RESEARCH NEWS

Treating PTSD with MDMA-Assisted Psychotherapy

Expanded U.S. Veterans Study Treats Tenth Subject
As of July 27, 2012, ten subjects (out of 24) have received at least one experimental treatment session in our ongoing U.S. Phase 2 Study of MDMA-assisted psychotherapy study for veterans with chronic, treatment-resistant PTSD. Two subjects have now completed the entire study, including the long-term follow up. A third subject reported that after one successful MDMA-assisted psychotherapy session, he felt so improved that he needed no further treatments with MDMA or any other drug; his improvement was confirmed in a 12-month follow up interview.

On February 22, 2012, the FDA accepted an amended protocol which increases the study size from 16 to 24 subjects and added the possibility of including firefighters and police officers suffering from PTSD as a result of their service. A larger group of subjects will give us greater statistical power to draw conclusions about the therapeutic effectiveness of our treatment method. We hope that investigating a treatment for this especially vulnerable group will eventually lead to research funding from the U.S. Department of Defense and/or the Veterans Administration. Including firefighters and police officers in the study will provide further evidence of MDMA-assisted psychotherapy’s effectiveness for an important social group, and help to reduce costs by increasing local recruitment.

Estimated study budget: $1,245,000
Already raised: $925,000
Needed to complete this study: $320,000

U.S. Proof of Principle Study: Long-Term Follow-Up Paper Accepted for Publication
On June 20, 2012, the results of a long-term follow-up of subjects who participated in our initial proof of principle study of MDMA-assisted psychotherapy for PTSD were accepted for publication by the Journal of Psychopharmacology. In the original study, 17 of 21 subjects who had suffered from PTSD as a result of sexual abuse, crime, or war no longer met criteria for PTSD after treatment. The long-term follow-up, conducted an average of 3½ years after the final experimental treatment session, demonstrates that these benefits were, on average, maintained. Additionally, of the subjects who were seeing a therapist prior to the study, 45% were no longer seeing one at the time of the follow-up survey; and 55% of those who were receiving psychiatric medications prior to the study were no longer taking them. These remarkable results confirm that the benefits of MDMA-assisted psychotherapy can persist over time. Check www.maps.org for an announcement of the final publication date, at which time the paper will be publicly available.

This study has been fully funded

MAPS Prepares to Start New Intern Study in Boulder
On May 4, 2012, the FDA approved our new study exploring the 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 working under supervision for credit towards licensure. 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.

On May 15, 2012, the DEA approved the protocol for the study. This study will begin recruiting and enrolling subjects once the DEA grants the Schedule 1 license to the study physician and the necessary site preparations, including obtaining a second business license for the site to comply with local zoning regulations, are complete. The study will take place in Boulder, Colorado with Marcela O’Hara as Principal Investigator.

Estimated study budget: $455,000
Already raised: $125,000
Needed to complete this study: $330,000

First Subject in Relapse Study Completes Follow-Up Evaluation after Successful Treatment
On April 27, 2012, the first subject in our relapse study completed their follow-up interview, two months after a single MDMA-assisted psychotherapy session. This study will enroll two subjects whose PTSD symptoms eventually returned after participating in our U.S. proof of principle study of MDMA-assisted psychotherapy for PTSD, which was completed in July 2010. This is an open label proof-of-principle study, investigating whether one additional MDMA-assisted psychotherapy session combined with multiple non-drug psychotherapy sessions can once again free these subjects from a diagnosis of PTSD.

Needed to complete this study: $55,000

MAPS and PRISM Work to Start Australian Study of MDMA-Assisted Psychotherapy for PTSD
MAPS is working with the Australian non-profit organization Psychedelic Research in Science and Medicine (PRISM) to obtain approval for an Australian study of MDMA-assisted psychotherapy for PTSD. On February 22, 2012, the Ethics Committee rejected the protocol, citing issues that MAPS and PRISM addressed in their May 31 response. On July 13, the Committee reiterated their decision to reject the protocol. PRISM and MAPS will continue working to initiate MDMA-assisted psychotherapy research in Australia. This study will compare the safety and effectiveness of MDMA-assisted psychotherapy for 12 subjects with chronic, treatment-resistant PTSD using two different dosages of MDMA combined with psychotherapy.

Needed to complete this study: $50,000
(additional funds provided by co-sponsor)

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Health Canada Requests Additional Changes to Canadian MDMA/PTSD Study Pharmacy

Pharmacist Colin Holyk has made multiple security upgrades to his pharmacy at the request of Health Canada.

On December 2, 2011, Health Canada issued the results of their second security inspection of the pharmacy where MDMA will be stored for our planned Canadian study of MDMA-assisted psychotherapy for PTSD. The report summarized several security-related changes that will be needed at the pharmacy before the Health Canada grants it the license to the study MDMA, including additional alarm systems, reinforcements to the entryways, and the addition of the words “Restricted Drug” to the MDMA label. A third security inspection will be required after the changes are made. As of September 1, 2012, the creation of additional security regulations following the initial inspection has delayed the study initiation by over nine months.

Estimated study budget: $527,000
Already raised: $15,000
Needed to complete this study: $508,000

Preparations Continue for Israeli MDMA/PTSD Study

Our Israeli site team is making their final preparations for our upcoming clinical trial of MDMA-assisted psychotherapy for PTSD. On February 1, 2012, the independent rater for the study completed training on the Clinician-Administered PTSD Scale (CAPS), a training which MAPS developed in order to standardize how the CAPS is administered across our diverse study sites. On December 25, 2011, contracts were finalized with the Beer Ya’akov Mental Hospital where the study will be conducted. As of September 1, 2012, the site was being prepared with “living room style” décor appropriate for MDMA-assisted psychotherapy sessions. After a final meeting with the clinical team, the site will begin screening and enrolling subjects. A significant percentage of subjects will be referred by the Israeli Defense Forces.

Estimated study budget: $381,000
Already raised: $0
Needed to complete this study: $381,000

Training Protocol Study Continues as Intern Study Therapist Teams Complete Training

Co-therapists Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., demonstrate an MDMA-assisted psychotherapy session.

From April 8-11, 2012, the therapist teams for our MDMA-assisted Psychotherapy for PTSD Intern Study completed our therapist training protocol in Charleston, South Carolina. This protocol is designed as a Phase 1 study of the psychological effects of MDMA in healthy volunteers, with subjects limited to people in MAPS’ therapist training program. In addition to providing new information about the effects of MDMA-assisted psychotherapy in healthy volunteers, the study will enable us to train therapists to conduct future MDMA/PTSD studies. Our Training Protocol Study is led by MDMA-assisted psychotherapy researchers and co-therapists Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N.

Estimated study budget: $265,000
Already raised: $0
Needed to complete this study: $265,000
Swiss MDMA/PTSD Study Paper Submitted for Publication in Peer-Reviewed Journal

On February 27, 2012, a paper describing the results of our Swiss pilot study of MDMA-assisted psychotherapy was submitted to a peer-reviewed scientific journal. The paper is 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 small number of subjects in this preliminary pilot study contributed to the results falling just short of statistical significance. The study did find clinically significant reductions in scores on the CAPS scale—larger than those associated with Zoloft and Paxil, the only currently approved medications for PTSD. The investigators are now awaiting the reviewers’ response to their submission.

This study has been fully funded.

Autism Research with MDMA-Assisted Therapy for Adults on the Autism Spectrum

MAPS is currently developing a protocol for a clinical study of the use of MDMA-assisted therapy for adults on the autism spectrum. The main objective of this study is to examine whether MDMA-assisted therapy could reduce or ease challenges associated with being on the autism spectrum.

On October 14, 2011, MAPS issued a Request For Proposals to support the development of a protocol for the first ever study of MDMA in this subject population. The research team has been selected and protocol development began in February 2012. We hope that the protocol will be approved and the pilot study ready to start by January 2013.

MAPS initially seeded the study with a $10,000 award to the selected research team. On January 25, 2012, the MAPS Board of Directors awarded $200,000 from Ashawna Hailey’s bequest to the study. We have a goal of raising additional funds through grants from leading autism advocacy groups such as Autism Speaks and federal funds available through the NIH, as well as from individual donors.

Newly Published by MAPS

Healing with Entactogens

This booklet explores MDMA and other entactogens as pharmacological adjuncts to group psychotherapy. It presents intimate insights into entactogenic experiences from first-hand accounts of clients who participated in group therapy sessions, and crucial background on the neurobiological and psychospiritual components of those experiences.

The word “entactogen” refers to a class of psychoactive compounds like MDMA that “produce a touching within.”

About the author

Torsten Passie, M.D., M.A., is Professor of Psychiatry and Psychotherapy at Hannover Medical School (Germany) where he serves as the Director of the Laboratory for Neurocognition and Consciousness. He is currently Visiting Professor at Harvard Medical School. Dr. Passie has conducted extensive research on the psychophysiology of altered states of consciousness, and is a leading European expert on the pharmacology and therapeutic use of psychedelic drugs.

“Torsten Passie’s research not only deals with the amplified psychotherapy possible with MDMA, but also with the neurophysiological and neurochemical correlates of the experience. His book deserves a place as an essential milestone in the integration of MDMA-type drugs into psychotherapeutic practice.”

—Ralph Metzner, Ph.D., psychotherapist and consciousness researcher
Ibogaine Observational Studies Near Completion in Mexico; Expand to New Zealand

**Seventh Subject Completes Follow-Up in Observational Study in Mexico**

As of April 6, 2012, seven out of 30 subjects had completed a 12-month follow up in our ongoing observational study of ibogaine treatment for addiction in Mexico. The 30th and final subject was enrolled in the study on August 29, 2011. All participants in this study have already received ibogaine-assisted therapy at one of two independent treatment centers in Mexico. Our study observes and evaluates the participants for addiction and quality of life for 12 months post treatment. The study’s final long-term follow-up visit is scheduled for September 2012. Data from this study will be compared with data from our soon-to-be-initiated observational ibogaine study in New Zealand.

Estimated study budget: $41,000
Already raised: $34,000
Needed to complete this study: $7,000

**First Two Subjects Enrolled in New Zealand Ibogaine Study**

On July 16, 2012, the first two participants were enrolled in our recently initiated observational study of ibogaine treatment for addiction in New Zealand. Both of these individuals are suffering from methadone dependence and are receiving treatment at independent ibogaine clinics in New Zealand. On February 22, 2012, the study was approved by the IRB. Lead investigator Dr. Geoff Noller, Ph.D., began enrollment shortly thereafter. This study is the second in our international series of observational studies of the safety and long-term effectiveness of ibogaine treatment for addiction, building on our nearly completed study in Mexico.

Already raised: $15,000
(additional funds provided by co-sponsor)

Medical Marijuana Research

**Protocol of Marijuana for Veterans with PTSD Submitted to Institutional Review Board**

On July 30, 2012, MAPS and Sue Sisley, M.D., submitted the FDA-approved protocol for our planned study of marijuana for veterans with PTSD for review by the University of Arizona Institutional Review Board (IRB). The IRB review is scheduled for August 28. MAPS also submitted a detailed cover letter explaining our rationale for various elements of the protocol design. The protocol received clearance from the FDA on April 28, 2011, but the study has been on hold since then due to NIDA’s refusal to sell researchers the marijuana needed for the study. We will respond to the NIDA/Public Health Service reviewers’ comments if the IRB also approves the study protocol.

**Federal Court Hears Oral Arguments in UMass Professor’s Lawsuit Against the DEA**

On May 11, 2012 the U.S. First Circuit Court of Appeals in Boston, Mass., heard oral arguments in the case of Lyle E. Craker v. Drug Enforcement Administration. The arguments are the culmination of 11 years of administrative and legal proceeding in response to the DEA’s denial of a license to Craker to start a production facility under contract to MAPS to grow marijuana exclusively for privately funded, federally regulated medical research.

Craker’s attorney from Washington, D.C., law firm Covington & Burling LLP, which is representing Craker pro bono, clarified the issues facing the court and urged the judges to require the DEA to issue Craker’s license. The DEA attempted to get the case thrown out before a ruling by claiming that the court has no jurisdiction over the issue, an argument that the court seems likely to reject. The court’s ruling should come in later this year. Meanwhile, the DEA is succeeding in preventing our medical marijuana research from moving forward.

Needed for protocol development and approval process: $20,000

**Treating End-of-Life Anxiety with LSD-Assisted Psychotherapy**

On August 8, 2012, the last long-term follow-up interview was conducted in our recently completed study of LSD-assisted psychotherapy for anxiety associated with advanced-stage illness in Switzerland. All twelve subjects have now completed the follow-up portion of this study, and the results are being prepared for publication in a peer-reviewed scientific journal.

This study has been fully funded