

Research News

Treating PTSD with MDMA-Assisted Psychotherapy

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U.S. Veterans Study: 14th Subject Treated; Site Passes Surprise DEA Inspection *Ongoing study*

Location: Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D., with co-therapist Annie Mithoefer, B.S.N.
Estimated study budget: \$1,380,000
Already raised: \$875,000
Needed to complete this study: \$500,000

On July 8, 2013, officials from the U.S. Drug Enforcement Administration conducted a surprise audit of the drug accountability logs for our ongoing study of MDMA-assisted psychotherapy for U.S. veterans, firefighters, and police officers with service-related PTSD. The officials confirmed that all of the MDMA had been adequately tracked and labeled. According to Principal Investigator Michael Mithoefer, M.D., the officials were “friendly and helpful...they’re reasonable people and it feels like we have a good working relationship.”

On July 5, the 14th subject received their first experimental MDMA-assisted psychotherapy session. This subject was enrolled on June 17. In total, 24 subjects will participate in this randomized, triple-blind study. Four subjects have now completed



Principal Investigator Michael Mithoefer, M.D., and co-therapist Annie Mithoefer, B.S.N., speak at Psychedelic Science 2013.

the study, including the long-term follow-up portion. On May 28, Michael Mithoefer presented preliminary results from the study at the 24th International Trauma Conference in Boston, Mass.

U.S. Intern Study: First Subject Receives MDMA-Assisted Psychotherapy in Boulder *Ongoing study*

Location: Boulder, Colorado
Clinical Investigator: Marcela Ot’alora, M.A., L.P.C.
Estimated study budget: \$475,000
Already raised: \$190,000
Needed to complete this study: \$285,000

On July 12, 2013, the first subject received their experimental treatment session in our new study of MDMA-assisted psychotherapy for PTSD in Boulder, Colorado. Led by Clinical Investigator Marcela Ot’alora, this study is exploring the safety and effectiveness of MDMA-assisted psychotherapy when

one member of the male/female co-therapist team is an experienced therapist and the other is an intern being trained in therapy, social work, or nursing. The use of interns is an effort both to reduce costs for future MDMA-assisted psychotherapy trials, and to train the next generation of psychedelic psychotherapists. The study will enroll 12 subjects with chronic, treatment-resistant PTSD due to sexual assault, military combat, or other causes. An amended study protocol was submitted to the FDA and Institutional Review Board on August 6 and 7, respectively.



Encapsulating MDMA for the study in Boulder, Colorado.

Israeli Study: Second Subject Completes All Experimental Treatment Sessions *Ongoing study*

Location: Beer Yaakov, Israel
Clinical Investigator: Moshe Kotler, M.D.
Estimated study budget: \$470,000
Already raised: \$39,000
Needed to complete this study: \$430,000

On July 10, 2013, the second subject completed their last experimental treatment in our ongoing Israeli study of MDMA-assisted psychotherapy for chronic, treatment-resistant PTSD. This study will enroll 10 subjects, some of whom will be soldiers with war-related PTSD referred by the Israeli Defense Forces. Data collected from this study will allow comparisons between the effects of different doses of MDMA on PTSD symptoms, and on symptoms of depression and sleep quality. Led by Clinical Investigator Moshe Kotler, M.D., this study is taking place at Beer Yaakov Mental Hospital. Adherence ratings for the first two subjects’ treatment sessions were completed on July 31.



The setting for MDMA-assisted psychotherapy at Beer Yaakov Mental Hospital, Israel.

Canadian Study: Institutional Review Board Approves Protocol Amendments

Study pending initiation

Location: Vancouver, British Columbia, Canada

Principal Investigators: Ingrid Pacey, M.D. and Andrew Feldmar, Ph.D.

Estimated study budget: \$578,000

Already raised: \$16,000

Needed to complete this study: \$560,000



The 9 grams of MDMA to be used in our Canadian study arrives at the study pharmacy.

On July 12, 2013, a Canadian Institutional Review Board approved an amended protocol and other study documents for our upcoming Canadian study of MDMA-assisted

psychotherapy for PTSD. Both Health Canada and the Canadian IRB have already approved this study. The amendments include several changes to the study design to complement our other ongoing studies around the world, including changes to dose levels, the schedule of subject visits, and the timing of treatment outcome assessments. Aligning our study protocols across sites enables us to compare data and make a stronger case for future Phase 3 studies. The amended protocol was submitted to Health Canada on August 2. Once Health Canada approves the amended protocol, we will begin screening and treating subjects. On April 16, 2013, after more than 2 ½ years of effort to make security adjustments to the study pharmacy as required by Health Canada, the nine grams of MDMA to be used in the study arrived.

Relapse Study: All Treatments Completed

Ongoing study

Location: Charleston, South Carolina

Principal Investigator: Michael Mithoefer, M.D.

Needed to complete this study: \$55,000 still needed

Treatments have been completed in our relapse study of MDMA-assisted psychotherapy for three subjects whose PTSD symptoms returned after participating in our now-completed U.S. flagship study, which was completed in July 2010. Treatment in the relapse study consisted of a single open-label full dose session of MDMA-assisted psychotherapy, accompanied by non-drug preparation and integrative psychotherapy sessions. On April 27, 2012, the first subject completed their follow-up interview, which revealed that the subject's score on the Clinician-Administered PTSD Scale was below the diagnostic cutoff for PTSD. These preliminary results suggest that a single additional MDMA-assisted psychotherapy session may be able to restore subjects who relapsed following successful prior treatment with MDMA-assisted psychotherapy.

Swiss Study: Results Published in *Journal of Psychopharmacology*

Study completed

Location: Solothurn, Switzerland

Clinical Investigator: Peter Oehen, M.D.

This study is complete and has been fully funded.

On January 1, 2013, the results from our now-completed Swiss pilot study of MDMA-assisted psychotherapy for 12 subjects with chronic, treatment-resistant PTSD became published in the *Journal of Psychopharmacology*, a peer-reviewed scientific journal. The paper, co-authored by Clinical Investigator Peter Oehen, M.D., and Ulrich Schneider, M.D., former president of the International Society for Traumatic Stress Studies, the world's largest organization for PTSD treatment providers and researchers, describes clinically significant decreases in PTSD symptoms following MDMA-assisted psychotherapy that approached statistical significance (0.06).

Australian Study: Researchers Continue Working to Start Study

Study awaiting approval

Location: Australia

In April 2013, Steve McDonald and Martin Williams of Psychedelic Research in Science and Medicine (PRISM) flew from Australia to attend Psychedelic Science 2013 in Oakland, California, where they discussed strategy with the MAPS clinical team and other international researchers on how to work towards creating an approvable study in Australia. In July 2012, the Ethics Committee rejected our protocol for an Australian study of MDMA-assisted psychotherapy for PTSD. We are continuing to explore options for initiating this research in Australia.

Training Protocol Study: Therapists Receive MDMA-Assisted Psychotherapy

Ongoing study

Location: Charleston, South Carolina

Principal Investigator: Michael Mithoefer, M.D., with co-therapist Annie Mithoefer, B.S.N.

Estimated study budget: \$200,000

Already raised: \$8,000

Needed to complete this study: \$192,000

In this randomized, double-blind, placebo-controlled crossover study, researchers administer a single MDMA-assisted psychotherapy session to healthy volunteers as part of training to be therapists in a MAPS-sponsored study of MDMA-assisted psychotherapy for PTSD. As of August 2013, three subjects have completed this study, all therapists in our ongoing Israeli study of MDMA-assisted psychotherapy for PTSD. This study is limited to therapists already involved in MAPS' clinical research program, and was cleared by the FDA in October 2009.

MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

FDA Approves Revised Protocol for New Study; Documents Prepared for IRB *Study awaiting approval*

Location: Los Angeles, California

Principal Investigators: Charles Grob, M.D., and Alicia Danforth, Ph.D.

Estimated study budget: \$259,000

Already raised: \$1,000

Needed to complete this study: \$258,000

On July 8, 2013, the U.S. Food and Drug Administration fully approved the amended protocol for our planned study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum, to be led by Principal Investigator Charles Grob, M.D., and Alicia Danforth, Ph.D., at Harbor-UCLA Medical Center/Los Angeles Biomedical Research Institute. In their first review, the FDA requested several changes to the subject screening and enrollment process. In our June 4 response, we presented a clear scientific argument



Principal Investigator Alicia Danforth, Ph.D., answers questions at *Psychedelic Science 2013*.

for why we did not feel those changes were necessary; significantly, the FDA found our argument persuasive and approved the protocol. We are now preparing to submit the study protocol and related documents for review by the Institutional Review Board at the study site.

LSD-Assisted Therapy for Anxiety

LSD-Assisted Psychotherapy for Anxiety Related to Life-Threatening Illness *Study completed*

Location: Solothurn, Switzerland

Principal Investigator: Peter Gasser, M.D.

This study is complete and has been fully funded.

On June 20, 2013 the paper reporting the results of our completed study of LSD-assisted psychotherapy for anxiety associated with life-threatening illness was submitted to the *American Journal of Psychiatry*, one of the world's top psychiatry journals. Publishing in such a prominent journal would have been a great step forward, but the editors rejected the paper without sending it to the reviewers. On August 9, 2013, we resubmitted the paper to the *Journal of Nervous and Mental Disease*, which published many of the pioneering LSD studies from 1956–1973. Led by Principal Investigator Peter Gasser, M.D., this was the first completed study of LSD in humans in over 40 years. The first subject was enrolled on April 23, 2008, and the last long-term follow-up interview was conducted on August 8, 2012.

What Are Phase 2 Clinical Trials?

Clinical trials test potential treatments in human volunteers to determine whether they should be approved for use in the general population. The U.S. Food and Drug Administration requires these studies to be conducted before a new treatment can be brought to market. Clinical trials are conducted in phases over many years.

Phase 1 Trials: Small studies in healthy subjects to collect basic safety data, such as the treatment's most common side effects and how long the effects last.

Phase 2 Trials: Small to medium-sized studies to collect preliminary data about whether a treatment works in people with a specific disease or condition. These trials also gather additional safety data, compare the treatment to a different treatment or placebo, and help researchers refine research methods for future trials.

End-of-Phase 2 Meeting: The study sponsor (MAPS) meets with the FDA to come to an agreement on how Phase 3 studies will be conducted, based on data collected in Phase 2.

Phase 3 Trials: Large, multi-site studies of hundreds or even thousands of subjects to gather more information about safety and effectiveness and compare the results in different populations.

New Drug Application: The study sponsor files a New Drug Application (NDA) with the FDA to request that the treatment be approved for marketing in the United States. The NDA includes all data collected in previous phases, as well as information about how the drug behaves in the body and how it is manufactured.

For more information, visit fda.gov.

Ibogaine Therapy for Addiction Treatment

Mexico Ibogaine Study: Results Presented at Global Ibogaine Therapist Alliance *Study completed*

Location: Mexico

Principal Investigator: Thomas Brown, Ph.D.

This study is complete and has been fully funded.

Principal Investigator Thomas Kingsley Brown, Ph.D., is now preparing a paper describing the results of our completed observational study of ibogaine-assisted therapy for opiate addiction in Mexico, to be submitted before the end of 2013. The 30th and final subject completed follow-up on September 10, 2012.

From October 2–6, 2012, the Global Ibogaine Therapist Alliance (GITA) conference in Vancouver, Canada, gathered international researchers and ibogaine treatment providers to discuss current science and policy surrounding the use of ibogaine in ritual and clinical practice. Brown was invited to present the study results twice at the conference.

In his first presentation to GITA members on October 5, Brown discussed the importance of documenting and publishing outcome data from observational research and encouraged ibogaine treatment providers to maintain and share records of treatments. On October 6, Brown participated in a public forum on ibogaine treatment along with a panel of researchers and providers.

New Zealand Ibogaine Study: Generous Donation Received; Seventh Subject Enrolled

Ongoing study

Location: New Zealand

Principal Investigator: Geoff Noller, Ph.D.

Estimated study budget: \$ 28,000

Already raised: \$13,000

Needed to complete this study: \$15,000

On January 11, 2013, Principal Investigator Geoff Noller, Ph.D., reported that our ongoing observational study of ibogaine treatment for opioid dependence in New Zealand had received an additional donation of about \$10,000 from Matt and Kristi Bowden's Stargate International Trust. The grant, which follows the Bowdens' earlier \$25,000 donation to MAPS-sponsored ibogaine projects in New Zealand and Mexico, could not have come at a better time, says Dr. Noller. "With the study gaining momentum, we're beginning to draw participants and interest in general, from around the country. While this is great news for ibogaine research in New Zealand, it also means extra resources are required, as each participant must be introduced to the study and then followed up on a monthly basis."

Ideally the research team aims to meet with each potential participant before their treatment, to build rapport for what will hopefully be a 12-month relationship between researchers and subjects. Despite recruitment starting slowly in 2012, the recent increase in interest suggests the target of between 20 to 30 par-

ticipants will be met, although the initial 18-month recruitment period may be extended to two years. On January 9, 2013, the seventh participant was enrolled in our ongoing observational study of ibogaine treatment for addiction in New Zealand.

Medical Marijuana

U.S. First Circuit Court Upholds NIDA Monopoly on Marijuana for Research

Location: Boston, Massachusetts

On April 15, 2013, the United States Court of Appeals for the First Circuit rejected University of Massachusetts-Amherst Prof. Lyle Craker's lawsuit against the Drug Enforcement Administration for denying him a license to grow marijuana for privately funded medical research. With its decision, the Court has ensured that the debate over the medical use of marijuana will continue to take place through political battles rather than through scientific research.

The decision brings to an end Craker's 12-year effort to end the National Institute on Drug Abuse's monopoly on the supply of marijuana for research. A laboratory at the University of Mississippi under contract to the National Institute on Drug Abuse is currently the only facility in the U.S. permitted to grow marijuana for research.

Prior to Craker's application, NIDA had refused to sell marijuana to two FDA- and Institutional Review Board-approved protocols sponsored by MAPS, preventing them from taking place. In September 2011, NIDA refused to sell marijuana to a third FDA-approved MAPS-sponsored protocol in 50 U.S. veterans with chronic, treatment-resistant posttraumatic stress disorder (PTSD).

Marijuana for Veterans with PTSD *Study pending*

Location: Phoenix, Arizona

Clinical Investigator: Sue Sisley, M.D.

Estimated protocol design and approval budget: \$ 20,000

Already raised: \$10,000

Needed to complete protocol design and approval: \$10,000
Study budget to be determined after protocol approval.

On April 21, 2013, at Psychedelic Science 2013, Clinical Investigator Sue Sisley, M.D. presented an overview of MAPS' planned study of smoked or vaporized marijuana for 50 U.S. veterans with chronic, treatment-resistant PTSD. This placebo-controlled, triple-blind, randomized crossover pilot study is the first of its kind, and will investigate the safety and efficacy of marijuana for PTSD. On October 25, 2012, the Institutional Review Board at the Uni-



Clinical Investigator Sue Sisley, M.D., in discussion after her presentation at Psychedelic Science 2013.

iversity of Arizona approved the protocol, following the FDA’s approval in April 2011. The study remains blocked by the Drug Enforcement Administration (see page 6) and the National Institute of Drug Abuse, which refuses to provide any of its monopoly supply of marijuana to the study.

Ayahuasca Treatment for Addiction

Ayahuasca Observational Study: Results Published *Study completed*

Location: British Columbia, Canada

Principal Investigator: Gerald Thomas, Ph.D.

This study has been completed and is fully funded.

In June, 2013, the results of a recently completed MAPS-sponsored observational study of ayahuasca-assisted therapy for addiction were published in *Current Drug Abuse Reviews*. This is the first study of its kind in North America and involved 12 members of a rural First Nations community, several of whom had been through multiple unsuccessful treatments for their problematic substance use. Combining Western psychotherapeutic techniques with South American shamanic healing practices, this study gathered preliminary evidence about the safety and effectiveness of ayahuasca-assisted therapy. The results, which were presented on April 20 at Psychedelic Science 2013, suggest that participants may have experienced positive psychological and behavioral changes in response to this therapeutic approach. Proper clinical studies are recommended to more adequately test the efficacy of this novel form of treatment.

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Supporter Spotlight: Christopher Butson

“I BELIEVE RICK DOBLIN AND the MAPS organization are not only revolutionizing the way the medical community are currently coping with those individuals living with trauma, addiction, and anxiety but they are also trailblazing the way forward by spreading true scientific fact-based knowledge about the healing capacities of psychedelic compounds and cannabis.

I have found the use of such compounds extremely valuable in my own life as they have helped me suppress addiction and reinforce not only the internal connection that exists between my own mind and body, but also my external connection to those people around me, thus contributing to the global community as a whole.

I have been donating to MAPS for several years now and it was only recently, after reading the last *Bulletin* [on “Psychedelics in Psychology and Psychiatry”], that I realized the true magnitude, extent, and depth of the research that MAPS was involved in. I really think that MAPS is slowly changing the world with this work. It is something that I feel passionate about and I am so happy to support the research.”



MAPS Supporter Christopher Butson

Christopher R. Butson is 39 years old and lives with his wife in Victoria, B.C., Canada. As a Remote Sensing Scientist for the province of British Columbia, he views and analyzes remotely acquired imagery of forested landscapes to guide and influence decision-making, monitor forest changes, and inform others about sustainable forest management practices.