

# MDMA-Assisted Therapy for PTSD

Clinical Evidence Summary • Empax Centre • April 2026

## What the Research Shows

Two Phase 3 randomised controlled trials (the gold standard of clinical evidence) evaluated MDMA-assisted therapy in adults with moderate to severe PTSD. This included participants with treatment-resistant presentations, comorbid conditions, and histories of childhood trauma.

71%

of MDMA participants  
no longer met PTSD  
diagnostic criteria after  
three treatment cycles

86.5%

reported clinically  
meaningful  
improvement in  
symptoms

d =  
0.7–0.9

large treatment effect  
size (vs therapy  
+ placebo)

Source: Mitchell et al., Nature Medicine 2021 (n=90, severe PTSD) & 2023 (n=104, moderate-severe PTSD)

## Key Findings

**Substantial symptom reduction:** Average CAPS-5 score reductions of 23–24 points in the MDMA group versus 14–15 points with therapy alone, roughly a 60% greater improvement with MDMA-assisted therapy.<sup>1,2</sup>

**Durable outcomes:** 67% of participants in the severe-PTSD cohort no longer met diagnostic criteria for PTSD after just three dosing sessions, compared with 32% receiving therapy alone.<sup>1</sup>

**Treatment-resistant populations:** Participants had longstanding PTSD (mean duration ~14 years) and many had failed prior treatments including SSRIs, psychotherapy, or both.<sup>1,2</sup>

**Well tolerated:** No deaths or serious treatment-related adverse events. The most common side effects were transient (jaw clenching, nausea, reduced appetite) and resolved within the session.<sup>1,2</sup>

**Supported by meta-analyses:** Multiple systematic reviews (2024–2025) across all available RCTs confirm MDMA-AT produces statistically significant and clinically meaningful improvements in PTSD symptoms versus placebo.<sup>3,4</sup>

## Regulatory + Government Endorsement

**TGA-approved access:** As of 1 July 2023, the Therapeutic Goods Administration reclassified MDMA to Schedule 8 for supervised therapeutic use by Authorised Prescriber psychiatrists.<sup>5</sup>

**DVA funding:** In November 2025, the Australian Department of Veterans' Affairs began funding psychedelic-assisted psychotherapy for eligible clients, a signal of government confidence in the evidence base.<sup>6</sup>

**ICER review:** The US Institute for Clinical and Economic Review (2024) found MDMA-AT demonstrated clinically meaningful benefits for PTSD, though noted the need for additional confirmatory data.<sup>7</sup>

## References

1. Mitchell JM et al. Nature Medicine. 2021;27:1025–1033. (Phase 3, severe PTSD)
2. Mitchell JM et al. Nature Medicine. 2023;29:2473–2480. (Phase 3, moderate-severe PTSD)
3. Shahrour G et al. Neuropsychopharmacology Reports. 2024;44:672–681. (Systematic review & meta-analysis)
4. Yong ASJ et al. Aust NZ J Psychiatry. 2025. (Overview of systematic reviews & meta-analyses)
5. TGA. MDMA & psilocybin access pathways, 1 July 2023. tga.gov.au
6. DVA. Psychedelic-assisted psychotherapy funding announcement, November 2025. dva.gov.au
7. ICER. Evidence Report: Treatment for PTSD. June 2024. icer.org