Research News

Treating PTSD with MDMA-Assisted Psychotherapy

mdmaptsd.org

MDMA capsules from MAPS' completed Phase 2 trial of MDMA-assisted psychotherapy for PTSD in Boulder, Colorado.

Phase 3 Trials: Open-Label Lead-In Study Begins

In MAPS' completed Phase 2 trials, 61% of 107 participants who completed three sessions of MDMA-assisted psychotherapy no longer qualified for posttraumatic stress disorder (PTSD) after two months following treatment. At the 12-month follow-up, 68% no longer had PTSD. All Phase 2 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.

As of April 4, 2018, MAPS Public Benefit Corporation (MPBC) clinical research staff have completed 13 of 14 Study Initiation Visits for an 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 for our Phase 3 co-therapy teams. Each new co-therapy team will work with a single participant at their respective study site with supervision provided by MAPS' therapy training team.

Eleven open-label study sites have been granted Schedule I licenses by the U.S. Drug Enforcement Administration (DEA), and six open-label study sites have received the study drug. The study site in Fort Collins, CO, has conducted experimental treatment sessions with two participants, and the New Orleans, LA, study site has completed their first experimental treatment session; other sites will begin open label enrollment soon.

MAPS' Phase 3 trials, starting in the summer of 2018, will

assess the efficacy and safety of MDMA-assisted psychotherapy in adult participants with PTSD at sites in the U.S., Canada, and Israel. Over a 12-week treatment period, participants will be randomized to receive 12 90-minute non-drug preparatory and integration sessions, along with three day-long sessions of either MDMA or placebo in conjunction with psychotherapy, about a month apart. The primary endpoint will be the Clinician Administered PTSD Scale (CAPS-5), as assessed by a blinded pool of independent raters.

MAPS' Phase 3 trials will be 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
Farmington, CT | research institution
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 | research institution
Montreal, Canada | private practice
Vancouver, Canada | research institution
Israel | research institution

These Phase 3 trials build on the promising results of MAPS' completed Phase 2 trials, and are the final phase of research required by the FDA before deciding whether to approve MDMA as a legal prescription treatment for PTSD, which MAPS estimates could happen by 2021. Once approved, MDMA will be required to be used in only conjunction with psychotherapy in a clinical setting.

MAPS and MPBC are excited to reach this milestone toward bringing healing to those suffering from PTSD with MDMA-assisted psychotherapy. Donations are currently being sought to reach MAPS' goal of raising $26.7 million to complete the Phase 3 studies required to gain approval from the FDA for MDMA-assisted psychotherapy.

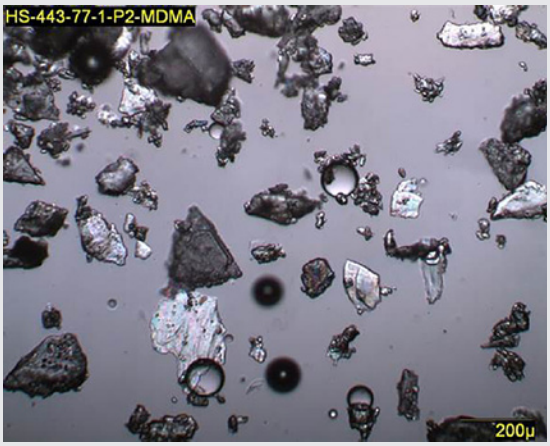
Approval from the European Medicines Agency (EMA) will likely require additional funds. MAPS began negotiations with EMA on March 1, 2018, and will travel to London, UK, to meet with EMA in Summer 2018. Additional expenses of $5-$10 million will include research for other regulatory agencies around the world, therapist training, Expanded Access, and FDA-required Phase 4 studies in adolescents with PTSD. With $26.2 million in hand or in multi-year pledges, there's still a funding gap we need to close.

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

GMP MDMA Imported to U.S.

On March 13, 2018, the MDMA that will be used in MAPS' upcoming Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD was successfully imported into the United States from our third-party pharmaceutical vendor in the UK. The compound, manufactured by Onyx Scientific Ltd. using a synthetic precursor, is certified under current Good Manufacturing Processes (cGMP), and was synthesized using the same route that will be used to manufacture MDMA for post-approval sales. The product will also be used for planned toxicology and clinical pharmacology studies. As the MDMA dosing regimen is three single-dose treatments per patient, the planned amount of drug product needed for commercial distribution is far lower than approved medications requiring daily dosing.

Drug product formulation studies are complete for the immediate release solid oral dosage form. Hydroxypropylmethyl cellulose (HPMC) capsules will be prepared by third-party cGMP drug product manufacturer, Sharp Clinical Services, Inc. (US). The final formulation includes only MDMA, mannitol, and magnesium stearate. Based on preliminary studies conducted with our previous MDMA supply for Phase 1 and Phase 2 trials, the drug product achieved greater than 80% dissolution at 15 minutes, indicating that the active compound is immediately and completely released from the capsules within 15 minutes. Based on only small differences in formulation, the Phase 3 and commercial formulations are anticipated to be comparable.



Results Published by The Lancet Psychiatry: MDMA-Assisted Psychotherapy for Veterans with PTSD

On May 1, 2018, the results of MAPS' pioneering U.S. Food and Drug Administration (FDA)-regulated clinical trial of MDMA-assisted psychotherapy for the treatment of post-traumatic stress disorder (PTSD) in veterans, firefighters, and police officers were published in the peer-reviewed journal *The Lancet Psychiatry.*

The publication has already received widespread international media attention in *The New York Times, CNN, Reuters, Fox News, Agence France Presse, British Forces News, Stars & Stripes,* and much more.

The double-blind, placebo-controlled, Phase 2 pilot study in 26 participants found that one month after their second day-long experimental session, 68% in the full-dose MDMA group did not qualify for a diagnosis of PTSD, compared to 29% in the low-dose MDMA (active placebo) control group. The 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. On average, the positive results were sustained one year later.

Led by Michael Mithoefer, M.D., and Ann Mithoefer, B.S.N., in Charleston, South Carolina, the trial was one of MAPS' six completed Phase 2 pilot studies of MDMA-assisted psychotherapy for PTSD. Trial participants included veterans (22), firefighters (3), and police officers (1), all with service-related PTSD.

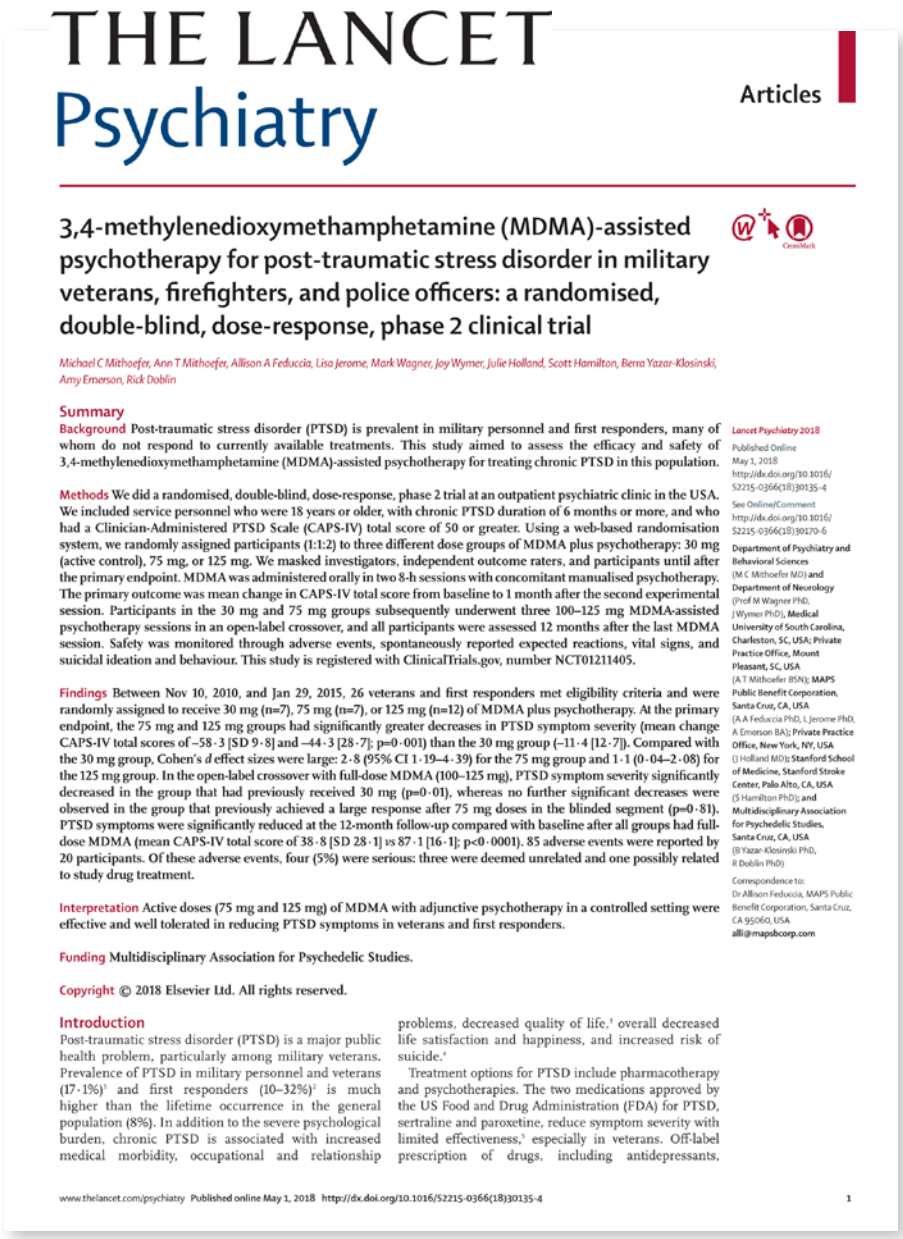
"The MDMA alone or the therapy alone don't appear to be as effective," explains Dr. Mithoefer. "The MDMA seems to act as a catalyst that allows the healing to happen."

"I was actually able to forgive myself," explains study participant Nigel McCourry. "There are also still some challenges I have to face from time to time related to the PTSD. But now I am able to work through them without getting stuck."

The study replicated previous research showing an acceptable risk profile for MDMA, with the most frequently reported adverse reactions during experimental sessions being anxiety, headache, fatigue, and muscle tension. Adverse reactions one week following treatment included anxiety, fatigue, and insomnia. Temporary elevations in pulse, blood pressure, and temperature were also recorded during MDMA sessions, and did not require medical intervention.

"At least one in two PTSD patients cannot tolerate or do not respond adequately to existing treatments, so there is an urgent need for better treatments for the millions of military veterans and others with PTSD," said Dr. Mithoefer. "These results are further evidence that MDMA, used just two times at monthly intervals, can make psychotherapy much more effective and better tolerated. I'm excited that Phase 3 trials will soon confirm whether this therapy can be approved for widespread use in a few years."

The Lancet Psychiatry article was authored by Michael Mithoefer, M.D., Ann Mithoefer, B.S.N., Allison Feduccia, Ph.D., Lisa Jerome, Ph.D., Mark Wagner, Ph.D., Joy Wymer, Ph.D., Julie Holland, M.D., Scott Hamilton, Ph.D., Berra Yazar-Klosinski, Ph.D., Amy Emerson, B.A.., and Rick Doblin, Ph.D.



THE LANCET
Psychiatry

Articles

3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for post-traumatic stress disorder in military veterans, firefighters, and police officers: a randomised, double-blind, dose-response, phase 2 clinical trial

Michael C Mithoefer, Ann T Mithoefer, Allison A Feduccia, Lisa Jerome, Mark Wagner, Joy Wymer, Julie Holland, Scott Hamilton, Berra Yazar-Klosinski, Amy Emerson, Rick Doblin

Summary

Background Post-traumatic stress disorder (PTSD) is prevalent in military personnel and first responders, many of whom do not respond to currently available treatments. This study aimed to assess the efficacy and safety of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy for treating chronic PTSD in this population.

Methods We did a randomised, double-blind, dose-response, phase 2 trial at an outpatient psychiatric clinic in the USA. We included service personnel who were 18 years or older, with chronic PTSD duration of 6 months or more, and who had a Clinician-Administered PTSD Scale (CAPS-IV) total score of 50 or greater. Using a web-based randomisation system, we randomly assigned participants (1:1:2) to three different dose groups of MDMA plus psychotherapy: 30 mg (active control), 75 mg, or 125 mg. We masked investigators, independent outcome raters, and participants until after the primary endpoint. MDMA was administered orally in two 8-h sessions with concomitant manualised psychotherapy. The primary outcome was mean change in CAPS-IV total score from baseline to 1 month after the second experimental session. Participants in the 30 mg and 75 mg groups subsequently underwent three 100–125 mg MDMA-assisted psychotherapy sessions in an open-label crossover, and all participants were assessed 12 months after the last MDMA session. Safety was monitored through adverse events, spontaneously reported expected reactions, vital signs, and suicidal ideation and behaviour. This study is registered with ClinicalTrials.gov, number NCT01211405.

Findings Between Nov 10, 2010, and Jan 29, 2015, 26 veterans and first responders met eligibility criteria and were randomly assigned to receive 30 mg (n=7), 75 mg (n=7), or 125 mg (n=12) of MDMA plus psychotherapy. At the primary endpoint, the 75 mg and 125 mg groups had significantly greater decreases in PTSD symptom severity (mean change CAPS-IV total scores of −58·3 [SD 9·8] and −44·3 [28·7]; p=0·001) than the 30 mg group (−11·4 [12·7]). Compared with the 30 mg group, Cohen's *d* effect sizes were large: 2·8 (95% CI 1·19–4·39) for the 75 mg group and 1·1 (0·04–2·08) for the 125 mg group. In the open-label crossover with full-dose MDMA (100–125 mg), PTSD symptom severity significantly decreased in the group that had previously received 30 mg (p=0·01), whereas no further significant decreases were observed in the group that previously achieved a large response after 75 mg doses in the blinded segment (p=0·81). PTSD symptoms were significantly reduced at the 12-month follow-up compared with baseline after all groups had full-dose MDMA (mean CAPS-IV total score of 38·8 [SD 28·1] *vs* 87·1 [16·1]; p<0·0001). 85 adverse events were reported by 20 participants. Of these adverse events, four (5%) were serious: three were deemed unrelated and one possibly related to study drug treatment.

Interpretation Active doses (75 mg and 125 mg) of MDMA with adjunctive psychotherapy in a controlled setting were effective and well tolerated in reducing PTSD symptoms in veterans and first responders.

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Introduction

Post-traumatic stress disorder (PTSD) is a major public health problem, particularly among military veterans. Prevalence of PTSD in military personnel and veterans (17·1%)[1] and first responders (10–32%)[2] is much higher than the lifetime occurrence in the general population (8%). In addition to the severe psychological burden, chronic PTSD is associated with increased medical morbidity, occupational and relationship problems, decreased quality of life,[3] overall decreased life satisfaction and happiness, and increased risk of suicide.[4]

Treatment options for PTSD include pharmacotherapy and psychotherapies. The two medications approved by the US Food and Drug Administration (FDA) for PTSD, sertraline and paroxetine, reduce symptom severity with limited effectiveness,[5] especially in veterans. Off-label prescription of drugs, including antidepressants,

New MDMA Articles Published in Peer-Reviewed Journals

In March 2018, the peer-reviewed journal *Progress in Neuro-Psychopharmacology and Biological Psychiatry* published a new article by Allison Feduccia, Ph.D., and Michael C. Mithoefer, M.A., of MAPS Public Benefit Corporation (MPBC), focusing on how fear extinction and memory reconsolidation could be some of the mechanisms underlying the beneficial outcomes seen in research into MDMA-assisted psychotherapy for reducing PTSD symptoms.

Feduccia, A. A., Mithoefer, M. C. (2018). MDMA-Assisted Psychotherapy for PTSD: Are Memory Reconsolidation and Fear Extinction Underlying Mechanisms? *Progress in Neuro-Psychopharmacology & Biological Psychiatry,* 221-228.

From the abstract: By reducing activation in brain regions implicated in the expression of fear- and anxiety-related behaviors, namely the amygdala and insula, and increasing connectivity between the amygdala and hippocampus, MDMA may allow for reprocessing of traumatic memories and emotional engagement with therapeutic processes. Based on the pharmacology of MDMA and the available translational literature of memory reconsolidation, fear learning, and PTSD, this review suggests a neurobiological rationale to explain, at least in part, the large effect sizes demonstrated for MDMA in treating PTSD.

Another article, "Potential Psychiatric Uses for MDMA", published in *Clinical Pharmacology & Therapeutics* by Michael C. Mithoefer, M.D., and Berra Yazar-Klosinski, Ph.D., was one of the journal's top 10 most downloaded papers in 2017. The paper received 2,339 downloads over the course of last year.

Yazar-Klosinski, B. B., Mithoefer, M. C. (2017). Potential Psychiatric Uses for MDMA. *Clinical Pharmacology & Therapeutics,* 194-196.

From the abstract: Phase 2 trials of MDMA-assisted psychotherapy have demonstrated initial safety and efficacy for treatment of PTSD, with potential for expansion to depression and anxiety disorders. In these trials, single doses of MDMA are administered in a model of medication-assisted psychotherapy, differing from trials involving daily drug administration without psychotherapy.

In November 2017, three more articles from MAPS staff and researchers were published in peer-reviewed scientific journals, including an update on MAPS' MDMA drug development program in *Psychopharmacology* and two letters to the editor about the need for more effective PTSD treatments in *Biological Psychiatry* and the *New England Journal of Medicine.*

Feduccia, A. A., Holland, J., Mithoefer, M. C. (2017). Progress and promise for the MDMA drug development program. *Psychopharmacology,* 1-11.

From the abstract: "Pharmacotherapy is often used to target symptoms of PTSD, but does not provide definitive treatment, and side effects of daily medication are often problematic…The most promising drug studied as a catalyst to psychotherapy for PTSD thus far is MDMA."

Feduccia, A. A., Mithoefer, M. C., Jerome, L., Holland, J., Emerson, A., Doblin, R. (2017). Response to the Consensus Statement of the PTSD Psychopharmacology Working Group. *Biological Psychiatry.*

From the abstract: "We are writing in response to the Letter to the Editor by John Krystal and colleagues…This timely research statement pointed out some of the barriers to translating a wealth of PTSD research into effective pharmacological strategies…The addition of two promising candidates—cannabis and MDMA—would make this report more comprehensive."

Mithoefer, M. C., Jerome, L., Monson, C. (2017). Posttraumatic Stress Disorder Correspondence. *New England Journal of Medicine.*

From the abstract: "MDMA therapy has been shown to produce lasting improvement in symptoms of PTSD and in personality changes supportive of recovery. Proposed mechanisms of action include fear extinction, greater ease in addressing emotionally upsetting material, and strengthening of the therapeutic alliance through increased empathy and self-compassion."

Therapist Training Study Enrolls 54th Participant

Ongoing study
Location: Charleston, South Carolina, and Boulder, Colorado
Principal Investigator: Michael Mithoefer, M.D., (Charleston), and Marcela Ot'alora, M.A., L.P.C. (Boulder)
Sub-Investigator: Annie Mithoefer, B.S.N., (Charleston)

On February 27, 2018, the 54th participant enrolled in our ongoing 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. On February 15, 2018, Senior Clinical Research Associate Charlotte Harrison of MPBC traveled to Colorado for a monitoring visit of the study site in Boulder, which included a thorough review of the study's documentation, database, files, and adherence to regulations.

MDMA Therapy Training Program: Update on Supervision Process *Training Program*

Location: Charleston, South Carolina, and Boulder, Colorado
Therapy Training Team: Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., Marcela Ot'alora G., M.A., L.P.C.

As of April 2018, the MDMA Therapy Training Program (**maps.org/training**) is supporting the final segment of training for Phase 3 therapy teams. Supervision of therapists is a major focus of active Phase 2 open-label trials in the US and Canada, and will continue to be an important aspect of the training program going forward. When therapy pairs treat their first study participant in the open-label trials, they receive feedback from a supervisor (an expert MDMA-assisted psychotherapy researcher) in regular meetings. Also, with the help of trained adherence raters, supervisors review video recordings of therapy sessions. The careful review of these therapy sessions

informs how a supervisor guides therapy pairs in their further training while aiming to improve treatment outcomes. MAPS' open-label trials currently include three supervisors and 12 adherence raters supporting 40 new therapy pairs. Completion of this program is a prerequisite for anyone working on a therapy team in a MAPS-sponsored Phase 3 trial. The MAPS Therapy Training Program plans to train approximately 300 therapists in anticipation of MDMA-assisted psychotherapy becoming an FDA-approved prescription treatment by 2021.

At this point, the training program is not accepting applications, however you can sign up to receive updates when future training opportunities become available. Learn more by visiting **maps.org/therapists**.

Cognitive Behavioral Conjoint Therapy for PTSD: Fourth Dyad Completes Long-Term Follow-Up Interview *Ongoing study*

Location: Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D.,
Sub-Investigator: Candice Monson, Ph.D.

On March 3, 2018, the fourth dyad (pair of participants) completed their long-term follow-up interview in our ongoing study of MDMA combined with Cognitive Behavioral Conjoint Therapy (CBCT) for PTSD at our Charleston, South Carolina site. The third dyad completed the six-month follow-up interview on October 25, 2017. This study has enrolled dyads with one participant diagnosed with PTSD and one concerned significant other who does not have PTSD but does experience psychosocial distress. MDMA will be administered to both participants to help facilitate communication and connection between participants and therapists.

The primary goal of this study is to develop a combined method of MDMA with CBCT for PTSD. This is the first MAPS-sponsored MDMA study conducted with VA-affiliated researchers and the first to employ measures developed for the DSM-5. There are several important reasons to include significant others in PTSD treatment, in addition to the data supporting the efficacy of CBCT for PTSD.

Startle Testing with MDMA: First Participant Receives Experimental Treatment *Ongoing study*

Location: Emory University in Atlanta, Georgia
Principal Investigator: Barbara Rothbaum, Ph.D.

On March, 15, 2018, the first participant completed an experimental session in our ongoing study of the effect of MDMA on startle testing in healthy volunteers. As of March 19, 2018, a total of 43 people have completed preliminary phone screening for enrollment opportunities. This study may be followed by another study exploring the combination of MDMA with Prolonged Exposure in PTSD patients.

MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

Social Anxiety Study Officially Completed

Study Completed
Location: Los Angeles, California
Principal Investigators: Charles Grob, M.D., and Alicia Danforth, Ph.D.

On July 10, 2017, investigators completed the formal closeout of our study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum. All treatment sessions and long-term follow-up interviews for this study have been completed. Led by Principal Investigators Charles Grob, M.D., and Alicia Danforth, Ph.D., this is a collaborative study between MAPS and the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center. The data from this study are now being prepared to be submitted for publication in a peer-reviewed scientific journal.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted therapy for autistic adults diagnosed with social anxiety, (2) determining if additional studies in this area are warranted, and (3) initiating a new program of research into a possible beneficial use of MDMA building on collected case accounts.

MDMA-Assisted Psychotherapy for Anxiety Associated with Life-Threatening Illness

14th Participant Completes Long-Term Follow-Up Interview

Ongoing study
Location: Marin, California
Principal Investigator: Phil Wolfson, M.D.
Co-Therpaist: Julane Andries, L.M.F.T.

On March 19, 2018, the 14th of 18 participants completed their 12-month follow-up interview in our ongoing Marin, Calif., study of MDMA-assisted psychotherapy for anxiety associated with life-threatening illness. This study is gathering preliminary data about the safety and efficacy of MDMA-assisted psychotherapy for anxiety associated with a diagnosis of a life-threatening illness.

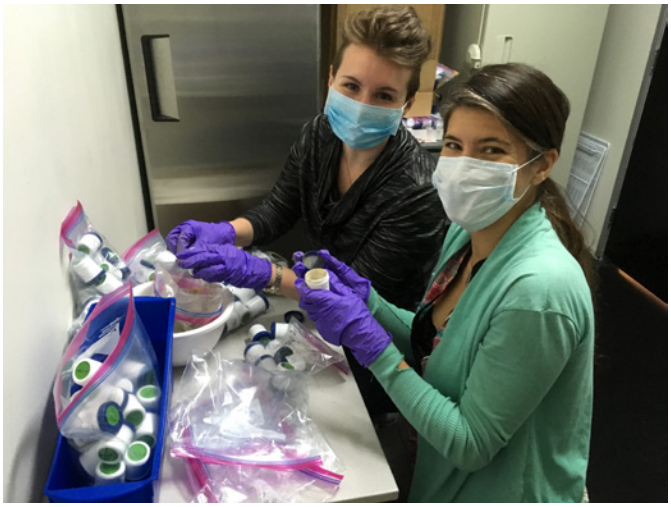
Goals for this study include (1) gathering data on the safety and effectiveness of MDMA-assisted psychotherapy for participants with anxiety associated with life-threatening illness; (2) determining if additional studies are warranted; and (3) initiating MDMA-assisted psychotherapy research for a new clinical indication.

Medical Marijuana Research

50th Participant Enrolls in Smoked Marijuana Trial for Chronic PTSD in Veterans

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

On March 28, 2018, the 50th of 76 participants enrolled and received study drug in the first-ever clinical trial of smoked marijuana (cannabis) for posttraumatic stress disorder (PTSD) in U.S. veterans. Taking place at the Scottsdale Research Institute (SRI) in Phoenix, Arizona, this clinical trial is evaluating the safety and efficacy of four different potencies of marijuana for symptoms of PTSD in 76 U.S. veterans. To learn more, visit the new recruitment website at **wecanstudy.org.**



Senior Clinical Research Associate Charlotte Harrison and Clinical Research Associate Alia Lilienstein, M.D., M.P.H., preparing study drug for the first-ever clinical trial of smoked marijuana (cannabis) for posttraumatic stress disorder (PTSD) in U.S. veterans on June 13, 2017, at the Scottsdale Research Institute in Arizona.

Ayahuasca Research

Data Collection Survey Underway *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 as a therapy for PTSD. The results of the survey are currently being summarized and prepared for publication, at which point the survey will shift its focus to general ayahuasca use for a variety of conditions, including PTSD, depression and substance abuse/addiction. The data collection is being sponsored by MAPS, with Jessica Nielson, Ph.D., as the Principal Investigator.

Ayahuasca is a psychoactive brew or tea most commonly derived from *Banisteriopsis caapi,* a vine containing monoamine oxidase inhibitors (MAOIs), and the leaves of *Psychotria viridis* or other plants containing N,N-dimethyltryptamine (DMT), and often several other admixture plants. Ayahuasca is legal in many countries in South America.

The revised survey is a shorter and simplified version of the original survey, and 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-Assisted Therapy 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.* Sponsored by MAPS in Mexico and New Zealand, both studies show that ibogaine should be further studied as a potential treatment for opioid dependence in rigorously controlled studies.

Ibogaine is a psychoactive compound usually extracted from the West African *Tabernanthe iboga* plant. In animals, a single dose of ibogaine decreases signs of opioid withdrawal and produces sustained reductions in the self-administration of heroin, morphine, cocaine, nicotine, and alcohol. Ibogaine is illegal in the U.S., and legal but unregulated in Canada and Mexico. New Zealand, South Africa, and Brazil authorize the use of ibogaine by licensed medical practitioners. While its mechanism of action is not yet fully understood, it differs from that of standard opioid agonist treatments such as methadone and buprenorphine which maintain dependence, and thus may show promise as an innovative pharmacotherapy for opioid addiction.

Ultimately, the authors of the studies conclude that given the potential demonstrated by ibogaine's substantive treatment effect in opioid detoxification, its novel (though not yet fully understood) pharmacological mechanism of action, and its clinical effect in opioid-dependent participants who have not satisfactorily responded to other treatments, ibogaine has promise for future research and development as a novel pharmacotherapy for opioid addiction.

Download both articles for free at **maps.org/ibogaine**.