Research News

Treating PTSD with MDMA-Assisted Psychotherapy

FDA Agrees to Expanded Access Program for MDMA-Assisted Psychotherapy for PTSD

On December 20, 2019, the U.S. Food and Drug Administration (FDA) agreed to MAPS' application for an Expanded Access program for MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD).

The purpose of the Expanded Access program is to allow early access to potentially beneficial investigational therapies for people facing a serious or life-threatening condition for whom currently available treatments have not worked, and who are unable to participate in Phase 3 clinical trials.

"We commend FDA for recognizing the great unmet medical need of PTSD by allowing access to MDMA-assisted psychotherapy on a compassionate basis for people with treatment-resistant PTSD," said MAPS Founder and Executive Director Rick Doblin, Ph.D. "We are delighted to begin generating real-world evidence about this potential new treatment."

The Expanded Access protocol will allow 50 patients to receive MDMA-assisted psychotherapy, following the MAPS treatment protocol (maps.org/treatmentmanual). MAPS hopes to expand the number of patients eligible to receive treatment in the Expanded Access Program. MAPS has proposed to the FDA that after the first 35 patients, it will submit patient data for the agency to consider whether to expand the program.

The Expanded Access protocol differs from MAPS' ongoing Phase 3 clinical trials in that it is limited to treatment-resistant patients with moderate to severe treatment-resistant PTSD. Other differences are that the FDA is requiring at least one therapist of each therapy pair to have a medical or clinical doctorate degree (M.D., Ph.D., or equivalent), there is no control group, and patients are responsible for the costs of their own treatment.

Up to 10 qualifying treatment sites will be selected to begin the Expanded Access program, to be announced in the next few months. Over 120 site applications have been received to date. Once the program begins, patients can apply to the individual Expanded Access sites.

"The resurgence of research into using drugs such as MDMA to catalyze psychotherapy is the most promising and exciting development I've seen in my psychiatric career," said Michael Mithoefer, M.D., Acting Medical Director for MAPS Public Benefit Corporation. "Combining the powerful effects of pharmacology with the potential depth of psychotherapy is a compelling model for harnessing advances in neuroscience and psychopharmacology without ignoring the complexity, richness and innate capacity of the human psyche. I'm delighted that the Expanded Access Program will now allow some patients to access to this modality as MAPS' Phase 3 research continues."

MAPS' Expanded Access protocol must still be approved by the U.S. Drug Enforcement Administration (DEA) and the Institutional Review Board (IRB). Based on the FDA's review as well as the DEA and IRB's existing support of MDMA-assisted psychotherapy clinical trials, MAPS does not anticipate delays in those approvals.

This is the second time that a government agency has allowed such a program for MDMA-assisted psychotherapy. On February 3, 2019, the Israeli Ministry of Health announced the approval of Compassionate Use for MDMA-assisted psychotherapy for PTSD, which will also allow 50 patients to receive the treatment. Patients with PTSD will be eligible to receive treatment at four sites throughout Israel.

MAPS is currently sponsoring ongoing Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD at 15 sites in the U.S., Canada, and Israel. In August 2017, the FDA granted Breakthrough Therapy Designation to MDMA-assisted psychotherapy for PTSD. The Phase 3 trials are expected to be completed in 2021, meaning that the FDA could approve the treatment as early as 2022. MAPS is also initiating Phase 2 trials in Europe, starting this month.

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 moderate to 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 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.

We are currently seeking research volunteers for Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD. Volunteers will help contribute to scientific knowledge and will help us better understand if MDMA-assisted psychotherapy works for the treatment of PTSD. MAPS conducts clinical trials under the guidance and regulations of the U.S. Food and Drug Administration (FDA) in collaboration with all federal regulators, including the Drug Enforcement Administration (DEA). To learn more about our clinical trials or apply to be a study participant, visit this website: mdmaptsd.org

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.

Phase 2 Open-Label Lead-In Study of MDMA-Assisted Psychotherapy for PTSD: Data Under Review

On December 10, 2019, MAPS Public Benefit Corporation (MAPS PBC) completed an interim lock of the existing database for our Phase 2 open-label lead-in study of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) at sites across the United States and Canada. A total of 42 people were enrolled in the study, with 37 treated, and a total of 36 participants completed the study. With this preliminary set of data from 36 subjects, the research team will analyze the data for submission to FDA and will write a paper for submission to a peer-reviewed scientific journal. 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 have developed a 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: 89th Participant Enrolled, New Trial Location Approved in Santa Fe, New Mexico

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)

As of January 17, 2020, 89 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: 29th Participant Completes Experiment

Ongoing Study

Location: Emory University in Atlanta, Georgia

Principal Investigator: Barbara Rothbaum, Ph.D.

On March 4, 2020, the 29th 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

Director of Training and Supervision: Shannon Carlin, A.M.F.T.

Happy Spring from the MDMA Therapy Training Program! The Training and Supervision Department is currently focused on supervision, adherence rating, and video programs to support Phase 3 studies in the United States, Canada, Israel, and European Union. The MDMA Therapy Training Program is currently training approximately fifty therapists preparing to work on the upcoming Expanded Access program for MDMA-assisted psychotherapy for PTSD. In addition to Expanded Access, MDMA Therapy Training Program is focusing efforts towards competency framework and curriculum development to support the growing body of MDMA therapy professionals. The MDMA Therapy Training Program is not currently enrolling; stay tuned to the MDMA Therapy Training Newsletter for more updates. Sign up at mapspublicbenefit.com/therapy-training!

While MAPS PBC is not currently recruiting new sites and the MDMA Therapy Training Program is not actively enrolling new trainees, qualified and interested sites and therapists may still submit an application to be considered at a later date. Information about application requirements and instructions to apply and can be found at mapspublicbenefit.com/training/program-application-requirements.

The MAPS PBC Therapy Provider Connect Portal (connect.mdmatherapytraining.com) is a community discussion forum for therapy providers, physicians, and facilities to connect with one another to develop a site or treatment staff, in order to become eligible to participate in a MAPS PBC MDMA/PTSD protocol.

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.

Phase 3 trial participant enrollment is open at multiple sites. Please bookmark our Participate in Research page and check it frequently for updates.

maps.org/participate/participate-in-research