



Frequently Asked Questions: MDMA-Assisted Psychotherapy for PTSD

- **What is PTSD?**
 - PTSD is a serious, long-lasting, and life-threatening condition when not adequately treated, highlighting the need for expedited approval of new therapies. PTSD sufferers may relive their traumatic experiences through nightmares and flashbacks, have difficulty sleeping, and feel detached from daily life. Approximately 7% of the U.S. population, and 11-17% of U.S. military veterans, will have PTSD sometime in their life.
- **What is MDMA-assisted psychotherapy?**
 - MDMA-assisted psychotherapy uses MDMA to improve the effectiveness of psychotherapy. The treatment involves *only two or three administrations* of MDMA in conjunction with psychotherapy in a controlled therapeutic setting, as part of a 12-week course of psychotherapy. In this treatment, MDMA is not the treatment by itself, but must be administered together with psychotherapy. Once approved, patients will not be able to take the MDMA home—patients won't be filling their prescriptions at their local pharmacy. Instead, MDMA will only be available through a doctor and only in supervised therapeutic settings from certified clinicians.
- **What's the status of clinical trials of MDMA-assisted psychotherapy for PTSD?**
 - MAPS is working to make MDMA legally available for use in therapeutic settings. We are now conducting the clinical trials needed for the Food and Drug Administration (FDA) to approve the use of MDMA combined with psychotherapy for the treatment of posttraumatic stress disorder (PTSD).
 - In the fall of 2018, MAPS is beginning Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD. Provided the results confirm the Phase 2 trial results, doctors may be able to legally prescribe MDMA for use in psychotherapy, not as a take-home drug but only for use in controlled therapeutic settings, by 2021.
 - On August 16, 2017, the FDA granted Breakthrough Therapy Designation to MDMA for the treatment of PTSD. The FDA grants this designation for treatments that (1) are intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition; and (2) preliminary clinical evidence indicates may demonstrate substantial improvement over existing therapies.
- **What have the results been so far?**
 - Phase 2 clinical trials have shown that MDMA may enhance the therapeutic process for people suffering from PTSD. This effectiveness may be related to

MDMA's ability to reduce fear and defensiveness, enhance communication and introspection, and increase empathy and compassion, which may improve the effectiveness of psychotherapy for PTSD.

- In MAPS' completed Phase 2 trials with 107 participants, 56% no longer qualified for PTSD after treatment with MDMA-assisted psychotherapy, measured two months following treatment. At the 12-month follow-up, 68% no longer had PTSD. Most subjects received just 2-3 sessions of MDMA-assisted psychotherapy. All participants had chronic, treatment-resistant PTSD, and had suffered from PTSD for an average of 17.8 years.
 - MDMA transiently increases heart rate, blood pressure, and body temperature in a dose-dependent manner that is generally not problematic for physically healthy individuals. Adverse Events involving administration of MDMA in MAPS studies have been uncommon and non-life threatening. Phase 2 trial results are currently being prepared for publication.
- **Why MDMA?**
 - MDMA is a synthetic compound widely recognized for its ability to decrease fear and defensiveness while increasing trust and empathy. It may open a "window of tolerance" in patients undergoing psychotherapy for PTSD, enhancing the effectiveness of psychotherapy.
 - MDMA directly reduces activity in the amygdala, a brain region that helps regulate fear and anger and which is often overactive in PTSD patients. By reducing this activity, MDMA may help people feel less afraid of their traumatic memories, and therefore to be able to share them more comfortably with their therapists.
 - MDMA stimulates the release of specific hormones, such as oxytocin and prolactin, which occur naturally in the human body and are associated with feelings of trust, bonding, and intimacy. Due to their trauma, PTSD sufferers often isolate themselves, or have difficulty trusting their therapists enough to adequately process their emotions. MDMA may facilitate the psychotherapeutic process by helping people feel safer and more connected to themselves and to their therapists.
 - MDMA also enhances activity in the prefrontal cortex, facilitating memory and attention. This is related to MDMA's effect of stimulating serotonin and dopamine release in the brain.