

Research News

Treating PTSD with MDMA-Assisted Psychotherapy

mdmaptsd.org

14th Subject Treated in Ongoing Veterans Study; Agencies Approve Amended Protocol

Ongoing study

Location: Charleston, South Carolina

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

Estimated study budget: \$1,395,000

Already raised: \$881,000

Needed to complete this study: \$513,000

On November 8, 2013, the 14th subject began treatment in our ongoing study of MDMA-assisted psychotherapy for 24 U.S. veterans, firefighters, and police officers with service-related PTSD. On October 3, the U.S. Drug Enforcement Administration approved the amended study protocol. The change includes an addition of a 100 mg dose condition (along with 30 mg, 75 mg, and 125 mg). The randomized, triple-blind protocol amendment received approval from the Food and Drug Administration on October 6 after passing the 30-day review period without comment, with approval from the Institutional Review



Principal Investigator Michael Mithoefer, M.D., and co-therapist Annie Mithoefer, B.S.N., led a workshop on MDMA-assisted psychotherapy at Psychedelic Science 2013.

Board on August 28. There are currently over 450 people on the waiting list for this study for 11 more openings, sadly demonstrating the large number of treatment-resistant veterans and first responders with PTSD.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy in people suffering from war-related trauma; (2) comparing the effectiveness of the treatment for people with war-related trauma versus for people with trauma related to sexual abuse, assault, and other causes; (2) comparing different doses of MDMA for therapeutic effectiveness and ability to create a successful double-blind; and (3) increasing awareness and support for our work by assisting a population with mainstream public recognition.

Second and Third Subjects Treated in New Boulder Study; IRB Approves Amended Protocol

Ongoing study

Location: Boulder, Colorado

Clinical Investigator: Marcela Ot'alora, M.A., L.P.C.

Estimated study budget: \$582,000

Already raised: \$193,000

Needed to complete this study: \$389,000

On October 4 and 9, 2013, the second and third subjects began treatment in our ongoing study of MDMA-assisted psychotherapy for PTSD in Boulder, Colorado. Both subjects are women suffering from chronic, treatment-resistant PTSD as a result of sexual

abuse. On August 13, the Institutional Review Board approved an amended protocol, which includes changes to the dosing schedule (adding a 100 mg dose condition) and the addition of two



Encapsulated MDMA for the study in Boulder, Colorado.

safety measures. 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 study will enroll 12 subjects with PTSD due to sexual assault, military combat, or other causes. Recent flooding in Boulder delayed experimental treatment sessions by about a month, and caused damage to our treatment room that has now been repaired.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD from a variety of causes, (2) comparing different doses of MDMA for therapeutic effectiveness and ability to create a successful double-blind, (3) exploring whether using intern co-therapists can reduce costs while maintaining treatment effectiveness, and (4) training the next generation of psychedelic psychotherapists.

Third Subject Enrolled; First Two Subjects Complete 2-Month Follow-Up in Israeli Study

Ongoing study

Location: Beer Yaakov, Israel

Clinical Investigator: Moshe Kotler, M.D.

Estimated study budget: \$463,000

Already raised: \$39,000

Needed to complete this study: \$423,000

On October 30, 2013, the third subject was enrolled in our ongoing Israeli study of MDMA-assisted psychotherapy for chronic, treatment-resistant PTSD. Two-month follow-up evaluations were conducted for the first two subjects on September 17 and October 3. This third subject will enable our third (of three) co-therapist team to start treating subjects.

This study will enroll 10 subjects, some of whom will be soldiers with war-related PTSD referred by the Israeli Defense Forces. 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.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD mostly related to war and terrorism, (2) comparing different doses of

MDMA for therapeutic effectiveness and ability to create a successful double-blind, (3) working in direct association with the Israeli Ministry of Health, and (4) exploring the use of MDMA-assisted psychotherapy in other cultural contexts.

Canadian Study: Health Canada 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: \$592,000

Already raised: \$16,000

Needed to complete this study: \$576,000

On September 6, 2013, Health Canada approved an amended protocol for our upcoming Canadian study of MDMA-assisted psychotherapy for PTSD. The amendments include several changes to the study design to complement our other ongoing studies around the world, including changes to dose levels (adding a 100 mg dose condition), 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. On August

20, the amended protocol was submitted to the U.S. Food and Drug Administration, and the initiation visit was conducted from August 22–24. After working for over five and a half years, we can now start screening subjects once the study site is set up.



Encapsulated MDMA in safe storage for the Canadian study.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD from a highly skilled co-therapist team, (2) comparing different doses of MDMA for therapeutic effectiveness and ability to create a successful double-blind, and (3) initiating the first Canadian research into the potential benefits of psychedelic psychotherapy in over 40 years.

All Treatments Completed in Relapse Study

Ongoing study

Location: Charleston, South Carolina

Principal Investigator: Michael Mithoefer, M.D.

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

All 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 one-year follow-up interview, which revealed that the subject's score on the Clinician-Administered PTSD Scale was below the diagnostic cutoff for PTSD. The last follow-up interview is scheduled for May 2014.

The goal of this study is to determine whether a single additional MDMA-assisted psychotherapy session can restore subjects who relapsed following successful prior treatment with MDMA-assisted psychotherapy.

Researcher Claims Swiss Study Showed Large Treatment Effect, Not Small

Study completed

Location: Solothurn, Switzerland

Clinical Investigator: Peter Oehen, M.D.

This study is complete and has been fully funded.

On August 27, 2013, the *Journal of Psychopharmacology* published a Letter to the Editor from a researcher not affiliated with MAPS or with our completed Swiss pilot of MDMA-assisted psychotherapy for 12 subjects with chronic, treatment resistant PTSD. The letter, by Henri Chabrol of the University of Tou-

louse, France, pointed out that the study had a large effect size not previously reported in the January 2013 publication of the results in the same journal. The study paper describes clinically significant decreases in PTSD symptoms following MDMA-assisted psychotherapy that approached statistical significance (0.06), remarkable in such a small pilot study. In the unsolicited yet most welcome letter, Chabrol explains why our traditional statistical method should have been supplemented by an effect size calculation, and in fact subjects showed “on average, a substantial improvement in PTSD symptoms over the course of MDMA-assisted psychotherapy.” The journal also published a reply from study Principal Investigator Peter Oehen, M.D. The original paper was co-authored by Dr. Oehen along with 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. Receiving this unsolicited positive feedback on our results from an independent expert highlights both the importance of international collaboration in psychedelic research and the sincere caution with which we report our results.

Goals for this study included (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD in a different cultural context, and (2) pioneering the use of low dose MDMA as an active placebo.

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.

Goals for this study include (1) gathering evidence for the safety and effectiveness of MDMA-assisted psychotherapy for subjects with PTSD in a different cultural context, and (2) initiating the first clinical psychedelic research in Australia.

Therapists Receive MDMA-Assisted Psychotherapy in Training Protocol *Ongoing study*

Location: Charleston, South Carolina

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

Estimated study budget: \$460,000

Already raised: \$8,000

Needed to complete this study: \$452,000

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 November 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 approved by the FDA in October 2009.

Goals for this study include (1) providing therapists with direct experience of MDMA when taken in a therapeutic context to enhance their ability to conduct effective MDMA-assisted psychotherapy, and (2) collecting additional data on the safety of MDMA-assisted psychotherapy in healthy volunteers taking MDMA in a therapeutic context.

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MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

Protocol Changes Approved by IRB and State Advisory Panel *Study awaiting approval*

Location: Los Angeles, California

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

Estimated study budget: \$302,000

Already raised: \$1,000

Needed to complete this study: \$301,000

On October 16, 2013, the Institutional Review Board (IRB) 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. On September 30, the Research Advisory Panel of California (RAPC) approved the amended protocol. The RAPC review is an additional layer of approval required only in California for research with Schedule I drugs. The study will begin screening and enrolling subjects after the research pharmacy and principal investigator receive their Schedule I licenses from the Drug Enforcement Administration, for which applications were respectively submitted on October 2 and October 9. Dr. Grob has already received his DEA Schedule I license and the pharmacy license is in process. We anticipate that we will be able to begin screening subjects in early 2014.

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.

LSD-Assisted Therapy for Anxiety

Final Report Submitted from Swiss Study; Paper Resubmitted for Publication *Study completed*

Location: Solothurn, Switzerland

Principal Investigator: Peter Gasser, M.D.

This study is complete and has been fully funded.



The last LSD capsule from the Swiss study.

On September 17, 2013 the Final Report for our completed study of LSD-assisted psychotherapy for anxiety associated with life-threatening illness was submitted to Swissmedic. The

report includes information about the study protocol, how the study was conducted, and all data in both raw and analyzed formats. This report is required under International Council on Harmonization/Good Clinical Practice (ICH/GCP) as well as FDA regulations. Led by Principal Investigator Peter Gasser, M.D., the first subject was enrolled on April 23, 2008, and the last long-term follow-up interview was conducted on August 8, 2012. On November 14, 2013, the paper describing the results was resubmitted for publication in the *Journal of Nervous and Mental Disease* with responses to reviewer comments.

Goals for this study were (1) gathering evidence for the safety and effectiveness of LSD-assisted psychotherapy for subjects with anxiety related to advanced-stage illness, and (2) completing the first study of LSD humans in over 40 years.

Ibogaine Therapy for Addiction Treatment

Tenth Subject Enrolled in New Zealand Ibogaine Study; Treatment Death Pauses Enrollment and Raises Safety Concerns *Ongoing study*

Location: New Zealand

Principal Investigator: Geoff Noller, Ph.D.

Donations are needed to support ibogaine research.

On September 20, 2013, the 10th participant was enrolled in our ongoing observational study of ibogaine-assisted treatment for opioid dependence in New Zealand. In this study, Principal Investigator Geoff Noller, Ph.D., is collecting follow-up data from subjects undergoing treatment at an independent ibogaine center in New Zealand. Dr. Noller was previously collecting data from two treatment centers, but one of these centers has now closed due to a recent death in treatment at a time when the patient was not under medical supervision. The death has raised significant concerns in the New Zealand ibogaine treatment community, and emphasizes the importance of establishing clear treatment protocols, which were not followed at the facility where the death took place. Treatments were halted at both facilities after the death but have resumed at the facility with a continued record of no significant health issues and where patients are continually monitored. Dr. Noller reported that he felt "very confident" in the remaining provider's practice and anticipates that the study is likely to be completed in Spring 2015.

Goals for this study include (1) gathering preliminary evidence about the safety and potential benefits of ibogaine-assisted therapy for opiate addiction, (2) supplementing the data from our completed observational ibogaine study in Mexico, and (3) initiating and encouraging psychedelic research in New Zealand.

Medical Marijuana

Marijuana for Veterans with PTSD Study Protocol Resubmitted to HHS *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 October 24, 2013, MAPS resubmitted to the U.S. Department of Health and Human Services the protocol for our Food and Drug Administration (FDA) and Institutional Review Board (IRB)-approved study of marijuana to treat symptoms of PTSD in 50 U.S. veterans with chronic, treatment-resistant PTSD. Currently, the National Institute on Drug Abuse holds a monopoly on the supply of marijuana for research in the U.S. Under current federal policies, reviewers from the Public Health Service (PHS, a division of the Department of Health and Human Services/HHS) must approve all privately funded research seeking to use NIDA marijuana. The FDA approved the protocol in April 2011, but HHS reviewers unanimously rejected the protocol in September 2011, preventing the study from going forward. At the time of the HHS rejection, the study had not yet been approved by an IRB.

In October 2012, the IRB at the University of Arizona approved the study protocol. The IRB accepted all of the core elements of our design, added several safety measures and proce-

dures, and rejected HHS' critiques of the protocol design. We are requesting that HHS agree to sell MAPS the marijuana needed for the study, as well as to abandon the PHS review process entirely, which exists

only for marijuana and not for research with any other drug. MAPS is also working with other groups on a Congressional Sign-On letter to HHS Secretary Kathleen Sebelius urging her to eliminate the PHS review and require NIDA to sell marijuana to sponsors of all protocols that obtain approval from FDA, IRB, DEA, and relevant state authorities [full story on page 36].

Goals for this study include ending the obstruction of medical marijuana drug development research by the National Institute on Drug Abuse (NIDA). If successful, our goals will also include (1) collecting evidence for the safety and effectiveness of marijuana for symptoms of PTSD in U.S. veterans; (2) starting the research needed to make whole-plant marijuana a legal, FDA-approved prescription medicine; (3) comparing the safety and effectiveness of smoking vs. vaporization as medical marijuana delivery systems; and (4) comparing the effectiveness of strains of marijuana with different ratios of THC and CBD for symptoms of PTSD.



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



Psychedelic Science 2013 videos are available online! Visit maps.org/videos.

At Psychedelic Science 2013, over 100 of the world's leading researchers and more than 1,900 international attendees gathered to share recent findings on the benefits and risks of LSD, psilocybin, MDMA, ayahuasca, ibogaine, 2C-B, ketamine, marijuana, and more, over three days of conference presentations, and two days of pre- and post-conference workshops.

Ayahuasca Treatment for Addiction

Results Published from Canadian Observational Study *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 was 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 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. Health Canada indicated openness to approving research protocols utilizing standardized, freeze-dried, encapsulated ayahuasca; but the South American shamans who administered the ayahuasca indicated that they were only willing to work with ayahuasca prepared in the traditional manner as a tea.

Goals for this study included (1) gathering preliminary evidence about the safety and potential benefits of ayahuasca-assisted therapy for problematic substance use and quality of life, and (2) initiating and encouraging psychedelic research in Canada.

MAPS in the Media



Timothy Leary's Transformation From Scientist to Psychedelic Celebrity

by Greg Miller

October 1, 2013



Sanjay Gupta: Only 6 Percent Of Marijuana Research Considers Medical Benefits

by Shaunacy Ferro

August 12, 2013



Molly is the New Club Drug, But What's In It?

by Frank Owen and Lera Gavin

October 20, 2013



MDMA Still Irrationally Restricted, Despite Medical Benefits

by Brendan Ferreri-Hanberry

August 7, 2013



Marijuana Is Helping Our Vets Cope With War

by Josh Zepps

November 11, 2013



Electronic Dance Music's Love Affair With Ecstasy: A History

by P. Nash Jenkins

September 20, 2013



Making Psychedelic Trips Safe—Even at Burning Man

by April Short

August 9, 2013



Do Party Drugs Have a Place in the Medical Office?

by Heidi Anne Duerr, MPH

October 2, 2013

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