



Colorado Study Shows Benefits of MDMA-Assisted Psychotherapy for Treating Chronic PTSD

Results published in the *Journal of Psychopharmacology*

ON OCTOBER 29, 2018, THE RESULTS of the largest-ever U.S. Food and Drug Administration (FDA)-regulated clinical trial of MDMA-assisted psychotherapy for the treatment of chronic posttraumatic stress disorder (PTSD) were published in the peer-reviewed *Journal of Psychopharmacology*.

Sponsored by the non-profit Multidisciplinary Association for Psychedelic Studies (MAPS), the double-blind, placebo-controlled, Phase 2 pilot study in 28 participants found that one month after their second day-long experimental session, 42.9% in the active-dose (100 mg and 125 mg) MDMA groups did not qualify for a diagnosis of PTSD, compared to 33.3% in the low-dose MDMA (40 mg active placebo) control group. The results were even more notable 12 months after the third active-dose experimental session, which found that one year following treatment with MDMA-assisted psychotherapy, 76% of participants no longer had PTSD.¹

Led by Marcela Ot'abora, MA, LPC, in Boulder, Colorado, the trial was the largest of MAPS' six completed Phase 2 pilot studies of MDMA-assisted psychotherapy for PTSD. Trial participants included 28 people with chronic PTSD from military service, sexual assault, and other causes.

"Our study demonstrated that different therapy teams were able to get similarly robust results, further strengthening the case for MDMA-assisted psychotherapy as a promising option for the treatment of PTSD," said Principal Investigator Marcela Ot'abora. "Plus, the results of the study indicate that this treatment has the potential to greatly improve the lives of people suffering from PTSD, regardless of the source of their trauma. After treatment, a great majority of our participants have reported feeling more connected to themselves and to others, more joy, more compassion, and with new skills for facing life's challenges."

The study replicated previous research showing an acceptable risk profile for MDMA, with the most frequently reported adverse reactions during experimental sessions being anxiety,

jaw clenching, headache, muscle tension, dizziness, fatigue, and low mood. Adverse reactions one week following treatment included insomnia, low mood, irritability, and ruminations. Temporary elevations in pulse, blood pressure, and temperature were also recorded during MDMA sessions, and did not require medical intervention.

In August 2017, based on the results of MAPS' Phase 2 trials, the FDA granted Breakthrough Therapy Designation to MDMA-assisted psychotherapy for PTSD, acknowledging that it "may demonstrate substantial improvement over existing therapies" and agreeing to expedite its development and review.

Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD began in September 2018, and will enroll 200-300 participants across 16 sites in the U.S., Canada, and Israel. If the Phase 3 trials demonstrate significant efficacy and an acceptable safety profile, FDA approval is expected by 2021.

The *Journal of Psychopharmacology* article was authored by Marcela Ot'abora G., MA, LPC; Jim Grigsby, Ph.D.; Bruce Poulter, MPH, RN; Joseph William Van Derveer III, M.D.; Sara Gael Giron, MA; Lisa Jerome, Ph.D.; Allison A. Feduccia, Ph.D.; Scott Hamilton, Ph.D.; Berra Yazar-Klosinski, Ph.D.; Amy Emerson, BS; Michael C. Mithoefer, MD; and Rick Doblin, Ph.D.

¹The course of double-blind treatment included 13.5 hours of non-drug psychotherapy and 16 hours (two day-long experimental sessions) of either full-dose or low-dose MDMA-assisted psychotherapy. After completing the initial double-blind portion of the study, participants who were initially randomly selected to receive active-dose MDMA then received a third day-long experimental session with active-dose MDMA and 4.5 additional hours of non-drug psychotherapy. Participants initially randomized to the low-dose group then received three day-long active-dose MDMA sessions and 18 additional hours of non-drug psychotherapy.