# Psychedelics 102: Psychedelic-Assisted Psychotherapy

**Larry Shapiro, Ph.D.**
Owner, Quantum Behavioral, LLC
lshapiro@quantumbehavioral.com | www.quantumbehavioral.com | 314-809-3964

# Disclaimer

⚠ This presentation is offered for **educational purposes only** by Larry Shapiro, Ph.D., a licensed psychologist, and reflects current emerging science and evolving clinical practice in the field. The content is intended to support professional understanding and informed dialogue – it does not constitute clinical, medical, or legal advice. Quantum Behavioral, LLC does not endorse or recommend the use of any controlled substances outside of lawfully sanctioned research or therapeutic contexts.

# Learning Objectives

| 1 | 2 | 3 |
| --- | --- | --- |
| **Mechanism of Action** | **Combined Approaches** | **Informed Dialogue** |
| Review the basic mechanisms associated with psychedelic medicines. | Examine how psychedelic medicine may be integrated with psychotherapy in a clinically coherent manner. | Develop sufficient grounding to engage in an informed clinical conversation with clients, colleagues, or the public. |

# Why This Matters Clinically

## 12M

### Americans Used Psychedelics

In 2024, approximately 12 million U.S. adults 18+ reported using at least one psychedelic substance.

*Source: National Survey Investigating Hallucinogenic Trends, Denver Health, 2024*

## 11M

### Used Psilocybin in 2025

RAND Corporation reported that more than 11 million American adults used psilocybin in 2025.

*Source: Priest et al., RAND Corporation, 2026*

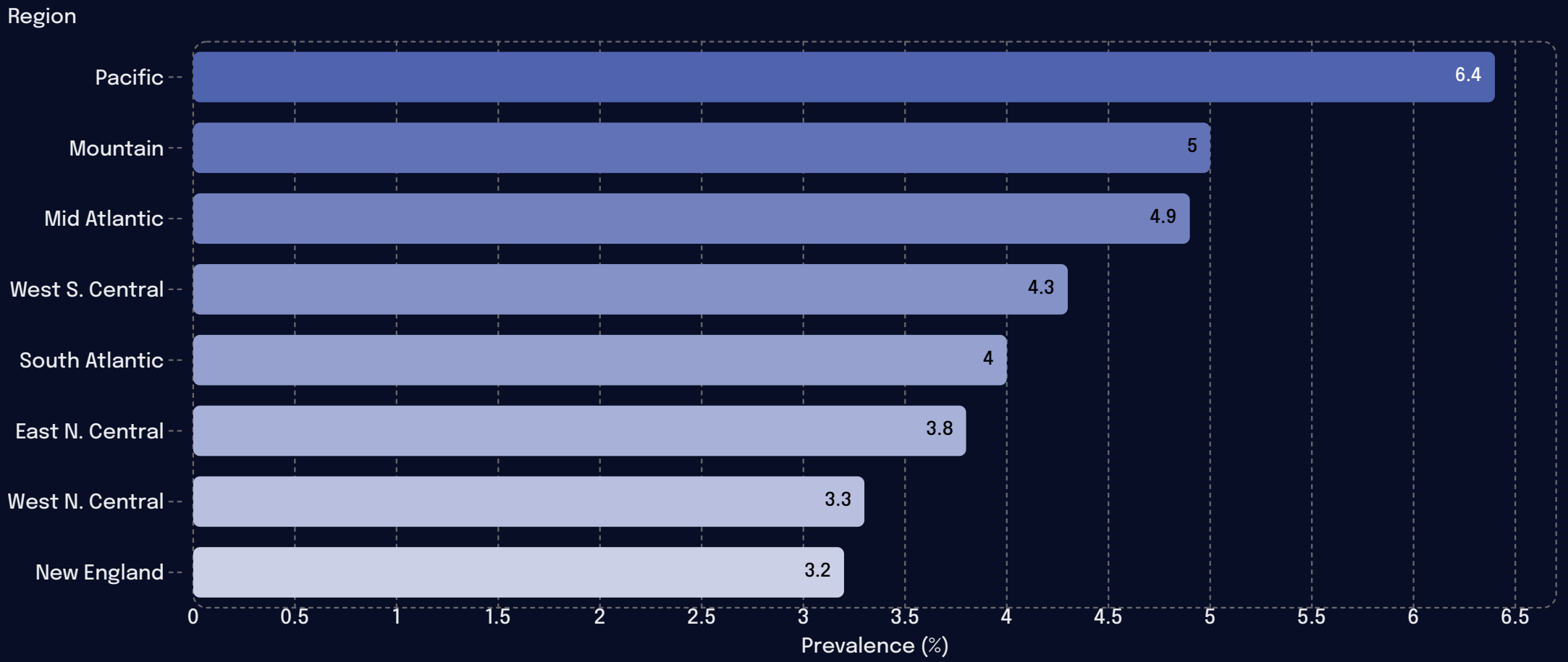
## 10M

### Adults Microdosed

Approximately 10 million adults reported microdosing psilocybin, LSD, or MDMA in 2025.

*Source: Priest et al., RAND Corporation, 2026*

# Prevalence by U.S. Region




*Source: National Survey Investigating Hallucinogenic Trends, Denver Health and Hospital Authority, 2024*

# APA Position on Psychedelic-Assisted Psychotherapy

# No Formal Position

- As of 2026, the APA has **not issued a formal policy statement** on psychedelic-assisted psychotherapy (PAP).
- This reflects the **evolving and emerging nature of the evidence base** – not opposition. The science is advancing rapidly, and formal positions take time to develop responsibly.
- The APA is **actively monitoring developments** in the field, and has published resources, continuing education materials, and task force reports addressing psychedelics and mental health treatment.

# Brief History and Milestones

1

### 1950s–1970s

Psychedelics were studied extensively in psychiatry, with more than 1,000 papers published and over 40,000 patients treated. This line of research later slowed markedly following Schedule I classification.

2

### 2000s

Research resumed under contemporary standards of trial design, ethics, and neuroimaging. Johns Hopkins, NYU, and Imperial College London became prominent centers of investigation.

3

### 2018

Michael Pollan published *How to Change Your Mind*, bringing psychedelic-assisted therapy into mainstream public discourse and significantly increasing cultural awareness of the therapeutic potential of psychedelics.

4

### 2017–2019

The FDA granted **Breakthrough Therapy** designation to MDMA-assisted therapy for PTSD and to psilocybin for treatment-resistant depression, reflecting preliminary evidence of potential clinical utility.

5

### 2023–2024

Phase 3 MDMA trials were completed. The FDA ultimately did not approve MDMA-assisted psychotherapy. At the same time, state-level reforms and expanded access programs continued to evolve.

EXECUTIVE ACTION

# April 18, 2026 Executive Order

## *Accelerating Medical Treatment for Serious Mental Illness*

- Advance the **National Priority Voucher Program** for psychedelics that have already received Breakthrough Therapy designations.
- Directs the **FDA, HHS, and the Department of Veterans Affairs** to share research data from VA hospital studies.
- **FDA and DEA** are directed to improve coordination in the handling of Schedule I substances within research settings.
- Calls on agencies to **expedite rescheduling** of psychedelic substances on a prioritized timeline.

EXECUTIVE ACTION

# FDA Priority Review Vouchers: April 24, 2026

**Following Executive Order 14401, the FDA issued Commissioner's National Priority Vouchers (CNPVs) to three companies — accelerating review timelines from months to weeks.**

## Compass Pathways

**Compound:** COMP360 (synthetic psilocybin)

**Indication:** Treatment-Resistant Depression (TRD)

**Note:** Phase 3 trial with 1,000+ participants; effects within 1 day, lasting 6+ months

## Usona Institute

**Compound:** Psilocybin (USO-001)

**Indication:** Major Depressive Disorder (MDD)

**Note:** Breakthrough Therapy designation granted 2019; nonprofit research institute

## Transcend Therapeutics

**Compound:** TSND-201 (methylone)

**Indication:** Post-Traumatic Stress Disorder (PTSD)

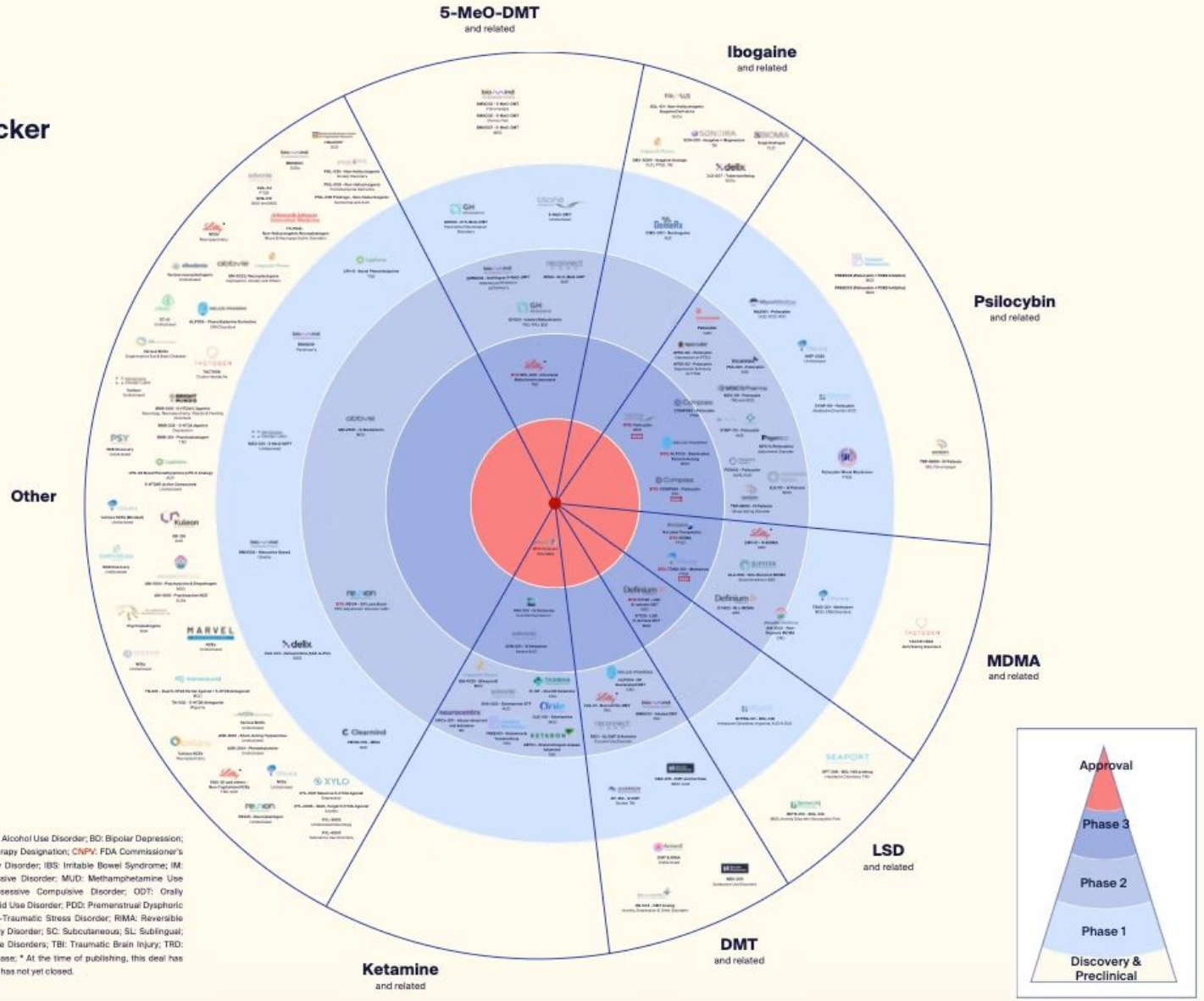
**Note:** Breakthrough Therapy designation July 2025; Phase 3 trial initiating

*Sources: FDA Press Release, April 24, 2026; STAT News; FierceBiotech; BioSpace*

Q3 2026

PSYCHEDELIC ALPHA

# Psychedelic Drug Development Tracker







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Syneos Health

Abbreviations: ASD: Autism Spectrum Disorder; AUD: Alcohol Use Disorder; BD: Bipolar Depression; BDII: Bipolar 2 Disorder; BTD: FDA Breakthrough Therapy Designation; CNPV: FDA Commissioner's National Priority Voucher; GAD: Generalised Anxiety Disorder; IBS: Irritable Bowel Syndrome; IM: Intramuscular; IV: Intravenous; MDD: Major Depressive Disorder; MUD: Methamphetamine Use Disorder; NCE: New Chemical Entity; OCD: Obsessive Compulsive Disorder; ODT: Orally Disintegrating Tablet; OTF: Oral Thin Film; OUD: Opioid Use Disorder; PDD: Premenstrual Dysphoric Disorder; PPD: Postpartum Depression; PTSD: Post-Traumatic Stress Disorder; RIMA: Reversible Inhibitor of Monamine Oxidase A; SAD: Social Anxiety Disorder; SC: Subcutaneous; SL: Sublingual; StUD: Stimulant Use Disorder; SUDs: Substance Use Disorders; TBI: Traumatic Brain Injury; TRD: Treatment-Resistant Depression; XR: Extended Release; * At the time of publishing, this deal has been announced by both AtaiBeckley and Eli Lilly, but has not yet closed.

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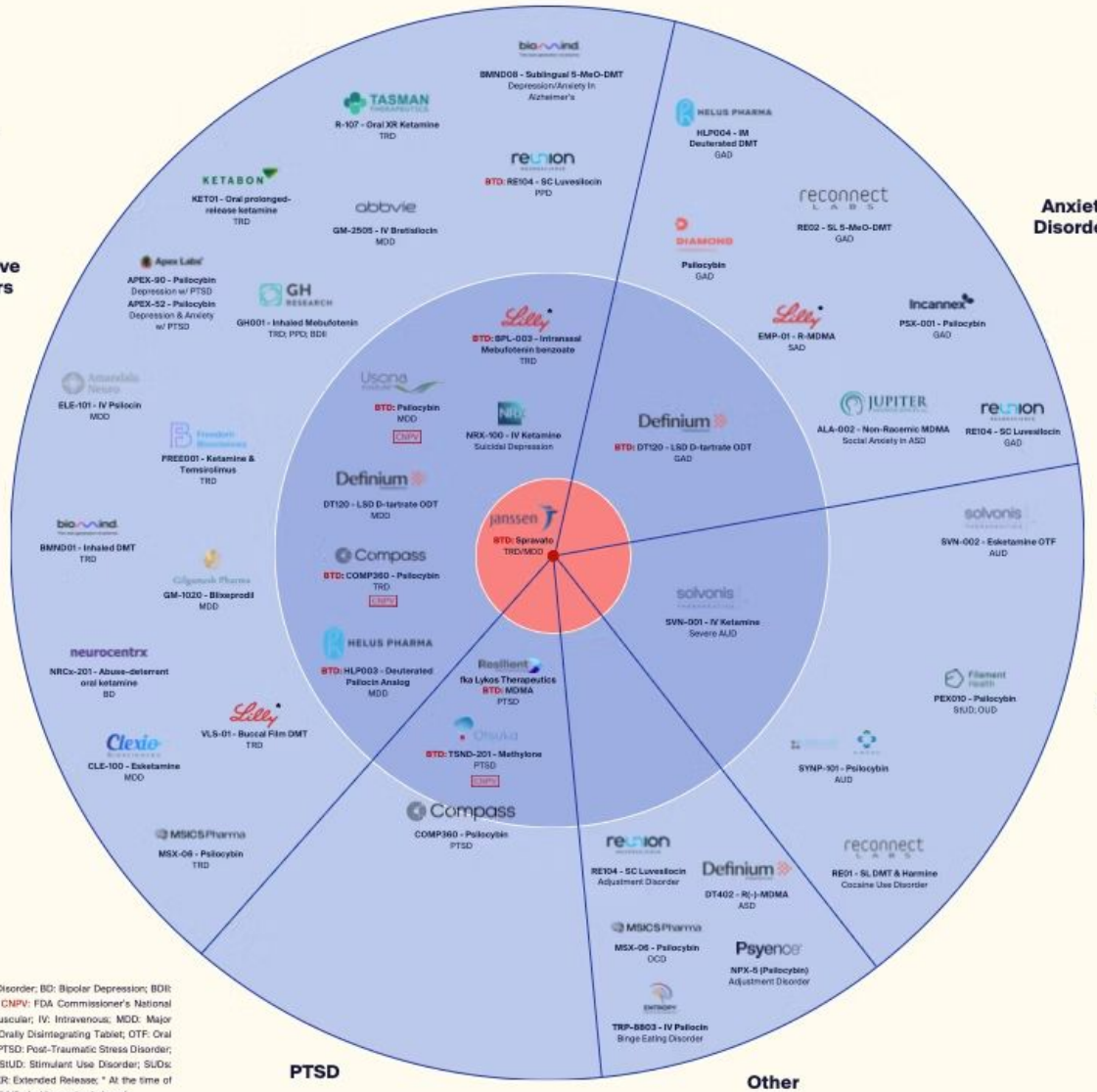
Q3 2026

PSYCHEDELIC ALPHA

# Psychedelic Drug Development Tracker

**BY INDICATION GROUPING**

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# Core Psychedelic Medicines: Primary Receptor Targets

| | |
|---|---|
| **Ketamine** | Glutamate (NMDA antagonist) |
| **Psilocybin** | Serotonin 5-HT2A, 5-HT1A |
| **LSD** | Serotonin 5-HT2A, 5-HT1A, Dopamine D1, D2, D3, D4 |
| **DMT** | Serotonin 5-HT2A, 5-HT1A, 2B, 2C, 1D, 5A, 6 & 7 |
| **5-MeO-DMT** | Serotonin 5-HT1A+, Dopamine D1 & D2, Norepinephrine, Glutamate (?) |
| **Ibogaine** | *Non-selective:* Serotonin, Dopamine, Glutamate, Opioid, Acetylcholine, Sigma 1 & 2, GDNF, BDNF |
| **MDMA** | Serotonin (SERT releaser; 5-HT1A, 5-HT2A indirect), Dopamine, Norepinephrine (monoamine releaser), Oxytocin (indirect) |

Receptor profiles vary considerably across these substances, and that variability has practical implications for mechanism of action, duration, and risk. Emerging evidence suggests these distinctions may be clinically relevant, but it is all still very new.

# Physical Safety: What the Data Show

## 1509

### Oregon Client Encounters

January–April 2025, under Oregon's state-licensed psilocybin program  6 adverse events (2 behavioral, 3 medical, 1 post-session) were reported. **No deaths were reported.** *Source: Oregon Health Authority, Oregon Psilocybin Services Data Dashboard, June 2025 (SB 303 / ORS 475A.372). Data cover January–April 2025.*

## <1%

### ED Visits from Hallucinogens

In a commercial insurance dataset of approximately 11 million substance-related ED admissions, hallucinogens accounted for less than 1%. *Source: Steinle, J.T., Gong, L., et al. (2025). Trends in Hallucinogen-Related Emergency Department and Hospital Admissions, 2016–2023. JAMA Network Open, 8(11), e2543453.*

Alcohol remains the leading contributor to emergency department and hospital admissions by a substantial margin. *Steinle & Gong (2025). Trends in Hallucinogenic-Related ED and Hospital Admissions, 2016–2023. JAMA Network Open, 8(11).*

# Psychological Safety Considerations

## Accepted Clinical Rule-Outs

### Psychosis

Current psychotic symptoms, or a personal or family history of psychotic disorder.

### Bipolar I

Current diagnosis of Bipolar I disorder, or a clearly documented past episode consistent with Bipolar I.

## Additional Risk Considerations

- **"Bad trip":** Acute psychological distress during a session, including panic, paranoia, or dysphoria.
- **HPPD:** Hallucinogen Persisting Perception Disorder – uncommon, but clinically meaningful when present.
- **Psychological vulnerability:** Pre-existing fragility or insufficient stability that may increase the likelihood of adverse reactions.
- **Functional disruption:** Marital, occupational, or social destabilization following the experience.

SHOUT OUT LOUD

# Psychotherapeutic Modalities Used in Psychedelic-Assisted Psychotherapy

### Psychoanalytic & Psychodynamic

Depth-oriented approaches that examine unconscious material and relational patterns that may emerge during sessions.

### CBT, CPT & ACT

Structured cognitive, behavioral, and acceptance-based frameworks used to address trauma-related symptoms and maladaptive beliefs.

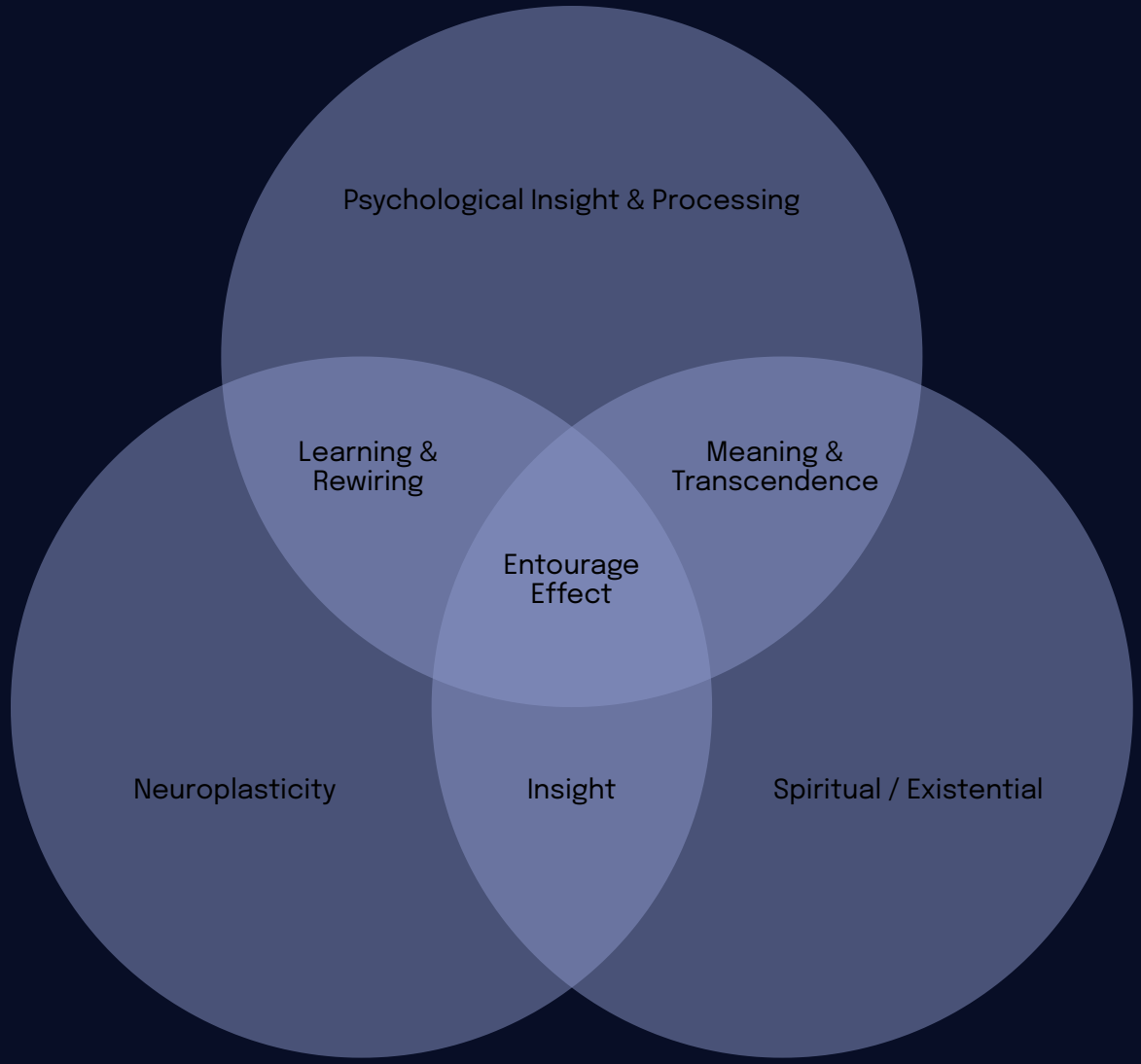
### Jungian, Art & Somatic

Symbolic and body-oriented approaches that may be clinically useful when working with imagery, affect, and embodied experience in psychedelic states.

### EMDR, Hypnosis & Other

Trauma-processing and altered-state modalities, including selected nontraditional facilitation approaches, where clinically appropriate and supported by the evidence base.

# Mechanisms of Change



# Key Components of Psychedelic-Assisted Psychotherapy

### Set

The client's mindset, expectations, intentions, and psychological state entering the experience.

### Setting

The physical and interpersonal environment in which the session occurs – including safety, aesthetics, and relational context.

### Intention

Collaborative pre-session clarification of what the individual hopes to examine, understand, or address.

### Integration

Post-session therapeutic work to make meaning of the experience in relation to the original intention and ongoing clinical goals.

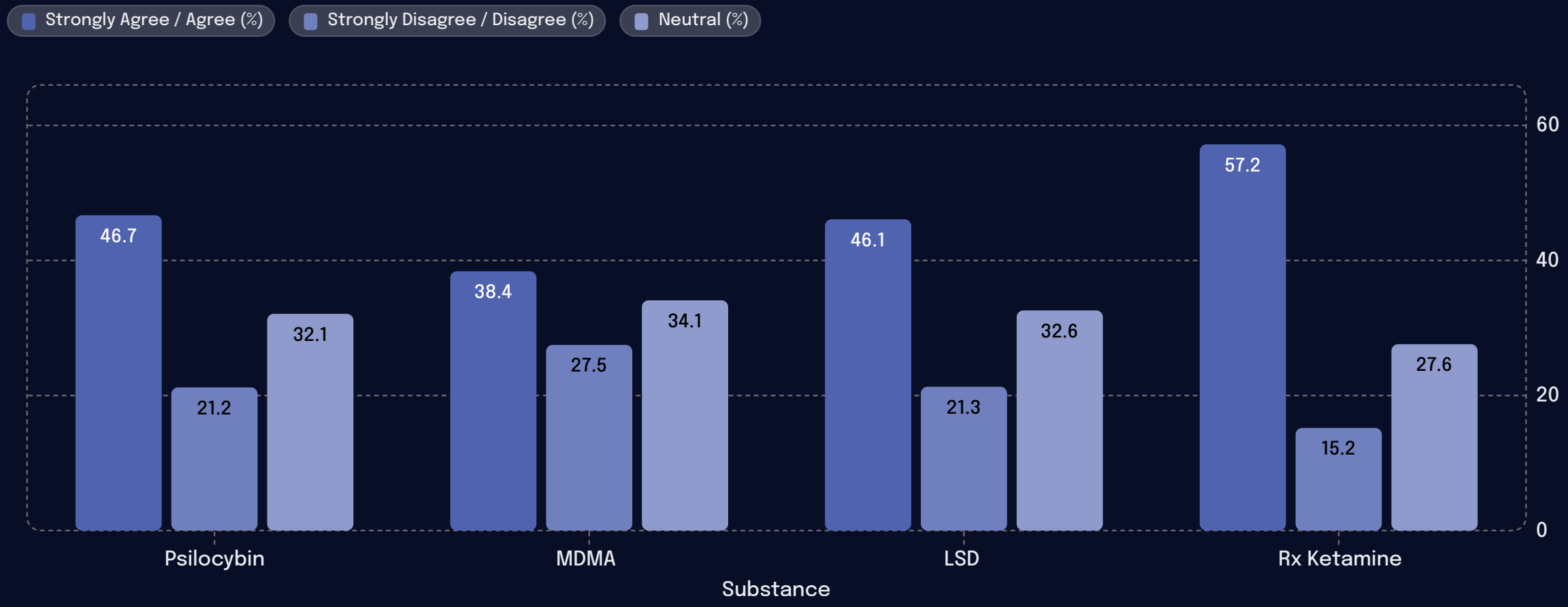
### Therapeutic Touch

Consensual, pre-determined hand placement used, when clinically indicated, to support physical safety and grounding during the session.

### Music

Carefully curated playlists are used during sessions to support emotional processing, guide the arc of the experience, and facilitate non-verbal expression of inner states.

# Perceived Improvement: Self-Report Data




*Source: National Survey Investigating Hallucinogenic Trends, Denver Health and Hospital Authority, 2024*

# Case Studies

The following cases describe individuals treated in psychedelic-assisted psychotherapy settings, representing a range of diagnoses and clinical histories:

01

**52-year-old retired Top Gun pilot** – PTSD and moral injury.

02

**71-year-old married woman** – 50-year history of OCD.

03

**46-year-old male combat medic** – Two combat tours, with childhood physical and sexual abuse.

04

**49-year-old woman** – History of incest and sexual trauma.

05

**50-year-old woman** – Five-year history of severe OCD.

06

**59-year-old female medical professional** – Treatment-resistant depression, with a history of physical abuse and sibling bullying.

# AI Acknowledgment

Portions of this presentation's layout and wording were refined with AI-assisted tools. All clinical content, literature review, case formulations, and professional opinions expressed are solely those of Larry Shapiro, Ph.D., and reflect his professional training and clinical experience. AI served as a drafting and formatting aid only – it did not provide independent clinical analysis or recommendations. Attendees are encouraged to consult primary sources for all cited research.

# Resources

## Training Programs

- **MAPS** – maps.org
- **Usona Institute** – usonainstitute.org
- **CIIS** – ciis.edu/psychedeliccenter
- **IPI** – psychiatryinstitute.com

## Recommended Books

- *How to Change Your Mind* – Michael Pollan (2018)
- *The Psychedelic Handbook* – Rick Strassman, M.D. (2022)

## Continuing Education

- **Psychedelic Support** – psychedelic.support/continuing-education

## General Information

- **Erowid** – erowid.org
- **Psychedelic Alpha** – psychedelicalpha.com

# Questions & Discussion

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**Larry Shapiro, Ph.D.** | Owner, Quantum Behavioral, LLC

lshapiro@quantumbehavioral.com

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314-809-3964