



CLINICAL TRIAL FACT SHEET

**MDMA-ASSISTED PSYCHOTHERAPY FOR PTSD
PHASE 3 CLINICAL TRIALS**

Study Title: A Randomized, Double-Blind, Placebo-Controlled, Multi-Site Phase 3 Study of the Efficacy and Safety of Manualized MDMA-Assisted Psychotherapy for the Treatment of Severe Posttraumatic Stress Disorder

Study Sponsor: MAPS, a 501(c)(3) nonprofit research organization

Study Sites:

- Los Angeles, CA | private practice
- San Francisco, CA | research institution
- San Francisco, CA | private practice
- Boulder, CO | private practice
- Fort Collins, CO | private practice
- Farmington, CT | research institution
- New Orleans, LA | private practice
- Boston, MA | research institution
- New York, NY | research institution
- New York, NY | private practice
- Charleston, SC | private practice
- Madison, WI | research institution
- Montreal, Canada | private practice
- Vancouver, Canada | private practice
- Israel | research institutions (two sites)

Study Summary:

This is a randomized, double-blind, placebo-controlled, multi-site clinical trial that assesses the safety and efficacy of **MDMA-assisted psychotherapy in 200-300 participants with severe posttraumatic stress disorder (PTSD) from any cause**, aged 18 and older.

The trial builds on the promising results of MAPS' completed Phase 2 clinical trials, and is the final phase of research required by the U.S. Food and Drug Administration (FDA) before deciding whether to approve MDMA as a legal prescription treatment for PTSD, required to be used in conjunction with psychotherapy in an inpatient setting.

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. Breakthrough Therapy Designation also means that the FDA will work closely with MAPS to provide guidance on the development of MDMA for post-traumatic stress disorder to design and conduct the development program as efficiently as possible.

On July 28, 2017, MAPS and the FDA reached agreement on the **Special Protocol Assessment** for Phase 3 clinical trials. This agreement confirms that the protocol design,

For more information or to schedule an interview, contact Brad Burge, MAPS Director of Strategic Communications, at brad@maps.org or 650-863-6887.



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clinical endpoints, planned conduct, and statistical analyses for the Phase 3 trials are acceptable to support regulatory approval by the FDA.

Prior Results

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.

Study Design

The Phase 3 program will take place at **approximately 15 research sites** in the U.S., Canada, and Israel (see list above). Participants will be randomized to receive **three sessions** of either MDMA or placebo in conjunction with psychotherapy over a **12-week treatment period**, along with non-drug preparatory and integration sessions (three each). MDMA is administered in three single-dose supervised psychotherapy sessions spaced three to five weeks apart, along with preparatory and integration sessions.

The **primary outcome measure** for the study is the Clinician-Administered PTSD Scale (CAPS-5), a semi-structured interview used in the majority of clinical trials for PTSD. Other measures will include the Inventory of Psychosocial Functioning, Beck Depression Inventory, and others. The CAPS-5 will be assessed by a blinded pool of independent raters.

About 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.

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About MAPS

Funding for the research is provided by the **Multidisciplinary Association for Psychedelic Studies (MAPS)**, a 501(c)(3) non-profit research and educational organization. Since its founding in 1986, MAPS has raised over \$47 million for psychedelic therapy and medical marijuana research and education. For more information, visit maps.org

MAPS-sponsored clinical trials are conducted by the **MAPS Public Benefit Corporation (MPBC)**, a wholly owned subsidiary of MAPS formed in 2015 for the special purpose of balancing social benefits with income from legal sales of MDMA, other psychedelics, and marijuana. For more information, visit mapsbcorp.com.

Donations are needed now to complete this vital research. No funding for this research is yet available from governments, for-profit pharmaceutical companies, or major foundations. MAPS has raised or pledged half of the approximately \$25 million needed to complete these trials and make MDMA-assisted psychotherapy a legal treatment for people suffering from PTSD, with \$12.5 million still needed. To make a contribution, visit maps.org/donate.

Statements

“The world’s populations need more compassion and empathy for one another. The study of MDMA provides one small but potentially important step toward reaching that goal.”
— Boris Heifets, MD, PhD, and Robert Malenka, MD, PhD, *Cell* (2016)

“When it comes to the health and well-being of those who serve, we should leave our politics at the door and not be afraid to follow the data. There's now an evidence base for this MDMA therapy and a plausible story about what may be going on in the brain to account for the effects.”
— Brig. Gen. (Ret.) Loree Sutton, MD, *The New York Times* (2012)

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