential interactions with medication.”

At Johns Hopkins University, where psychedelic research trials are conducted on an ongoing basis, screening includes not only detailed telephone interviews but also an extensive, one-to-two-day physical and psychiatric examination (Cosimano, 2021). This screening process involves medical and psychiatric interviews, physical examination, electrocardiogram (EKG) and blood draws, completion of questionnaires, and interviews with members of the study team (Cosimano, 2021). After approval by the FDA, it is likely that this level of screening may not be deemed necessary. In many clinical trials, including those sponsored by the Multidisciplinary Association for Psychedelic Studies (MAPS), which is currently conducting Phase 3 trials for MDMA to treat PTSD, psychological diagnostic tests to assess symptoms of the targeted condition are also given prior to treatment (Mithoefer & Mithoefer, 2021).

Using research-backed, validated assessment tools such as the clinician-administered PTSD scale for DSM-5 (CAPS-5) for PTSD or the Montgomery-Asberg depression rating scale (MADRS) can help the clinician gain a better understanding of the patient's MH/SUD diagnosis. These instruments should be repeated after treatment in order to track symptom improvement and care efficacy, and can also help with continued treatment innovations. A strong body of evidence shows that tracking symptoms over time using these tools can contribute to better outcomes, even though this approach (known as measurement-based care) is rare in mental health and substance abuse treatment (Fortney et al., 2015).

TRAUMA-INFORMED CARE

Key Takeaway: Psychedelics can often bring up traumatic events for patients, so therapists need to know how to both assess and work with trauma.

Many experts we interviewed agreed that trauma assessment is a crucial element of screening and assessment for psychedelic-assisted therapy. A trauma assessment during the screening phase will inform the therapist of what to explore during preparation and give indications of what may arise during the medication session.

There is a high potential for people with a trauma history to re-experience, process, or become aware of their trauma history while experiencing the effects of a psychedelic, according to the experts we interviewed. Therefore, it can be helpful for psychedelic-assisted therapy practitioners to have specific trauma training. Psychedelic-assisted therapy's capacity to uncover and potentially help transform the patient's relationship to these traumas requires both professional assessment skills and competence working knowledgeably and passionately with patients who have experienced trauma (Vaid & Walker, 2022).

Assuming the patient has a diagnosis for which treatment with a psychedelic drug is appropriate, and both psychological and physiological screenings are completed and all eligibility criteria are met, the patient can move on to preparation for the psychedelic experience. 🌐

THE FUTURE OF THE FIELD: SCREENING AND ASSESSMENT

In research and clinical trial settings, patients are meticulously screened for factors that could complicate or contraindicate treatment with psychedelics. In real-world clinical practice, this level of screening could become prohibitively expensive for many patients who would benefit from psychedelic-assisted therapy. Looking to the future, post-FDA approval, there are a number of important questions about screening that therapists will face, including:

- Are extensive medical tests necessary for all patients, or only some?
 - Can patients be assigned different assessment and testing protocols based on their medical/psychiatric histories and underlying risks?
 - How would these different risk "pools" be determined?
- How will different types of providers share the responsibility for screening?
 - Medical doctors, nurse practitioners, mental health professionals, and technicians may all have a role to play in assessing whether patients are ready for psychedelic-assisted therapy.
- If more than one psychedelic medication becomes available through FDA approval, how will therapists and patients decide which medication is best for their particular situation?

Preparation

Key Takeaway: Preparation is essential to successful psychedelic-assisted therapy and at minimum should include establishing a relationship of trust, educating the patient, obtaining informed consent, and establishing safety measures.

Once a patient passes screening and is cleared for psychedelic-assisted therapy, they begin preparing for the medication session. In current research trials, a typical preparation sequence consists of three 90-minute sessions. However, Annie Mithoefer, BSN, a sub-investigator for MAPS Public Benefit Corporation (which is developing MDMA for PTSD treatment), expressed her hope that the preparation phase would take place over a much longer time horizon, perhaps as part of an ongoing therapeutic process, once psychedelics become available legally for treatment. She explains that for some people, additional time in preparation can reduce anxiety and help them feel more ready for the experience.

The preparation process used by Yale University in psilocybin research trials includes several important components commonly found in treatment protocols. During this phase, the therapist should:

- “develop therapeutic rapport” with the patient
- “gather information about the [patient] and their history”
- educate the patient about the psychedelic experience and “seek to clarify the [patient’s] expectations of the medication session”
- “explain the logistics of the medication session”

- “delineate acceptable boundaries of interaction between the [patient] and the therapist, as well as safety measures” (Guss, Krause, & Sloshower, 2020).

We discuss each of these aspects of preparation, as well as informed consent, in greater detail below.

INFORMED CONSENT

Key Takeaway: Patients must be well-informed before they can consent to treatment. Patients should feel empowered to revoke consent at any time.

Patient education goes hand-in-hand with informed consent. Having clear informed consent processes increases the likelihood of safety, and may also be therapeutic in and of itself because it restores power to patients, according to Knighton. Especially for those who have been victims of abuse or violence, this can empower patients to “own their own safety,” they explain.

In a clinical context, therapists must obtain informed consent as part of the preparation process. The American Psychological Association defines informed consent as “a person’s voluntary agreement to participate in a procedure on the basis of his or her understanding of its nature, its potential benefits and possible risks, and available alternatives” (American Psychological Association, n.d.a).

Supportive touch such as hand holding is often a part of psychedelic-assisted therapy, and patients should explicitly consent to touch prior to the medication session (for further discussion, see “Establishing Boundaries and Safety Measures” below). Some clinicians find it helpful

to explicitly state to their patients that psychedelic therapy is never sexual as part of the establishment of boundaries around touch (Brian Richards, PsyD, personal communication, August 3, 2022).

In addition to a review of the potential benefits and possible risks of psychedelic-assisted therapy, components of an informed consent process could include additional elements such as commitment to treatment protocols. Examples from the *Yale Manual for Psilocybin-Assisted Therapy of Depression* are listed below, though these are all generally standard elements of psychedelic-assisted therapy consent processes.

From the *Yale Manual for Psilocybin-Assisted Therapy of Depression*:

- agreement to attend all preparation and integration sessions
- agreement to complete all evaluation instruments
- compliance with dietary and drug restrictions
- agreement to remain within treatment space during each medication session
- commitment to refrain from self-harm
- commitment to communicate suicidal ideation to therapist(s) or seek emergency room care if self-harm is imminent (Guss, Krause, & Slosower 2019).

After a patient receives this information, they should have ample time to discuss questions that arise and consult with loved ones or other providers. When satisfied with their level of knowledge, the patient should sign the informed consent form.

While signing a consent form is a legal requirement, it should not be seen as the end of the informed consent process. According to Andrew Penn, MS, PMHNP-BC,

“True informed consent is an ongoing, dynamic conversation that tracks the events in the therapeutic relationship. Additionally, it needs to be made clear that consent is an active, not passive process and can be withdrawn at any time by the patient without

having to provide a reason. Lacking this, it can become a subtly coercive force” (personal communication, August 4, 2022).

DEVELOPING THERAPEUTIC RAPPORT

Key Takeaway: Developing a sense of trust between the patient and the therapist is vital to successful psychedelic-assisted therapy.

Universally, experts we interviewed agree that cultivating trust and rapport with the patient is paramount during preparation because of the intense experiential effects of psychedelics, which can put patients in a very vulnerable state. **The relationship between the patient and their therapists, commonly known as the “therapeutic alliance,” is considered to be a cornerstone of psychedelic-assisted therapy and crucial for successful treatment.**

According to Dr. Robin Carhart-Harris, PhD, establishing therapeutic rapport is essential before the medication session:

“We have evidence that the rapport that is felt by the participant with the support people present with them is predictive of outcomes. If the sense of rapport is below a certain threshold, [the therapist] could potentially consider not doing the medication session.”

In a 2022 study, a research team including Carhart-Harris found that “Therapeutic alliance ahead of the second session had a direct impact on final depression scores.” Patients in the study received two psilocybin medication sessions. Notably, emotional breakthroughs during the first session had a sizable positive effect on therapeutic rapport, which in turn reduced depression scores at six weeks post-treatment (Murphy et al., 2022). However, not all patients will experience an emotional breakthrough, and patients should not feel pressured to have one.

Dr. Bill Richards, MDiv, STM, PhD explains that psychedelic-assisted therapy is more than just a drug response; it is how the patient responds to the “invitation that the drug provides.” With a sense of relational safety and trust, patients are able to surrender to and deeply engage in the experience. Without it, the patient may try to control the experience, which could then become overwhelming.

According to Dr. Brian Richards, PsyD,

“Importantly, the patient can consciously ‘choose to trust’ throughout their psychedelic experience. It can be helpful to think of trust as a conscious, volitional process, and encourage patients to readily speak to any rupture that occurs, however seemingly minor. Empowering patients in this way helps create a more collaborative interpersonal dynamic, and can help the patient fully let go, without needing to be vigilant to anything external” (personal communication, August 3, 2022).

Establishing trust with the patient is also critical in order to learn more about the patient and understand their unique case (Penn et al., 2021).

GATHERING PATIENT INFORMATION AND HISTORY

Key Takeaway: Learning more about the patient can inform treatment and support the development of therapeutic rapport.

During preparation, the therapist may try to gain a deeper understanding of the patient’s history with the mental health or substance use disorder for which they are seeking treatment (Guss, Krause, & Slosower, 2021; Penn et al., 2021). This gives the therapist an opportunity to express empathy for the patient’s lived experiences, which in turn helps establish trust and rapport (Guss, Krause, & Slosower, 2021).

According to Dr. Lynnette Averill, PhD, learning about the patient’s history can also

“give the therapist a good sense of what things may come up in the dosing sessions. How the person talks about these experiences can also give great insight into the likely cognitive distortions or beliefs that may be keeping people ‘stuck’” (personal communication, August 22, 2018).

In MDMA trials sponsored by MAPS, therapists also gather information that informs how a patient might react during the medication session and how the therapist might adapt to their preferences. According to Annie Mithoefer, “We ask them what would they like us to know about themselves, besides the trauma. What would make it a safe experience for them?”

“You’re trying to find out what happens when people are stressed,” Mithoefer explains, since anxiety and re-experiencing traumatic events are common during psychedelic-assisted therapy. Notably, the MAPS treatment manual instructs therapists to refrain from asking patients to describe their traumatic history in detail, although if the patient offers that information therapists should be ready to listen (Mithoefer, 2017).

The information gathered during this phase may result in changes to care delivery. According to Dr. Janis Phelps, PhD, if the patient has a complex history she would increase the amount of preparation. “The best therapists I know will insist on four to 10 hours with a person who is in very difficult straits before they will consider whether to use the medicine or not,” Phelps says. By focusing on developing the therapeutic alliance and understanding the individual, the therapist can decide how best to proceed. Changes to the treatment plan may include delaying or canceling the medication session, or adjusting the dose or route of administration. This level of flexibility and individualized treatment will become much more possible outside of the research environment, where protocols must be followed precisely.

EDUCATE THE PATIENT ABOUT THE PSYCHEDELIC EXPERIENCE

Key Takeaway: Patients should be prepared for a range of different experiences and given specific examples of sensations and feelings that may come up during the medication session.

Educating the patient about the range of subjective experiences they might have during the medication session is another important part of the preparation process. The range of non-ordinary states of consciousness and subjective experiences can vary widely during the medication session. Dr. Danielle Schlosser, PhD, senior vice president, clinical innovation at COMPASS Pathways, emphasized the importance of giving patients a window into what their psychedelic experience might be like. In COMPASS clinical trials, patients are given access to prior patients' testimonials, which can give them an idea of the broad possibilities of how a psychedelic experience (in this case, with psilocybin) can "look" and feel. An "orientation" to the psychedelic experience may be particularly important for those who are new to psychedelics, according to Mary Cosimano, LMSW, director of guide/facilitator services at the Johns Hopkins University Center for Psychedelic and Consciousness Research.

Adele Getty, MA, proposed a simple framework outlining three common types of psychedelic experiences:

First: a deep, interpersonal psychodynamic experience that can have profound emotional, psychological, and physical components to it. This experience can be experienced as challenging.

Second: a more objective experience that is insightful, informative, less emotional, and clear in its 'message.' Carrying these insights forward into their everyday life will be an important part of the integration process and aid the person to become a better version of themselves.

Third: the classic mystical experience that carries the patient into the transpersonal dimension where a deep connection with all that is facilitates a blissful state of healing.

Patients may experience elements of all three of these types, and it is not possible to predict ahead of time what any individual's experience will be.

It is important for patients to know that they may experience intense emotional content (Cosimano, 2021). To prepare for this, therapists can proactively reassure the patient that despite what may arise in their perception or physical experience during the medication session, the risk of physical harm is low. Therapists may provide tools and context for navigating the experience, such as recommending patients pay attention to their breath or call to mind aspects of their treatment goals or intention. At Johns Hopkins, Cosimano instructs patients to "accept whatever comes up in the moment [during the medication session], as though one has the belief that what is happening is exactly what is supposed to happen" (Cosimano, 2021). This kind of preparation supports a therapeutic mindset, reduces the risk of unproductive psychological reactions to the experience, and contributes to a meaningful medication session and potential healing.

According to Brian Richards, therapists often teach

"specific practices to help the patient self-regulate the physiology of the stress response and direct attention to the present moment throughout the experience. Intention, breath awareness, and repeated phrases (mantras) can help a patient tolerate and move through aspects of the psychedelic experience that might otherwise be overwhelming. Commonly used mantras include Bill Richards' 'Trust, let go, and be open,' and Ann Shulgin's 'Enter into it and look out through its eyes'" (personal communication, August 3, 2022).

During the medication session, patients may experience intense feelings of shame, guilt, fear, anxiety, or grief based on past experiences, but they should be encouraged to stay with these feelings and experience them fully (Mithoefer, 2017). Common adages used in the psychedelic-assisted therapy field include “the only way out is through” and “trust yourself and trust the medicine.” These perspectives can help patients reorient the medication session by facing what they experience head-on rather than intellectualizing the experience or engaging in behavioral avoidance. Therapists might also remind patients that they have taken medication and that the experience, whatever it may be in the moment, will come and go (Brian Richards, personal communication, August 3, 2022). Understanding and meaning-making may occur in the moment, but will just as likely come in the days and weeks after the medication session as part of integration.

Therapists may also need to manage patients’ expectations about the results of the therapy. Psychedelic-assisted therapy is not a miracle cure, and it may be helpful to educate patients about the range of outcomes they are

likely to have. Profound shifts in patients’ sense of self are also possible, which can affect not only the patient but also their relationships. Patients should be prepared for the possibility that even their closest relationships may change. Navigating these changes can be an important part of the integration process (see “Integration” below). Additionally, patients are often encouraged not to make any major life decisions in the weeks immediately following the medication session while they integrate their experiences and arrive at a new stasis.

MEDICATION SESSION LOGISTICS

Key Takeaway: The therapist will need to explain how the medication session will work and how patients should prepare for it in the preceding days.

In psychedelic-assisted therapy, psychedelic medicines are administered during a multi-hour appointment often referred to as the medication session. Patients should have a clear idea of how the medication session will proceed and how they should prepare for it. This could include instructions about the following:

INNER HEALER

In preparation for the medication session, Michael and Annie Mithoefer of MAPS recommend “talking about the idea of inner healing—preparing the participant and creating safety.”

The concept of an inner healer or inner healing intelligence is commonly found throughout psychedelic literature. It emphasizes connecting patients with their innate ability to heal and grow and seeks to empower patients to take responsibility for their own healing.

The concept was originally developed by Stanislov Grof (1980) and refined by Michael and Annie Mithoefer. Michael Mithoefer defines inner healing intelligence as “a person’s innate capacity to heal the wounds of trauma” (2017). While this definition specifically refers to inner healing in the context of trauma and PTSD, psychedelic therapists have extended the concept to apply to other diagnoses such as depression.

- What to eat before arriving: patients either fast (Mithoefer, 2017) or eat a light, low-fat breakfast due to the potential for nausea
- What to wear: comfortable clothing and layers to accommodate temperature fluctuations
- Reducing stress in the days leading up to and immediately after the medication session
- Refraining from drug and/or alcohol use in the days prior to their medication session
- Discussing use and/or any changes to normal medications
- Making arrangements for transportation to and from the medication session site since patients will not be permitted to drive themselves (L. Averill, personal communication, August 18, 2022)

Additionally, patients should be well-informed about the setting in which medication sessions are conducted. Prior exposure to the treatment room may be useful. A more thorough discussion of the setting, including the physical environment and the use of eyeshades and music can be found in the section titled “Set and Setting” below.

ESTABLISHING BOUNDARIES AND REVIEWING SAFETY MEASURES

Key Takeaway: Patients and therapists should discuss and explicitly agree on boundaries and safety measures prior to the medication session.

Preparation is also the time when the patient and therapist establish agreements for safety and interactions during the medication session. A frank conversation with patients around boundaries and safety during preparation is essential to set the stage for a successful and safe medication session.

In psychedelic-assisted therapy, previously agreed-upon touch can be very reassuring for a patient experiencing anxiety or panic, but it is not appropriate for all patients.

Therefore, experts encourage direct conversations about touch boundaries to establish clear expectations for interactions. For example, the patient and therapist may agree that, if needed, holding a hand or a hand on the shoulder could be supportive, but that hugging would not be wanted by the patient (Mithoefer & Mithoefer, 2021). Therapists must also set clear limits regarding what types of touch they are not willing to offer, even if asked (Brian Richards, personal communication, August 3, 2022).

If the patient has significant trauma, the therapist must navigate language and physical touch skillfully to avoid triggering a trauma response during the session. For example, Barry Walker, MEd, LMHC explains that touch should only be used during the medication session with explicit permission established during preparation. “You don’t know where people have been touched during their lives,” he said. “I would generally keep away from that without permission.” Walker added that simply sitting nearby can be a way to provide support without using touch. Consent for touch can also be revoked by the patient at any time, and the therapist must respect that preference.

In research settings, there are typically multiple safety measures in place to assure patients’ well-being, and patients should be briefed on each of them. These safety measures may include:

- Blood pressure and heart rate monitoring equipment and scheduled checks during the medication session (Guss, Krause, & Slosower, 2020)
- Presence of a medical doctor on site and/or ready access to emergency services and rescue medications
- After-hours contact instructions for the therapist(s) (Mithoefer, 2017)
- Controlling access to the room and setting expectations for when patients are permitted to leave (Johnson, Richards, and Griffiths, 2008)

- Requiring a support person to pick up and provide support for the patient after the session (A. Penn, personal communication, August 4, 2022)
- Video recording of sessions with real-time supervision from lead therapists in a separate control room (Brian Richards, personal communication, August 3, 2022)

See Johnson, Richards, and Griffiths (2008) for an in-depth discussion of safety in psychedelic-assisted therapy.

SUMMARY

Adequate and thoughtful preparation for the medication session is fundamental to the success of the treatment. Once patients and therapists have established trust, discussed the patient's relevant history (to the extent appropriate), and set expectations for the psychedelic experience, logistics, boundaries, and safety measures, they may be ready for the medication session. Both the therapist and the patient should feel they are ready to move forward, and it is important to note that the medication session is not a given for all patients who begin the preparation phase.

Before moving on to therapeutic approaches during the medication session, we must discuss two key elements that create the conditions for successful psychedelic-assisted therapy: set and setting. 🌀

THE FUTURE OF THE FIELD: PREPARATION

As the field of psychedelic-assisted therapy expands, there is much that is still to be learned about preparation. Researchers and therapists might ask:

- Are there ways to reduce costs associated with preparation without sacrificing patient outcomes?
 - For example, education about medication session logistics and the psychedelic experience might be facilitated through online learning modules, in group settings, and/or by technicians rather than one-on-one with licensed mental health professionals. Therapists could consider offering a knowledge quiz to patients to assess their understanding of the process (L. Averill, personal communication, August 18, 2022).
- Is it possible to establish an effective, strong therapeutic alliance through remote psychotherapy sessions? Are there any advantages or disadvantages to remote preparation sessions?
- Do all patients require the same level of preparation? How can therapists objectively assess when a patient is ready for the medication session? Can preparation time be reduced for patients with previous psychedelic-assisted therapy experience?
- Could scientifically validated tools and frameworks be implemented to predict preparedness for the medication experience? Specific tools could assess ego strength, coping skills, and stress and anxiety responses.

Set and Setting

Key Takeaway: The patient’s mindset as well as the social and physical environment have a significant impact on their experience during the medication session.

Set and setting are universally agreed-upon as critical aspects and influencers of effective outcomes among psychedelic researchers and practitioners. Anthropological accounts of indigenous and spiritual traditions that use psychedelics—many of which have existed in some form since the pre-Columbian era—often emphasize the importance of nondrug factors in shaping the participant’s experience (Hartogsohn, 2017). Likewise, early LSD researchers in the 1950s also observed the importance of nondrug factors such as personality and the physical environment in their experiments, but the term “set and setting” was popularized by Dr. Timothy Leary, PhD in the 1960s (Hartogsohn, 2017).

Michael Pollan provides a concise definition of set and setting in his 2018 book *How to Change Your Mind*: “Set is the mind-set or expectation one brings to the experience, and setting is the environment in which it takes place.” This definition is a distillation of Dr. Stanislov Grof, MD’s widely-accepted explanation published in his 1980 book, *LSD Psychotherapy*:

“The term set includes the expectation, motivations, and intentions of the subject in regard to the session; the therapist’s or guide’s concept of the nature of the LSD experience; the agreed upon goal of the psychedelic procedure; the preparation and programming of the session; and the specific technique of guidance used during the drug experience. The term setting refers to the actual environment, both physical and interpersonal, and to the concrete circumstances under which the drug is administered” (Grof, 1980).

There is broad recognition that contextual factors interact with the effects of the drug, including among the experts we interviewed. According to Michael and Annie Mithoefer, “the therapeutic effect [of psychedelic-assisted therapy] is not due simply to the physiological effects of the medicine; rather, it is the result of an interaction among the effects of the medicine, the therapeutic setting, and the mindsets of the participant and the therapists” (Mithoefer & Mithoefer, 2021). Below we discuss some of the key considerations for establishing a therapeutic set and setting.

SUPPORTING THE SET

Key Takeaway: Patients should enter the medication session in a calm, reflective state of mind.

There are a wide range of factors that can influence a patient’s mindset going into the medication session, including personality, cultural context, expectations or concerns about the psychedelic experience, stressors at home or work, and physical condition (Johnson, Richards, & Griffiths, 2008; Callaway, 2021). While many of these factors are outside of the therapist’s sphere of influence, therapists can support a calm, reflective mindset that is considered optimal for psychedelic-assisted therapy through adequate preparation, as described above. It is critical to develop a sense of trust and rapport with the patient, help set expectations about the experience to come, and reduce potential stressors (such as concerns about safety) to the extent possible.

The set also includes the patient’s mood and state of mind on the day of the medication session. If a patient arrives for their medication session in a state of distress,

it may be appropriate to postpone the session until they are more relaxed. This will potentially avoid a challenging or uncomfortable experience, which is thought to be more likely when a patient takes psychedelics in a state of agitation or ill-health (Johnson, Richards, & Griffiths, 2008).

DETERMINING THE SETTING

Key takeaway: Patients should feel safe and comfortable with both the physical and social environments of the medication session.

The setting for a medication session includes both the physical environment and social environment.

The social environment should be welcoming and friendly in order to avoid triggering any additional anxiety or stress. According to Dr. Matthew Johnson, PhD and colleagues at Johns Hopkins University, “It is difficult to overemphasize the importance of the interpersonal atmosphere created by study staff in influencing a volunteer’s response to a hallucinogen” (Johnson, Griffiths, & Richards, 2008).

The physical setting of the medication session is best when the location is familiar and feels physically and psychologically safe. Additionally, Knighton suggested that the setting should be individualized to each patient’s needs and assessed prior to the medication session. Patients are often encouraged to bring in items of personal significance, such as a stuffed animal, blanket, or meaningful photograph to help personalize the space.

Modern research protocols often call for a professional location that is relaxing and comfortable for the medication session. Many researchers use a “living room-like setting” with comfortable couches, soft lighting, and

decorative objects that are designed to make patients feel at ease (Johnson, Richards, & Griffiths, 2008). Therapists may offer a blanket, adjust the room temperature, or offer water as needed to enhance the patient’s comfort (Brian Richards, personal communication, August 3, 2022). Objects imbued with ritualistic or sacred meaning are also often incorporated into the space to the extent they are meaningful to the therapist. However, there is evidence that psychedelic-assisted therapy in a natural setting is also beneficial (Gandy et al., 2020). If a natural context is not possible, incorporating plants into the space or offering a flower as a connection to the natural world is often recommended (Gandy et al., 2020; Brian Richards, personal communication, August 3, 2022).

During the medication session, patients are often given eyeshades and headphones with carefully selected music to facilitate the inward focus of the medication session (Cosimano, 2021). While research on music in the context of psychedelic-assisted therapy is limited, it is intended to facilitate emotional release and processing and evoke mental imagery while also providing reassurance to the patient (Kaelen, 2021). According to Dr. Mendel Kaelen, PhD, “Studies indicate that music-evoked emotion is significantly enhanced under psychedelics, and that music plays a significant role in facilitating personally and therapeutically meaningful emotionality within sessions” (2021). Several experts interviewed by BrainFutures emphasize that music is vital to the psychedelic experience in treatment settings. Some treatment facilities share their playlists with patients after the medication session to help them recall and reconnect with the experience during integration (Brian Richards, personal communication, August 3, 2022).

Safety and security are also important considerations for the setting where the medication session will occur. Locations should be secure to prevent interruption and

also ensure quick access to emergency services in case a need arises during the medication session. Therapists may consider removing potentially harmful objects, such as furniture with sharp corners, and potential disruptions should be minimized (Johnson, Richards, & Griffiths, 2008). Eliminating distraction is particularly important during the medication session when patients are focused on their internal experience.

While a comfortable setting is widely considered to be one of the critical elements of successful psychedelic-assisted therapy, it is important to note that there is little research investigating particular elements of the physical setting design. 🌀

THE FUTURE OF THE FIELD: SET AND SETTING

Despite broad consensus that set and setting are highly influential on patient outcomes, these concepts remain somewhat subjective. Future research could support better outcomes by:

- Establishing validated measures to assess a patient's mindset going into the medication session and tying these measures to the patient's subjective experience and treatment outcomes.
- Further establishing links between aspects of the physical setting (such as access to nature, lighting, etc.) and the patient's subjective experience and treatment outcomes.
- Exploring how the setting can be optimally tailored to the patient's needs and preferences, especially through qualitative research that assesses patients' reactions to treatment settings.
- Understanding how characteristics of the music played during the medication session may influence the patient's experience.

Medication Session

Key Takeaway: During the medication session, the role of the therapist is primarily to support the patient’s inward-focused experience.

Once both the patient and therapist(s) feel that the patient is ready, psychedelic medicines are administered during a multi-hour appointment often referred to as the medication session. Patients take the medication under the supervision of one or more therapists and are usually encouraged to focus on their inward experience. The therapist remains with the patient until the effects of the psychedelic drug have worn off, often six to eight hours.

The therapist’s role during the medication session is to provide support and ensure the patient’s safety while allowing the psychedelic experience to unfold. This may include observing the manifestation of any physical or mental side effects that require a medical intervention. Most experts agree that a highly nondirective approach is called for during the medication session.

THE NONDIRECTIVE APPROACH IN PSYCHEDELIC-ASSISTED THERAPY

Key Takeaway: During the medication session, the therapist provides support and reassurance but generally refrains from attempting to influence the patient’s experience.

According to the American Psychological Association, in nondirective therapy “the therapist or counselor establishes an encouraging atmosphere and clarifies the patient’s ideas rather

than directing the process” (American Psychological Association, n.d.b). In the context of psychedelic-assisted therapy, this means allowing the patient to undergo their own experience and refraining from active guiding and advice-giving. During a medication session, the practitioner is often largely silent unless specifically engaged by the patient, aside from periodic check-ins or medical monitoring.

Annie Mithoefer describes the experience from the therapist’s point of view: “Once the MDMA is there, people in general...have a period of time where you can kind of trust the process. They will go inside and be with the experience.”

Schlosser shared a similar perspective: “Usually in standard psychotherapy there is a whole agenda,” she notes, continuing,

“Instead, in psilocybin therapy, it is elegantly simple: build the relationship, make sure they can trust you and feel safe, and then help them empower themselves so they can have the confidence to encounter anything in their experience; to experience it and not resist it, and to trust that it will lead to whatever it is they need to heal.”

Having previously established safety, trust, and rapport, the practitioner can rely on these foundations to gently support the patient should they encounter experiential challenges, such as feeling physically uncomfortable or frightened, recalling trauma, or having other unpleasant visions or experiences. This strategy rests on the concept of the inner healer, as previously discussed in the section titled “Educate the Patient about the Psychedelic Experience.” When the therapist remains supportive without interfering, it can allow the patient to discover

“the answer within, and that answer is most helpful when the participant discovers it on his or her own,” according to Cosimano (2021).

Bill Richards uses the analogy of midwifery to describe the therapist’s role:

“The therapist functions like a skilled midwife, stepping in at times for reassurance, but otherwise turning off the rational mind and resisting labeling everything while it is happening; not judging or pathologizing, but meeting them where they are and walking beside them while also providing grounding.”

Once the medicine experience diminishes to the point where the patient has returned to normal waking consciousness, more dialogue, direction, reflection, and processing can begin to take place. Many practitioners encourage their patients to journal, recalling as much of the experience as possible and recording the salient aspects of the experience which can then be used during integration to move towards healing goals and outcomes.

MEANING, SPIRITUALITY, AND HEALING

Key Takeaway: Spiritual and other meaningful experiences are common during the medication session and may be a factor that contributes to positive outcomes.

Several of the experts BrainFutures interviewed spoke to the mystical or spiritual nature of their work. Psychedelics can induce a state of ego dissolution at the high doses often used in research and clinical trials, producing profoundly meaningful subjective experiences that affect participants well after the medication session (Vaid and Walker, 2022).

Many modern participants in psychedelic-assisted therapy studies rank the experience among the most meaningful and/or spiritually significant experiences of their lives

THE FUTURE OF THE FIELD: MEDICATION SESSION

In many recent research trials, two therapists support the patient during the medication session, in part as a safety measure to protect patients from potential abuses (see “Safety and Ethical Practice” in this report). However, this could create access barriers by increasing the cost of psychedelic-assisted therapy. Future research could explore:

- Are two therapists necessary for all patients and in all circumstances? Are outcomes and safety measurably affected by the number of therapists present?
- Many cultures have traditionally used psychedelics in group settings as part of rituals. Can psychedelic-assisted therapy be successfully administered in group settings within the medical model? How can existing protocols be adapted and optimized for groups?
- Could multiple psychedelic medications be combined during treatment, and if so under what circumstances would this be beneficial (or harmful)?
- Can evidence-based protocols be developed to help therapists decide when further medical intervention is necessary during a medication session?

(Agin-Liebess et al., 2020; Johnson et al., 2016). Seminal research on psychedelics by Dr. Roland Griffiths, PhD, Bill Richards, and colleagues at Johns Hopkins University gives strong evidence that powerful mystical experiences are common in psychedelic-assisted therapy with psilocybin (Griffiths et al., 2008). Importantly, researchers have linked the experience of a mystical state during psychedelic dosing sessions to positive research outcomes (Ross et al., 2016). In psychedelic-assisted therapy, a profound, meaningful, and/or spiritual experience is therefore welcomed as one factor that may support healing. 🌱

Integration

Key Takeaway: Integration helps patients assimilate the insights of the psychedelic experience into their daily life and gain longer-term mental health benefits. It can also help patients process their experience and arrive at new, sometimes life-changing perspectives.

The psychedelic experience can be powerful, awe-inspiring, frightening, joyful, or all of these. According to Ingmar Gorman, PhD and colleagues in a 2021 paper on psychedelic harm reduction and integration, “Psychedelic integration is a process in which the patient integrates the insights of their experience into their life.” Experts believe that integration is crucial, and early evidence suggests that adequate integration may be a key factor that allows patients to realize the benefits of psychedelic-assisted therapy (Amada & Shane, 2022; Watts et al., 2017).

After the medication session, modern research protocols typically call for a sequence of three or more psychotherapy sessions that constitute the integration phase of psychedelic-assisted therapy (a total of four to seven hours). Integration may begin as soon as the morning following the medication session and often stretches over the course of a few weeks.

Notably, after FDA approval integration may not necessarily be limited to a short series of sessions. At the California Institute for Integral Studies (CIIS), where Phelps leads the Center for Psychedelic Therapies and Research (CPTR), faculty train future psychedelic therapists to work with patients on an ongoing basis in which psychedelic medication sessions will be “woven in” with

other methodologies rather than following a short-term sequence of preparation, medication, and integration as is typical of research studies. In this scenario, therapists would continue integration as long as it benefits the patient.

Where the approach to therapeutic support during the medication session is generally nondirective, during integration the therapist may take a more directive approach, often utilizing a specific therapeutic framework such as Acceptance and Commitment Therapy⁷ (Guss, Krause, & Slosower 2020) or Internal Family Systems⁸ (Mithoefer, 2017). During the integration phase, a therapist may assist the patient to assign meaning to their experiences, set concrete goals, and process their psychedelic experiences.

However, not all integration approaches use directive methods. For example, Schlosser notes that therapists in COMPASS Pathways’ psilocybin trials are instructed to use an approach called “method of inquiry” that empowers the patient to lead the integration process. Similarly, Walker suggests that patients should lead the conversation, prompted by questions from the therapist. He invites patients to talk about their medication session experience, but cautions against imposing any specific interpretation or framework. “We all have systems of thought, so we often try to interpret the person’s experience in our system of thought. [But] integration is not about the therapist, it’s about the person” (patient).

Walker also emphasizes the importance of addressing perceived changes in the diagnosed condition for which treatment is sought during integration. While discussion about the content of the psychedelic experience is also welcome, Walker believes that the therapist should

ask the patient to think specifically about their depression, PTSD, or other condition(s) after the medication session. In his words, “I want to respect what you [the patient] brought here,” i.e., the diagnosis. Therefore, the condition should be a central topic of conversation during integration psychotherapy.

It is not uncommon for patients to feel overwhelmed, anxious, or depressed in the days immediately after their medication session, so it is very important that they have access to an on-call therapist. This should not necessarily be taken as a sign of a longer-term mental health problem; most often, these feelings resolve, especially if the patient is given adequate integration support (Gorman et al., 2021). However, psychedelic therapy can temporarily and substantially worsen symptoms and necessitate intensive outpatient therapy (e.g., recollection of familial childhood sexual abuse), and both the patient and therapist need to be prepared for the unexpected (Brian Richards, personal communication, August 3, 2022). Longer-term adverse reactions are possible (see the section entitled “Safety” below), but even challenging

psychedelic experiences can lead to improved mental health outcomes over the long term (Gorman et al., 2021).

Patients can experience profound shifts in their symptoms, sense of wellbeing, and even worldview after the medication session. They may have an experience of “ontological shock,” which profoundly challenges their lifelong understanding of the nature of reality and who they are. This can be a result of experiences such as ego dissolution, visions of deceased loved ones, mystical experiences, and other similar non-ordinary experiences (Brian Richards, personal communication, August 3, 2022).

These often abrupt changes can significantly impact the patients’ relationship dynamics at home, at work, and in their communities, since they are no longer following the same “script,” as Walker puts it. Therapists can help patients navigate these relational changes by providing resources and conversation prompts for patients to share with loved ones at home. 🌐

THE FUTURE OF THE FIELD: INTEGRATION

Assessment and Measurement

Integration is also an appropriate time to reassess patients with clinical diagnostic scales that were used during screening and assessment to evaluate the efficacy of treatment. These diagnostic scales may not be the only helpful measurements, however. Therapists may also benefit from access to assessment tools that measure enhancements in resilience, creativity, or other traits that can be affected by psychedelic experiences.

New research proposes two new scales to measure integration: the Integration Engagement Scale, which measures “behavioral engagement with integration” activities, and the Experienced Integration Scale, which measures the “intrapyschic experience of integration” in three domains: feeling settled, harmonized, and improved (or “tangible benefits”) (Frymann et al., 2022). These scales can be used individually or in tandem to assess whether a patient has sufficiently integrated their experience. In the study, the researchers provide evidence that engaging in integration behaviors such as reflection on the psychedelic experience and application to daily life is correlated with higher experienced integration.

New Approaches

Just as researchers are beginning to explore group settings for medication sessions, group integration is also a promising new area of research (Siebert, 2022). The next wave of research could explore:

- To what extent could group integration therapy reduce costs and/or expand access to psychedelic-assisted therapy?
- Are there other psychosocial benefits to group integration, such as mutual support and formation of new friendships based on shared experience?
- Could integration take part in a community-based or ongoing setting, similar to the support group model often practiced with cancer patients or substance users? How would this model affect both costs and treatment outcomes?

Elements of Psychedelic-Assisted Therapy

BrainFutures found some consistency in both the published literature and the opinions of the experts we interviewed on many elements of psychedelic-assisted therapy. Screening and assessment set the stage for the therapeutic arc by enabling the therapist to understand the patient's individual mental health concerns and physiological health status, appropriateness and safety of psychedelic-assisted therapy, and their expectations for treatment (L. Averill, personal communication, August 18, 2022). Patients must be well-prepared for the psychedelic experience, both in terms of setting expectations and developing a strong therapeutic alliance with their therapist or therapists. This includes establishing appropriate set and setting to support the patient's healing process. There is also broad agreement that during the medication session, when the psychedelic experience takes place, therapists should take a nondirective approach to supporting patients. Finally, all agree that patients need to process their psychedelic experiences during follow-up psychotherapy sessions in order to integrate the experience.

Beyond these five elements, safety and ethical practice are also essential to successful psychedelic-assisted therapy. In the next section, BrainFutures outlines core safety concerns, including psychological safety, physiological safety, and potential harms from practitioner misconduct.

Safety and Ethical Practice

Safety is foundational to successful and ethical psychedelic-assisted therapy. As part of the approval process, experts predict that the FDA will require risk evaluation and mitigation strategies (REMS) for each psychedelic drug. REMS could include Elements to Assure Safe Use, such as requiring patient monitoring, specialized training or certification for prescribers, and “limitations on the type of healthcare setting that may dispense the drug” (Davis & Lampert, 2022). Although REMS can set a baseline for safety, it is ultimately incumbent upon therapists and prescribers to take proper precautions that will keep patients safe.

As noted in the “Screening” section of this report, psychedelic-assisted therapy may not be appropriate for all patients with MH/SUDs, even those with conditions for which psychedelics are indicated under prospective FDA approval. Further, for those who are cleared for psychedelic-assisted therapy, there are a number of psychological, physiological, and ethical issues that therapists should be aware of. This report highlights some of the most common and important safety issues to mitigate potential harms. See Appendix I for a partial list of safety concerns specific to ketamine, MDMA, and psilocybin. For more in-depth information about safety and harm reduction in psychedelic-assisted therapy, see Johnson, Richards, & Griffiths (2008) and Gorman et al. (2021).

PSYCHOLOGICAL SAFETY

Key Takeaway: While data on the psychological risks of psychedelics are incomplete and conflicting, psychosis and suicidality are the two most significant concerns that therapists should consider.

The most common psychological risks of psychedelic-assisted therapy are acute anxiety and psychotic thinking (such as “confusion or thought disorder and paranoia”), but these usually resolve within a few hours after the medication is given (Thomas & Malcolm, 2021). More persistent can be the experience of ontological shock when a patient’s worldview suddenly shifts. This is not an uncommon occurrence in psychedelic-assisted therapy, since the psychedelic experience can dramatically change perception and even lead to ego dissolution, or a loss of sense of self (Gorman et al., 2021). Even in the case of a challenging experience, experts generally believe that integration therapy can minimize the harm and maximize the potential benefits of the psychedelic experience (Gorman et al., 2021). In this section, we focus on some of the longer-term (though generally considered rare) psychological risks: psychosis, suicidality, and hallucinogen persisting perceptual disorder (HPPD).

PSYCHOSIS

Key Takeaway: Modern psychedelic researchers have screened out those with a predisposition to psychosis, but there is no conclusive evidence of an association between persisting psychosis and psychedelics.

While cases of LSD-induced persisting psychosis were reported in studies published before psychedelics were classified as Schedule I substances in the 1970s, in modern research a potential link between chronic psychotic symptoms and psychedelics is murky (Thomas & Malcolm, 2021). Nevertheless, modern psychedelics studies have excluded patients with psychosis or a family history of psychosis as a precaution (Thomas & Malcolm, 2021).

A 2015 study that reviewed lifetime use of the psychedelics LSD, psilocybin, and mescaline found no direct link between psychedelics and increases in mental or behavioral health conditions (Johansen & Krebs, 2015). Another study that surveyed 190,000 users of psychedelics found that psychedelic use was more likely to reduce psychological distress and suicidality (Hendricks et al., 2015).

Some of the experts we interviewed, however, raised concerns that psychedelics can carry psychological risks. For example, Gita Vaid, MD states that patients occasionally seek her out after using a psychedelic (in a non-clinical setting) because they are experiencing concerning symptoms such as hearing voices. Dr. Robin Carhart-Harris, PhD, argues that more data are needed to determine if “triggered psychotic disorders” are a potential risk of psychedelic-assisted therapy.

Dr. Alex Cardenas, MD, shares his view on working with patients who present with symptoms of psychosis after psychedelic-assisted therapy:

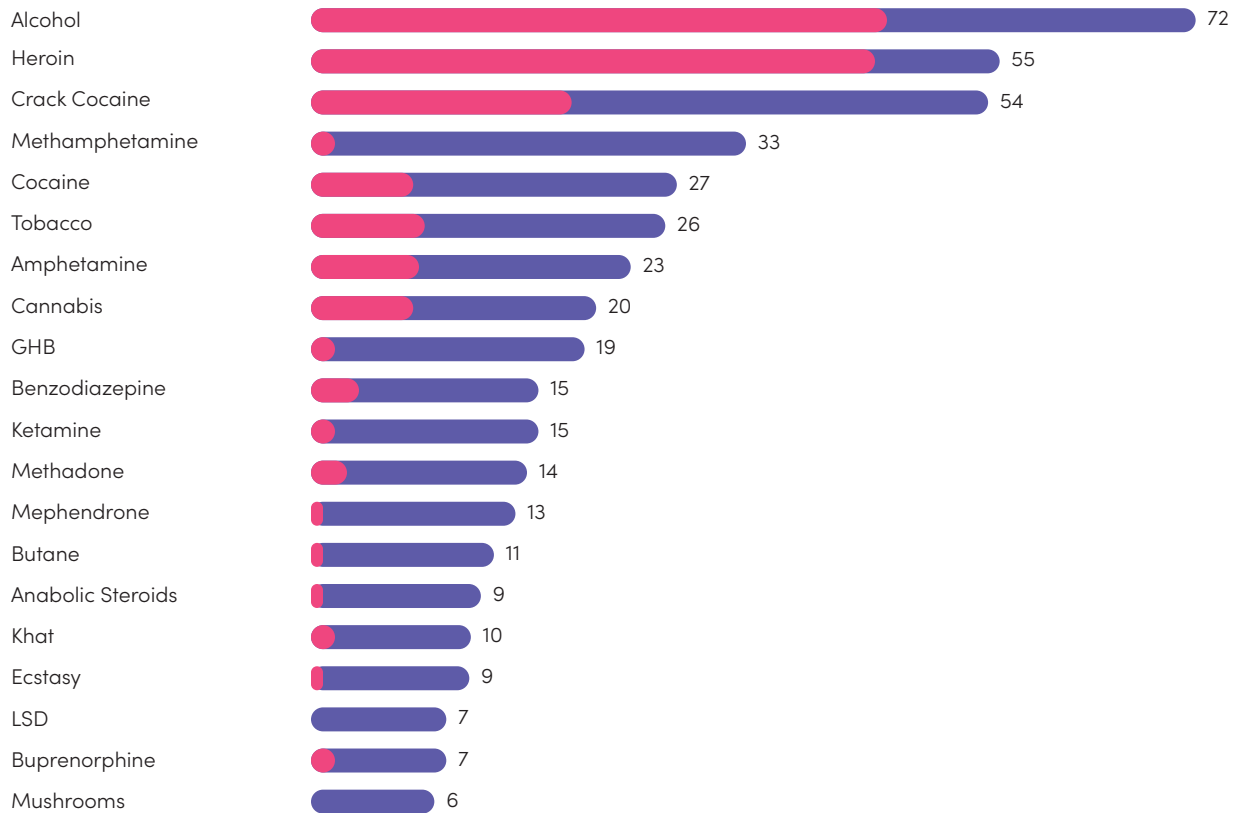
“While there will be cases of medical complications that need medical attention, there are also going to be people with complex responses, such as persistent psychedelic experiences that could present as psychosis, mania, and suicidality and these need to be treated inside a psychedelic safety net in line with Stanislav Grof’s idea of a spiritual emergency⁹ that can look just like psychiatric illness. These people, which could total up to one person out of 1,000 or 2,000 cases, need a specialized level of support, and keeping them in a psychiatric hospital could ultimately be more harmful.”

For each individual patient, therapists should carefully weigh the potential benefits of psychedelic-assisted therapy against the risk of triggering or exacerbating a psychotic disorder and discuss this risk-benefit calculation with the patient as part of the informed consent process.

SUICIDALITY

Key Takeaway: Therapists should monitor patients for suicidality, particularly in the early phases of integration.

It is not yet known whether suicide and suicidality are associated with psychedelic-assisted therapy and/or specific psychedelic compounds. Some of the experts BrainFutures interviewed believe there *may* be a link between psychedelic use and suicidality, but the possible association is complex. Carhart-Harris acknowledges that “the latest evidence is that [suicidality] improves rapidly in an impressive way” with psychedelic-assisted therapy, but it is also important to look at the extreme outliers in the data to determine whether suicide and suicidality are greater or lesser risks of psychedelic-assisted therapy compared to existing treatments for

FIGURE 2. HARM SCORES OF DRUGS TO USERS AND OTHERS

Note. The above graph shows the harms associated with using various drugs for the drug users (purple) and the harm caused to others that is related to drug use (red). Drugs are ranked from most harmful (top) to least harmful (bottom) using a weighted score of the assessment criteria for each drug. Harm to users was measured on nine criteria including items such as drug-specific mortality and damage, dependence, and loss of relationships. Harm to others was measured on seven criteria including crime, economic cost, and family adversities. Adapted from Nutt, D.J., King, L.A., Phillips, L.D. (October 2010). Drug harms in the UK: a multicriteria decision analysis. *Lancet* 376: 1558-1565. 10.1016/S0140-6736(10)61462-6

the same conditions (e.g., treatment-resistant depression, major depression, PTSD). This can be difficult to assess, particularly since many patients who could seek treatment through psychedelic-assisted therapy are already at heightened risk of suicidality due to underlying mental health conditions.

Dr. Michael Mithoefer, MD notes that short-term increases in suicidality can occur after an MDMA medication session, so therapists should screen for this and ensure that patients are informed about resources that are available if they are experiencing this symptom (Mithoefer, 2017).

HALLUCINOGEN PERSISTING PERCEPTUAL DISORDER (HPPD)

Key Takeaway: HPPD, which causes flashbacks or visual distortions, is a rare but noteworthy side-effect of psychedelic use.

HPPD is another potentially long-term adverse effect of psychedelic use, not necessarily in the context of psychedelic-assisted therapy. Researchers estimate that one in 20 users will experience Type 1 HPPD, characterized by brief “flashbacks” to the psychedelic experience, while about one in 50,000 users may experience Type 2, which can include “visual disturbances over months to years that cause distress or impairment” (Thomas & Malcolm, 2021). Researchers believe that HPPD is a much lower risk in clinical settings, but the mechanisms that cause HPPD are not well understood (Johnson, Richards, & Griffiths, 2008).

PHYSIOLOGICAL SAFETY

Key Takeaway: Most psychedelics are physiologically safe for healthy patients in the context of psychedelic-assisted therapy but patients should receive medical clearance before the medication session.

The risk of physical harm from most psychedelics compared to other commonly-used substances (such as alcohol) is low for physically healthy patients, especially in a supervised clinical context (see Figure 2). Patients should undergo medical screening to rule out any undiagnosed heart conditions which could lead to complications. Overall, there appear to be few serious physiological risks of injury or long-term harmful side effects.

During the medication session patients may experience some discomfort or acute adverse effects during the experience itself, which are generally fleeting. Depending on the compound, those effects can vary. Common side-effects of psychedelics include elevated blood pressure and heart rate, headaches, nausea, and fatigue (Thomas & Malcolm, 2021). Specific concerns for ketamine, MDMA, and psilocybin can be found in Appendix I, although these are not exhaustive lists.

ETHICS AND THERAPIST MISCONDUCT

Key Takeaway: Psychedelics can make patients particularly vulnerable to harm from therapist misconduct, so high ethical standards that protect patients are essential.

Many of the experts BrainFutures interviewed surfaced safety concerns that were related to the therapeutic process itself rather than risks inherently related to psychedelic medicines. Psychedelic-assisted therapy involves an intensive therapeutic relationship, and unfortunately this can allow opportunities for irresponsible or unethical conduct on the part of psychedelic therapists. These problems include (but are not limited to) the possibility of sexual and physical misconduct as participants are in very vulnerable, open states during the dosing session and may not have the same ability to assert boundaries, physically resist, or escape as they normally would.

High profile cases of sexual abuse have come to light in recent media reports and focused attention within the field on prevention (Lindsay, 2021). “Ethical misconduct is an unfortunate reality, and not just sexual exploitation, which happens in every field,” says Dr. Jamie Beachy, PhD, faculty co-director of the Center for Psychedelic Studies at Naropa University. She continues,

“Having two therapists present for medicine sessions does help protect clients from sexual violation, yet in some cases, it has not been enough. And there are other types of exploitation, such as financial exploitation—[for example] charging a client thousands of dollars for sessions when the therapist knows there is a low likelihood of improving the underlying condition.”

Incorporating real-time supervision into medication sessions as well as audio and video recording can also help reduce the risk of misconduct and rapidly highlight any need for specific guidance or additional supervision (Brian Richards, personal communication, August 3, 2022).

Beachy said the solution to these risks is not easy. Rather, it would require community-based ethical accountability. She is also an advocate for high standards of ethical training as part of psychedelic-assisted therapy credentialing.

Bill Richards agreed that therapists should hold each other accountable:

“To address the occasional therapist who abuses the relationship or gets unproductively involved with the client, such as having a sexual relationship, the main safeguard is for that therapist to be in a community and not get too isolated. Such a community would include group debriefing and facilitation. If you start getting grandiose and wear more feathers than usual, someone ought to be there to call you out on it.”

Therapists should adhere to the code of ethics for their particular profession or licensure to help ensure patients’ safety. Additionally, BrainFutures anticipates that emerging professional associations will soon publish ethical guidelines, which will provide additional guidance specific to the field of psychedelic-assisted therapy. 🌱

THE FUTURE OF THE FIELD: SAFETY

There is still a degree of uncertainty about what psychological conditions are contraindicated for treatment with psychedelic-assisted therapy. While careful screening can reduce the risk of potentially triggering or worsening psychotic symptoms, overly restrictive criteria carry the risk of denying care to those who could benefit.

A 2022 opinion essay in *JAMA Psychiatry* points out that “many patients with intractable posttraumatic stress disorder or major depressive disorder who may benefit from these therapies may have concerning personality features or family histories of schizophrenia or bipolar disorder” which would prevent them from accessing treatment under currently accepted protocols (Bradberry, Gukasyan, & Raison, 2022). The article calls for additional research on more diverse, representative patient populations that could help quantify the risk of triggering or exacerbating psychotic symptoms. In the

future, psychedelic-assisted therapy may eventually be expanded to safely include patients who are currently considered untreatable.

Notably, white, college-educated people tend to be overrepresented in study populations, so future research must also consider demographic diversity.

Additionally, researchers need to better understand the association between psychedelic treatment and suicidality, specifically:

- Are there certain markers that could help therapists better predict whether psychedelic-assisted treatment would reduce suicidality for a particular patient?
- Does psychedelic-assisted therapy trigger or exacerbate suicidality in certain patient populations, and if so how can these populations be screened?

Conclusion

Experts widely expect psychedelic medicines to gain approval from the FDA and become available for clinical use in the coming years, since Phase 3 trials of MDMA and Phase 2 trials of psilocybin are ongoing. In anticipation of this change, it is important that therapists have a working understanding of the emerging field of psychedelic-assisted therapy.

In this report, BrainFutures consolidates the views of nearly two dozen leading experts in addition to published research on the core elements of psychedelic-assisted therapy: screening, preparation, set and setting, medication session, and integration. We argue that it is critical that therapists give each of these elements of treatment the time and attention they are due rather than focusing solely on the medication session. Finally, we discuss some of the primary safety concerns that therapists should be aware of, including potential psychological and physiological issues as well as harm that can result from therapist conduct.

The vision of psychedelic-assisted therapy presented in this report presents a somewhat idealized model based on strict research protocols with small sample sizes. While this model has demonstrated impressive outcomes, it

may prove to be simply too expensive to scale up for real world implementation. Similarly, since many research models use two therapists during the preparation, medication, and integration phases of treatment, this exacerbates the inaccessibility of treatment by doubling the number of qualified therapists needed to treat the qualifying patient population. It is likely that scientists and therapists will need to find ways to reduce costs and expand access without sacrificing outcomes or safety. Throughout the report in our series of “The Future of the Field” sections, we suggest pathways that researchers could explore to address these issues.

While this report **is not** a guide or instruction manual for practicing psychedelic-assisted therapy, it provides an introduction to the field for those who are considering pursuing training in psychedelic-assisted therapy and integrating it into their practice. Given the promising research outcomes from clinical trials and the overwhelming need for mental health care in the United States, BrainFutures expects that there will be a demand for many thousands of therapists who are skilled in delivering psychedelic-assisted therapy post-FDA approval. We hope this paper will inspire future psychedelic therapists to provide compassionate, ethical, patient-focused care. 🌐

Appendices

APPENDIX I: CONTRAINDICATIONS AND SAFETY CONSIDERATIONS FOR SPECIFIC COMPOUNDS

As part of screening and assessment, the therapist or another qualified individual on the care team should identify existing conditions or circumstances that may elevate risk. Additionally, prescribers and therapists need to understand the potential risks of psychedelic compounds and educate their patients during preparation as part of the informed consent process. Following are some of the considerations for ketamine, which is already available for off-label use to treat MH/SUDs, and MDMA and psilocybin, which will likely be approved for use in the coming years. **This is not an exhaustive list of contraindications and safety considerations. Therapists and patients should consult a physician or another qualified individual for medical clearance.**

KETAMINE

Ketamine is contraindicated for patients with schizophrenia, as it may worsen this condition (Rosenbaum et al., 2021). The primary physical contraindications for ketamine are heart conditions such as heart failure and hypertension, especially in cases where an increase in blood pressure would create a risk for aneurysm, aortic dissection, or heart attack (Rosenbaum et al., 2021). Ketamine inhibits the reuptake of catecholamines, which can increase blood pressure, heart oxygen levels, and pulse rate (Green et al., 2011). Neurological side effects include headache and dizziness (most common), followed by sedation or drowsiness, faintness/light-headedness, poor coordination/unsteadiness, and tremor/involuntary movements (Sky, 2022). Ketamine also has the “potential for abuse and addiction,” although this has primarily been observed in recreational users (Bravo,

Grant, & Bennett, 2021). The ketamine enantiomer, esketamine, has already been approved by the FDA for the treatment of major depressive disorder (MDD) and suicidal ideation (when accompanied by an MDD diagnosis).

MDMA

Research has consistently shown that MDMA can elevate both heart rate and blood pressure as a result of norepinephrine release (Mithoefer & Mithoefer, 2021). As a result, Phase 2 trials of MDMA have excluded anyone with cardiovascular or cerebrovascular disease (Mithoefer & Mithoefer, 2021). MDMA also carries a risk of serotonin syndrome or other toxicities when used in combination with other drugs such as MAOIs (monoamine oxidase inhibitors), a type of antidepressant (Sillins et al., 2007). It is also contraindicated for patients taking Ritonavir, which is used to treat HIV/AIDS (Papaseit et al., 2012). Adequate patient screening could drastically reduce or eliminate the risk of toxicity from combining MDMA with other drugs. MDMA can also temporarily suppress immune and inflammatory responses, which could be an important consideration for immunosuppressed patients (Pacific et al., 2003). In at least one clinical trial participant, MDMA led to increased premature ventricular contractions (Shannon, Colbert, & Hughes, 2021). Psychologically, MDMA may worsen symptoms of bipolar disorder and schizophrenia (Thomas & Malcolm, 2021). Additionally, while recent research trials have enrolled patients with histories of suicidality, MAPS investigators Michael and Annie Mithoefer caution that “without proper attention to follow-up integration and support, suicide could be a risk” of MDMA (Mithoefer & Mithoefer, 2021).

PSILOCYBIN

Psilocybin presents a low toxicity risk, and adverse reactions are predominantly limited to nausea and initial anxiety at the beginning of and sometimes during the experience, which typically resolves as the psychedelic effects diminish (Sky, 2022). Research investigating biological changes from psilocybin and potential contraindications found increases in heart rate and blood pressure in some patients (Ross et al., 2016). Psychologically, psilocybin is thought to aggravate symptoms of psychosis, so modern researchers have excluded individuals with psychotic spectrum illnesses and/or a family history of these conditions (Ross et al., 2021). The risk of psilocybin use in patients with bipolar depression is not well understood, so prescribers should exercise caution (Gard et al., 2021).

APPENDIX II: EXPERT BIOGRAPHIES

Biographies of the experts BrainFutures consulted for this paper are included below.

LYNNETTE AVERILL, PHD

Dr. Averill is an Associate Professor at Baylor College of Medicine and a Research Psychologist at the VA with ongoing affiliations at Yale and the National Center for PTSD. Unfortunately, she lost her father—a Marine—to suicide at a young age. Her loss fueled a life dedicated to researching and furthering novel, improved mental health treatments. Dr. Averill became actively involved in policy and advocacy work after serving as a subject matter expert (SME) in Texas for HB 1802, which funded a clinical study of psilocybin to treat PTSD in Veterans. After linking up with Brett Waters and Lt. Gen. Martin Steele to co-found Reason for Hope, she has briefed several members of Congress and testified or served as SME in Connecticut, Pennsylvania, New Hampshire, and Maine.

JAMIE BEACHY PHD, MDIV

Jamie Beachy PhD, MDiv, is Assistant Professor for Naropa University's Master of Divinity program and Faculty Co-Director for the Naropa Center for Psychedelic Studies. She currently serves as a co-therapist with the MAPS MDMA-assisted therapy Phase 3 study in Boulder.

Dr. Beachy is a chaplain, ACPE certified Spiritual Care Educator, and ethics consultant who advises palliative care chaplaincy organizations including the California State University Shiley Haynes Institute for Palliative Care.

ALEX CARDENAS, MD, MA

Alex Cardenas, MD, MA, is the son of first and third generation immigrants and the grandson of a curandera (healer). He is a community and safety-net psychiatrist who has worked in the public mental health and public education space since 1999 as a provider, administrator,

researcher, and advocate. Educated at Yale (BA in psychology) and Stanford (MD, MA in Policy, Organizations, and Leadership Studies), his clinical background pulls from relational, dynamic, and biological lineages. He has dedicated his clinical career to bringing the highest standards of care to underserved communities. After graduating from the inaugural class of the Certificate in Psychedelic Assisted Therapy and Research Program from California Institute to Integral Studies (CIIS), Dr. Cardenas began to engage the community around the need for infrastructure-level institutions to legitimize, develop, and community-govern the reemergence of the psychedelic field.

As Co-Executive Director of American Psychedelic Practitioners Association (APPA), he is focused on the policies and advocacy needed to ensure that psychedelic-assisted therapies are shepherded into the healthcare system with integrity and fidelity to their history and transformative potentials so that they are safe, effective, and accessible to all who could benefit.

ROBIN CARHART-HARRIS, PHD

Robin Carhart-Harris moved to Imperial College London in 2008 after obtaining a PhD in Psychopharmacology from the University of Bristol, focused on the serotonin system, and an MA in Psychoanalysis from Brunel University, 2005. Dr. Carhart-Harris has designed human brain imaging studies with LSD, psilocybin, MDMA, and DMT, a clinical trial of psilocybin for treatment-resistant depression, a double-blind randomized controlled trial comparing psilocybin with the SSRI, escitalopram, for depression, published in the *New England Journal of Medicine*, and a multimodal imaging study in first time users of psilocybin. He has published over 100 scientific papers. Dr. Carhart-Harris founded the Centre for Psychedelic Research at Imperial College London in April 2019, the first of its kind. In 2021, he was listed in *TIME* magazine's '100 Next', a list of 100 rising stars shaping the future. Also in 2021, he moved to University of California, San Francisco, becoming the Ralph Metzner

Distinguished Professor in Neurology and Psychiatry. At UCSE, Dr. Carhart-Harris will serve as Director of the new Psychedelics Division within the translational neuroscience center, Neuroscape.

MARY COSIMANO, LMSW

Mary Cosimano, LMSW, has been with the Department of Psychiatry at Johns Hopkins University School of Medicine in the Center for Psychedelic and Consciousness Research since 2000 when they began research with psilocybin. She is currently a psychedelic session guide and has served as Director of Clinical Services and as a research coordinator. She has been involved with all the psilocybin studies and has conducted close to 500 studies including Club Drug studies with Salvia Divinorum and Dextromethorphan. Ms. Cosimano has trained postdoctoral fellows, faculty, clinicians, and research assistants as guides and has taught individual and group meditation to breast cancer patients in a Johns Hopkins research study. She teaches at California Institute to Integral Studies (CIIS) for their Psychedelic-Assisted Therapies and Research and conducts trainings for therapists in psychedelic psychotherapy. In 2003 she started a meditation group for employees in her department. She also has 15 years of experience with direct patient care as a hospice volunteer.

INGMAR GORMAN, PHD

Dr. Gorman earned his doctorate in Clinical Psychology at the New School for Social Research and completed his clinical training at Mount Sinai Beth Israel Hospital, Columbia University, and Bellevue Hospital. He completed an NIH postdoctoral fellowship at New York University in 2017. He served as site co-principal investigator on Phase 2 and Phase 3 clinical trials of MDMA-assisted Psychotherapy for Post-Traumatic Stress Disorder and is currently a study therapist on the same study. Dr. Gorman has published on the topics of classic psychedelics, ketamine, MDMA, and Psychedelic Harm Reduction

and Integration. He has co-authored treatment manuals for clinical trials including 5-MeO-DMT in the treatment of treatment resistant depression and alcohol use disorder, as well as psilocybin in the treatment of alcohol use disorder and binge eating disorder. He is the co-founder and Chief Executive Officer of Fluence, a psychedelic therapy training company.

PHYLLIS GREENWALD, MD

Phyllis Greenwald, M.D. retired in 2017 from a 35 year career in psychiatry to become involved in psychedelic assisted research and treatment. Her prior clinical experience involved working with individuals suffering from a broad range of conditions, in both inpatient and outpatient settings. She also has considerable experience in administrative roles in both hospital settings and the health insurance industry. Intrigued by the therapeutic potential of psychedelics, she was certified in 2017 by the California Institute of Integral Studies (CIIS) in Psychedelic Assisted Treatment and Research. In addition to her current role as a session facilitator at Johns Hopkins CPCR, she works as an adherence rater on the MAPS MDMA/PTSD studies.

EMMA KNIGHTON, MA, LMHC

Emma Knighton, MA, LMHC, is a white, queer, able-bodied femme. She is a somatic trauma therapist, psychedelic integration therapist, embodied organizer, and conscious leader. In their clinical work, Mx. Knighton works at the intersection of complex PTSD from childhood abuse, queer identity development, and consciousness exploration. Her clinical and leadership approach is grounded in queer, consent, feminist, and anti-oppression/pro-liberation theories. Mx. Knighton teaches courses on integrating trauma-informed consent practices into psychedelic-assisted therapy and strives to be in service to the psychedelic space with integrated mind, body, spirit, and community. Mx. Knighton holds a master's in counseling psychology from Bastyr University, a Certificate in Psychedelic Assisted Therapy and Research from CIIS,

and a master's level Certificate in Holistic Health from St. Catherine University. A lifelong learner, she is in sacred relationship with their ancestors, tree elders, plant teachers, and the collective consciousness.

Mx. Knighton is focused on community building, systems change, and empowering through education and shared resources. She is committed to centering equity and those most impacted by the work in the process of integrating psychedelic services with the wider healthcare system.

JANIS PHELPS, PHD

Janis Phelps, PhD, is a leader in the field of psychedelic therapy training as the Director of the Psychedelic Therapies and Research at the California Institute of Integral Studies (CIIS) Center. As the Center's founder, Dr. Phelps developed and launched the first university accredited, post-graduate training program for psychedelic therapy and research. She has held the position of the Dean of Faculty of the six doctoral departments in the CIIS School of Humanities and Social Sciences. Her 2018 journal publication, *Developing Guidelines and Competencies for the Training of Psychedelic Therapists*, outlines best practices in the academic training of medical and mental health professionals in this field. These ideas are further developed in two book chapters and journal publications. Dr. Phelps is a board member of the Heffter Research Institute, which has conducted highly influential psilocybin-assisted psychotherapy research since the 1990s. A licensed clinical psychologist, she is a board of trustee and key founder in the creation of the national certification board for psychedelic therapists (BPMT). She consults and presents on methods of scaling effective training programs to meet the burgeoning need for well-trained mental health and medical professionals in the field of psychedelic medicine. Dr. Phelps maintains a private clinical practice in Mill Valley, CA.

ANNIE MITHOEFER, BSN

Annie Mithoefer, BSN, is a Registered Nurse living in Asheville, North Carolina, where she is now focused primarily on training and supervising therapists conducting MAPS-sponsored clinical trials, as well as continuing to conduct some MAPS research sessions in Charleston, South Carolina. Between 2004 and 2018, she and her husband, Michael Mithoefer, MD, completed two of the six MAPS-sponsored Phase 2 clinical trials testing MDMA-assisted therapy for PTSD, as well as a study providing MDMA-assisted sessions for therapists who have completed the MAPS Therapist Training, and a pilot study treating couples with MDMA-assisted therapy combined with Cognitive Behavioral Conjoint Therapy. Ms. Mithoefer is a Grof-certified Holotropic Breathwork Practitioner, is trained in Hakomi Therapy, and has 25 years experience working with trauma patients, with an emphasis on experiential approaches to therapy.

MICHAEL MITHOEFER, MD

Michael Mithoefer, M.D., is a psychiatrist living in Asheville, NC, with a research office in Charleston, SC. In 2000, he began collaborating with MAPS on the first U.S. Phase 2 clinical trial of MDMA-assisted psychotherapy. He and his wife, Annie Mithoefer, B.S.N., have since conducted two of the six MAPS-sponsored Phase 2 clinical trials testing MDMA-assisted psychotherapy for PTSD, as well as a study providing MDMA-assisted sessions for therapists who have completed the MAPS-sponsored MDMA Therapy Training Program, and a pilot study treating couples with MDMA-assisted psychotherapy combined with Cognitive-Behavioral Conjoint Therapy. He is now Senior Medical Director for Medical Affairs, Training and Supervision at MAPS Public Benefit Corporation (MAPS PBC). He is a Grof-certified Holotropic Breathwork Facilitator, is trained in EMDR and Internal Family Systems Therapy, and has nearly 30 years of experience treating trauma patients. Before going into psychiatry in 1991, he practiced emergency medicine for ten years,

served as medical director of the Charleston County and Georgetown County Emergency Departments, and held clinical faculty positions at the Medical University of South Carolina. He has been board-certified in Psychiatry, Emergency Medicine, and Internal Medicine.

ANDREW PENN, MS, PMHNP

Andrew Penn, MS, PMHNP is an Associate Clinical Professor in the UCSF School of Nursing and practices as a psychiatric NP at the San Francisco VA. He works on psychedelics studies of psilocybin and MDMA in the Translational Psychedelics Research (TrPR) lab at UCSF. A leading voice in nursing, he is a cofounder of the Organization of Psychedelic and Entheogenic Nurses ([OPENurses.org](https://openurses.org)), advocating for the perspective of nurses in psychedelic therapy, lectures internationally, and has published on psychedelics in the American Journal of Nursing, Frontiers in Psychiatry, and The Journal of Humanistic Psychotherapy. He can be found at [Andrewpennnp.com](https://andrewpennnp.com)

BRIAN D RICHARDS, PSYD

Brian D Richards, PsyD, completed a Master's degree in Existential-Phenomenological Psychology at Duquesne University, a PsyD at the University of Denver School for Professional Psychology, and a Postdoctoral Fellowship at the Johns Hopkins Behavioral Pharmacology Research Unit, where he contributed to some of the original research administering psilocybin with cancer patients and healthy normal adults. Dr. Richards was formerly a Clinical Director with MedOptions, the largest behavioral health provider in the United States. He now cares for patients with a cancer diagnosis at Maryland Oncology Hematology, The Aquilino Cancer Center. Dr. Richards also teaches and mentors students at the California Institute for Integral Studies, the leading Psychedelic Medicine Certificate Program worldwide. He is a Subject Matter Expert on Psilocybin with the Board

of Psychedelic Medicine and Therapies, and is working with BrainFutures on Coding and Reimbursement for Psychedelic-Assisted Therapy.

Dr. Richards was a Lead Psychologist on an innovative, simultaneous group administration high-dose psilocybin trial with cancer patients at the Bill Richards Center for Healing in Rockville, Maryland. This cutting-edge, purpose-built psychedelic medicine clinic—located in a busy outpatient oncology center, is the first of its kind in the world, and may serve as a prototype for future Sunstone Therapies clinics nationwide.

Dr. Richards' clinical and research interests include meaning-centered psychotherapy, mystical experience, brain science-based approaches to vibrant health and wellness, and working with treatment refractory patients. He finds joy and meaning practicing yoga, gourmet cooking, working in nature, growing medicinal mushrooms, and caring for the natural world.

WILLIAM A RICHARDS, MDIV, STM, PHD

William A. Richards (Bill), a psychologist in the Center for Psychedelic and Consciousness Research in Baltimore, has been implementing research studies with psilocybin within the psychiatry department of the Johns Hopkins School of Medicine since 1999. He also is associated with the Program in Psychedelic Therapies and Research at the California Institute of Integral Studies (CIIS) and psilocybin research with Sunstone Therapies at the Aquilino Cancer Center in Rockville Maryland. His graduate degrees include M.Div. in Teaching and Research in Religion (Yale), S.T.M. in the psychology of religion (Andover-Newton) and Ph.D. in Education (Catholic University). He studied with Abraham Maslow at Brandeis University and with Hanscarl Leuner at Georg-August University in Göttingen, Germany, where his involvement with psychedelic research originated in 1963.

From 1967 to 1977, he implemented projects of psychotherapy research with LSD, DPT, MDA, and psilocybin at the Maryland Psychiatric Research Center, including protocols designed to investigate the promise of psychedelics in the treatment of alcoholism, depression, narcotic addiction, and the psychological distress associated with terminal cancer, and also their use in the training of religious and mental-health professionals. His recent research at Johns Hopkins has focused on the potential value of psilocybin in the continuing education of professional religious leaders from different world religions. His book, *Sacred Knowledge: Psychedelics and Religious Experiences*, has been released by Columbia University Press, and is now translated into six additional languages.

DANIELLE SCHLOSSER, PHD

Dr. Danielle Schlosser is the Senior Vice President of Clinical Innovation at COMPASS Pathways, a mental health company dedicated to accelerating access to evidence-based innovation in mental health. COMPASS' first program is focusing on research activities to support regulatory approval of COMP360 psilocybin therapy for people with treatment resistant depression. At COMPASS, Dr. Schlosser leads the function responsible for developing the clinical care model, conducting therapy optimization research, and therapist training. Prior to COMPASS, Dr. Schlosser was responsible for developing the vision and overall strategy of the behavioral health portfolio at Verily Life Sciences, an Alphabet company. At Verily, the behavioral health portfolio spanned R&D, innovation initiatives, and commercial care programs.

Dr. Schlosser remains on the faculty at the University of California, San Francisco where she used to lead a translational neuroscience lab. Her lab developed digital therapeutics for individuals with serious mental illness and its work was featured in several media outlets including, CNN, Technical Times, Fortune Magazine,

and the Pacific Standard. Dr. Schlosser serves as Board Chair of OneFifteen, Co-Chair of the World Economic Forum Global Futures Council on Mental Health and Technology; and she remain a faculty mentor for several fellowship programs at UCSF, including the distinguished ACGME Clinical Informatics Fellowship Program; the Clifford Attkinson Clinical Services Research Training Program; and the Psychology and Medicine: An Integrative Research Approach fellowship.

SCOTT SHANNON, MD, FAACAP

Dr. Scott Shannon has been a student of consciousness since his honors thesis on that topic at the University of Arizona in the 1970s. Following medical school, MDMA assisted psychotherapy became a facet of his practice before this medicine was scheduled in 1985. He then completed a Psychiatry residency at a Columbia program in New York. Dr. Shannon studied cross-cultural psychiatry and completed a child/adolescent psychiatry fellowship at the University of New Mexico. He has published four books on holistic and integrative mental health including the first textbook for this field in 2001.

Dr. Shannon is a past President of the American Holistic Medical Association and a past President of the American Board of Integrative Holistic Medicine. He serves as a site Principal Investigator and therapist for the Phase 3 trial of MDMA assisted psychotherapy for PTSD sponsored by Multidisciplinary Association for Psychedelic Studies (MAPS). He has also published numerous articles about his research on cannabidiol (CBD) in mental health. Dr. Shannon founded the Psychedelic Research and Training Institute (PRATI) to train professionals in ketamine-assisted psychotherapy and deliver clinically relevant studies. He lectures all over the world to professional groups interested in a deeper look at mental health issues and a paradigm shifting perspective about transformative care.

PENELOPE TARASUK, PHD

International Diplomate, IAAP Jungian Psychoanalyst, PhD, author of *POLISHING THE BONES: the analysis and long treatment with a woman artist through her death, and practicing artist*; Penelope is a certified Stan Grof Holotropic facilitator and completed her studies: CIIS/CPTR 2021.

After her personal 'Good Friday' experiment with LSD at age twenty-five, in 1973 she met Stan Grof, MD at Spring Grove State Hospital, affiliated with John Hopkins Medical School. She was invited into his LSD training research program to assist and guide terminally ill and alcoholic patients. She had the honor of meeting with his pioneering colleagues, including Bill Richards, PhD. Unfortunately the research was halted by the DEA. At that crossroad, she began to study and practice yoga and Tibetan Buddhism. Over fifty years in human service, psychotherapy practice, and community mental health; she also studied death and dying with Dr. Kubler-Ross's assistant, Minister Maulimo Omara, and was certified as a Family Therapist at the Family Institute of Cambridge, MA in 1978. Her initial breathwork training began in 1989 with two women: an Australian healer and an NYU Professor and Cell biologist. That training included time in nature and swimming in the ocean with wild dolphins followed by breathwork and art. She resumed studies with Stan Grof from 1994, certified in 2019. She's been working with dream groups and NOSC over many years. She has a deep commitment to integration of these experiences into personal and collective life. She is deeply interested in childbirth and dying, the twin human initiations, and feels that psychedelics can help us both live and die with greater meaning.

BARRY WALKER, MED, LMHC

Barry Walker is a psychotherapist (M.Ed., LMHC) with over forty years of professional experience. He lives in Tarrytown, NY, with his wife Peggy. He has contributing interests in music, political psychology, education, and tennis. Especially music. Mr. Walker pursued degrees in Education, Psychology, Business Administration, and West African Studies along the way. He trained in various Body Oriented approaches to psychotherapy, like Bioenergetics, becoming a trainer, and several other treatment paradigms: Jungian Analysis, Gestalt, Family Systems, Psychodrama, and Voice Dialogue.

For the past fifteen years Mr. Walker has been actively interested in the issue of how the established worlds of psychiatry and psychotherapy will be able to weave themselves into the world of Psychedelics Assisted Psychotherapy currently exploding in the communities of the healing arts. In particular, he is interested in the role music and sound play as agents of growth and healing. He is part of a small team of professional musicians researching roles music can play in the processes the various psychedelic medicines initiate.

He is looking towards the coming time when the now-illegal psychedelic medicines will be available for use by highly trained therapists and guides. He hopes to be part of those training environments as they unfold. In the meantime, he respects deeply the research processes whose goals are to access the rich potential that current neuroscience research is illuminating and forecasting.

Born in Canada, he has traveled extensively in Africa, Asia, and Europe, living in East Africa as a teacher, and in the UK while in graduate school. Lastly, in full disclosure, he's a better musician than he is a tennis player. Sadly.

GITA VAID, MD

Gita Vaid, MD, is a board certified psychiatrist and psychoanalyst practicing ketamine assisted psychotherapy in New York City. She is a co-founder of the Center for Natural Intelligence (www.thecenterfornaturalintelligence.com), a multidisciplinary laboratory dedicated to psychedelic psychotherapy innovation and clinical practice. Dr. Vaid completed her psychiatric residency training at NYU Medical Center and her psychoanalytic training at the Psychoanalytic Association of New York. She trained as a fellow in clinical psychopharmacology and neurophysiology at New York Medical College and completed a research fellowship at NYU Medical Center. Dr. Vaid serves as the Director of Psychedelic Awareness at The Chopra Foundation and is on Faculty at The Ketamine Training Center.

WILL VAN DERVEER, MD

Will Van Derveer, MD, is co-founder of Integrative Psychiatry Institute, which trains psychotherapists in psychedelic-assisted therapy in collaboration with MAPS and Usona. His clinic in Boulder, CO provides integrative psychiatry and ketamine-assisted psychotherapy for treatment-resistant depression and PTSD.

Dr. Van Derveer was a co-investigator on MAPS studies investigating MDMA-assisted psychotherapy for chronic PTSD, now in Phase 3 under break-through designation by FDA.

Emphasizing the role of trauma as a key underrecognized cause of a wide range of human suffering is a central message of his work, due in part to his personal journey healing his own childhood trauma.

RACHEL YEHUDA, PHD

Rachel Yehuda, PhD, is an Endowed Professor of Psychiatry and Neuroscience of Trauma. She is also Director of Mental Health at the James J. Peters Veterans Affairs Medical Center. Dr. Yehuda is a recognized leader in the field of traumatic stress studies, PTSD, and inter-generational trauma. In 2019, Dr. Yehuda was elected to the National Academy of Medicine for her seminal contributions to understanding the psychological and biological impact of traumatic stress. In 2020, Dr. Yehuda established and now directs the Center for Psychedelic Psychotherapy and Trauma Research.

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Endnotes

1. BrainFutures recognizes that while psychedelic compounds have a long history of use in ceremonial, communal, informal, and recreational contexts across the world, “psychedelic-assisted therapy” in this paper refers exclusively to the use of psychedelics in combination with psychotherapeutic support in a clinical setting to treat a specific mental health or substance use condition.
2. Although ketamine and MDMA are not considered classic psychedelics, they are usually classified as psychedelics due to the subjective effects of the drugs. Ketamine is an FDA-approved anesthetic, but increasing evidence shows it is efficacious for treating conditions such as depression and PTSD.
3. Throughout this paper, we use the term “patient” to mean the person participating in psychedelic-assisted therapy. While much of the literature uses the terms “participant” or “volunteer” to denote that psychedelics have been given in an experimental research setting, BrainFutures uses the term “patient” in anticipation of future approval of one or more psychedelic drugs and their following clinical use.
4. See Appendix II for a full list of interviewees and their biographies.
5. See Appendix I for a list of common contraindications for ketamine, MDMA, and psilocybin with additional resources.
6. Knighton uses the pronouns she and they interchangeably. BrainFutures uses both pronouns to refer to Knighton throughout this report.
7. Acceptance and Commitment Therapy is a form of psychotherapy that emphasizes psychological flexibility, mindfulness, and behavior change (Hayes, n.d.)
8. Internal Family Systems is a form of psychotherapy based on the concept that the mind has multiple “parts” with different qualities that can often conflict. Internal Family Systems “focuses on healing the wounded parts and restoring mental balance and harmony by changing the dynamics that create discord among the sub-personalities and the Self” (Psychology Today, 2022)

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BrainFutures was launched in 2015 by the nation's second oldest mental health advocacy organization, the Mental Health Association of Maryland (MHAMD). For more than 100 years, MHAMD has addressed the mental health needs of Marylanders of all ages through programs that educate the public, advance public policy, and monitor the quality of mental healthcare services. Building on this success, and bolstered by a cross-disciplinary advisory board of leading experts, BrainFutures brings together diverse stakeholders, policy-makers, funders, and influencers to accelerate and scaffold national adoption of effective practices targeting four main areas: youth, workforce, mental health treatment, and older adults. Breakthroughs in our understanding of the brain have the potential to improve learning outcomes for children, optimize functioning at work, enhance treatment for mental health or substance use problems, and maintain sharp thinking as we age.

BrainFutures writes evidence-based issue briefs and releases recommendations that fill knowledge gaps related to brain-focused applications targeting the above segments of society. These educational resources highlight the latest advances in brain plasticity and how their application is transforming quality of life for people of all ages. Through this process, we not only gain insight from experts and innovators, we also foster support for change, building coalitions and cross-disciplinary collaborations to advance both adoption and access to new breakthrough applications. Ultimately, by informing the public, cultivating influential relationships, and connecting communities of diverse advocates we help propel the change that is needed to make meaningful progress.

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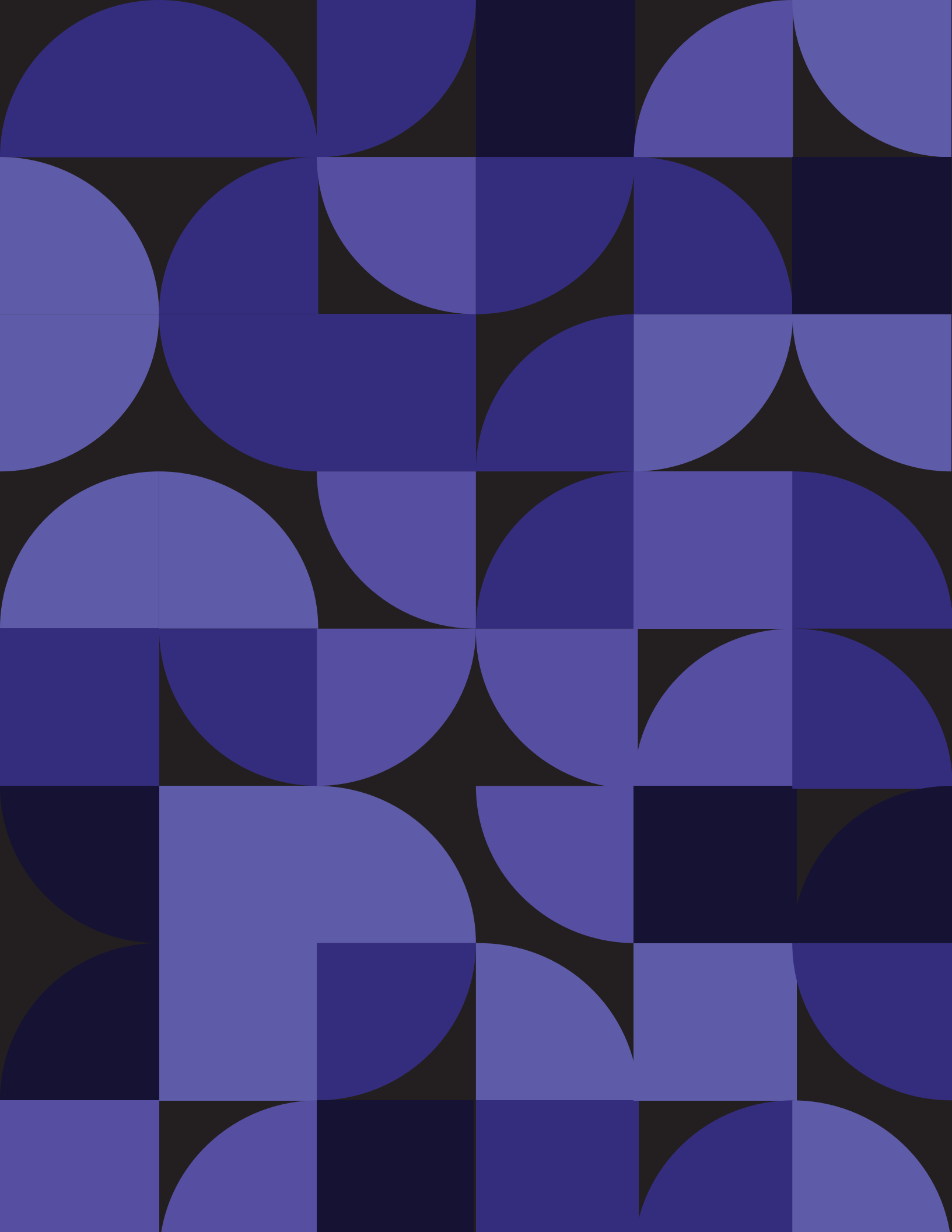
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