

Research News

Treating PTSD with MDMA-Assisted Psychotherapy

PHASE 3 TRIALS OF MDMA-ASSISTED PSYCHOTHERAPY FOR PTSD

OUR FDA-REGULATED PHASE 3 CLINICAL TRIALS of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) are taking place at 15 locations across the United States, Canada, and Israel.

The Phase 3 clinical trials are assessing the efficacy and safety of MDMA-assisted psychotherapy in adult participants with severe PTSD. Over a 12-week treatment period, participants will be randomized to receive 12 non-drug preparatory and integration sessions lasting 90 minutes each, along with three day-long sessions about a month apart of either MDMA or placebo in conjunction with psychotherapy. The primary endpoint will be the Clinician Administered PTSD Scale (CAPS-5), as assessed by a blinded pool of independent raters.

The trials are the final phase of research required by the FDA before deciding whether to approve MDMA as a legal prescription treatment for PTSD. If approved, MDMA will be required to be used in conjunction with psychotherapy in an outpatient setting.

The Phase 3 trials are being conducted at the following 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
 New Orleans, LA | private practice
 New York, NY | research institution
 New York, NY | private practice
 Charleston, SC | private practice
 Madison, WI | research institution
 Boston, MA | private practice
 Montreal, Canada | private practice
 Vancouver, Canada | research institution
 Be'er Ya'akov, Israel | research institution
 Tel HaShomer, Israel | research institution

As of September 17, 2019, all 15 Phase 3 sites have officially enrolled a subject.

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.

On August 16, 2017, the FDA granted Breakthrough Ther-

apy 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.

There is now a clear path ahead to make MDMA a legal medicine for millions of people suffering from PTSD. Help heal trauma: maps.org/donate

ISRAEL APPROVES COMPASSIONATE USE OF MDMA-ASSISTED PSYCHOTHERAPY FOR PTSD

On February 3, 2019, the Israeli Ministry of Health announced the approval of Compassionate Use for MDMA-assisted psychotherapy for PTSD, which will allow 50 patients to receive the therapy within a treatment protocol. Patients with PTSD will be eligible to receive treatment at four sites throughout Israel, including Rambam Medical Center in Haifa and psychiatric hospitals in Be'er Yaakov, Lev Hasharon, and Be'er Sheva.

"The ministry is taking this seriously and with appropriate caution, an in-depth investigation has been carried out. There is a considerable population in Israel of people suffering from PTSD that is resistant to other treatment," said Bella Ben-Gershon of Israel's Ministry of Health to Haaretz Newspaper.

OPEN-LABEL LEAD-IN STUDY OF MDMA-ASSISTED PSYCHOTHERAPY FOR PTSD: ALL SITES FULLY ENROLLED

As of April 3, 2019, all sites are officially fully enrolled in our Phase 2 open-label lead-in study of MDMA-assisted psychotherapy for PTSD at planned Phase 3 sites across the United States and Canada. The purpose of this study is to provide the final training and supervision for our co-therapy teams as they work with one study participant with PTSD. The same treatment approach will be used in Phase 3. We are currently developing long-term follow-up protocol for this multi-site open-label Phase 2 study, which will assess symptoms of PTSD in participants 12 months after completing treatment.

Therapist Training Study: 85th Participant Enrolled, New Trial Location Approved in Santa Fe, New Mexico

Ongoing Study

Locations: Charleston, South Carolina, and Boulder, Colorado, and Santa Fe, New Mexico

Principal Investigators: Zhenya Gelfand, M.D. (Charleston), and Marcela Ot'alora G., M.A., L.P.C. (Boulder), George Greer, M.D. (Santa Fe)

Sub-Investigator: Annie Mithoefer, B.S.N. (Charleston)

To date, a total of 85 participants have enrolled in our Phase 1 study of the psychological effects of MDMA when used in a therapeutic setting by healthy volunteers. Enrollment in this multi-site study is limited by invitation only to therapists in

training to work on MAPS-sponsored clinical trials of MDMA-assisted psychotherapy for PTSD.

We have launched a third study location in Santa Fe, New Mexico, for our ongoing therapist training study, which also takes place in Boulder, Colorado, and Charleston, South Carolina. The new study site in Santa Fe has received Drug Enforcement Administration (DEA) and Institutional Review Board (IRB) approval and will be led by Principal Investigator George Greer, M.D. The study site in Boulder is led by Principal Investigator Marcela Ot'alora, M.A., L.P.C., and the study site in Charleston is led by Principal Investigator Zhenya Gelfand, M.D.

Startle Testing with MDMA: 20th Participant Completes Experiment

Ongoing Study

Location: Emory University in Atlanta, Georgia

Principal Investigator: Barbara Rothbaum, Ph.D.

On September 18, 2019, the 20th participant completed their participation in our ongoing study of the effect of MDMA on startle testing in healthy volunteers. Led by Principal Investigator Barbara Rothbaum, Ph.D., this study is conducted at Emory University in Atlanta, Georgia. If you have tried MDMA and live near Atlanta, you may be eligible to enroll in this study investigating the effects of MDMA on the startle response. For more information, please contact callan.m.coghlan@emory.edu.

MDMA Therapy Training Program Update

Training Program

Therapy Training Team: Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., Marcela Ot'alora G., M.A., L.P.C.

In January 2019, MAPS Public Benefit Corporation (MAPS PBC) submitted an MDMA-assisted psychotherapy for PTSD protocol to the U.S. Food and Drug Administration (FDA) as part of an application to participate in the FDA Expanded Access (EA) program. We've received and responded to several rounds of comments from FDA regarding our protocol submission for Expanded Access, and we are continuing our negotiations with the FDA and are optimistic for . The Expanded Access program's purpose is to grant access to potentially beneficial investigational treatments for individuals or populations facing a serious or immediately life-threatening condition for which there is no satisfactory treatment currently available. If approved, MAPS PBC will start with a limited number of qualified sites to provide MDMA-assisted psychotherapy for participants with treatment-resistant PTSD under a MAPS PBC protocol.

Sites in the U.S. and U.S. territories interested in being considered to participate in an MDMA/PTSD protocol may now apply with MAPS PBC to assess eligibility and obtain the prerequisite training to administer MDMA-assisted psychotherapy. The basic requirements of a qualified site are (1) treatment facility conducive to MDMA-assisted psychotherapy, (2) therapy team, qualified and able to complete MDMA Therapy Training Program, and (3) prescribing physician who can obtain a DEA Schedule I license for MDMA.

Additional site and practitioner requirements are posted on our website. Each site must submit one site questionnaire and all applicants interested in training need to complete a therapy training application for providers. Only applicants affiliated with a qualifying site can be considered for training at this time. MAPS PBC will review applications on an ongoing basis, as they are received.

The MDMA Therapy Training Program has launched a series of trainings to prepare therapy providers to become eligible to work on an MDMA-assisted psychotherapy for PTSD protocol. Our most recent MDMA Therapy Training Program retreat took place from October 1-8, 2019, in Asheville, North Carolina, and will be led by Annie Mithoefer, B.S.N., and Michael Mithoefer, M.D. See also Shannon Clare Carlin's article in this issue about MAPS' Psychedelic Medicine and Cultural Trauma Community Workshop and the MDMA Therapy Training for Communities of Color, which took place in Louisville, Kentucky on August 10-17, 2019.

Sign up and stay tuned to the Training Program Newsletter to receive updates on upcoming trainings at mapspublicbenefit.com.

Medical Marijuana Research

76th and Final Participant Enrolls in Smoked Marijuana Trial for Chronic PTSD in Veterans

Study Completed: February 20, 2019

Location: Phoenix, Ariz.

Coordinating Principal Investigator: Marcel Bonn-Miller, Ph.D. (University of Pennsylvania)

Co-Investigator/Site Principal Investigator: Sue Sisley, M.D. (private practice)

Co-Investigator: Paula Riggs, M.D. (University of Colorado)

On February 8, 2019, MAPS-sponsored researchers officially completed the first-ever clinical trial of smoked marijuana (cannabis) as a treatment for PTSD symptoms, with all 76 veterans enrolled and treated. The data from the study are now being analyzed and prepared for publication in a peer-reviewed biomedical journal.

“We are thrilled to finally be at the finish line of this nearly 10-year saga trying to get this crucial clinical trial completed,” said Site Principal Investigator Sue Sisley, M.D. “We are immensely grateful to all of the study’s supporters, especially the veteran service organizations who helped us with patient recruitment.”

Disclaimer: This study was supported by funding from the Colorado Department of Public Health and Environment (CDPHE). The content and opinions are those of the grantee/authors and do not represent the official views of CDPHE.

Ayahuasca Research

Data Collection Survey Continues

Ongoing study

Principal Investigator: Jessica Nielson, Ph.D.

We are currently collecting responses for the revised version of our anonymous questionnaire about the potential risks and benefits associated with using ayahuasca in treatment for PTSD. The data collection is sponsored by MAPS, with Jessica Nielson, Ph.D., as Principal Investigator. We welcome participation from anyone that has tried ayahuasca in any context or setting, including those who took the first version of the survey. To participate in the survey, visit surveymonkey.com/r/AyaPTSD.

Ibogaine Treatment for Drug Addiction

Observational Research Published in American Journal of Drug and Alcohol Abuse

Study Completed

Locations: Mexico and New Zealand

Principal Investigators: Thomas Kingsley Brown, Ph.D. (Mexico) and Geoff Noller, Ph.D. (New Zealand)

On May 25 and April 12, 2017, the promising results of MAPS-sponsored observational studies of treating opioid dependence with ibogaine-assisted therapy were published in the peer-reviewed American Journal of Drug and Alcohol Abuse. Download both articles for free at maps.org/ibogaine.

Participate in Research

MAPS sponsors clinical trials around the world that require human participants. Our studies have strict enrollment criteria based on the goal of the study and the condition the study is investigating.

Our new study recruitment website is now accepting applications to participate in clinical trials of MDMA-assisted psychotherapy for PTSD at mdmaptsd.org.