Clinical Research Update

Treating PTSD with MDMA-Assisted Psychotherapy

Long-Term Follow-Up Results Published in *Journal of Psychopharmacology*
Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D., with co-therapist Ann Mithoefer, B.S.N.
This study is completed and has been fully funded

On November 20, 2012, the outstanding results of our long-term follow-up of subjects who participated in our initial proof of principle study of MDMA-assisted psychotherapy for PTSD were published online in the *Journal of Psychopharmacology*. The follow-up study extends the promising results of the initial study, published in 2010, which found that 83% of those receiving MDMA-assisted psychotherapy no longer qualified for a PTSD diagnosis two months after treatment. The long-term follow-up, conducted an average of 45 months (over 3.5 years) after MDMA-assisted psychotherapy, showed that these remarkable benefits were sustained over time.

Subjects included survivors of sexual assault and abuse and a military veteran. None of these subjects had responded adequately to existing psychotherapies and drug treatments for PTSD. Subjects had suffered from PTSD for an average of over 19 years. “With such encouraging data, including evidence of long-term effectiveness after only two or three MDMA-assisted psychotherapy sessions, there is now no doubt that this research should be expanded to larger clinical trials,” said Dr. Michael Mithoefer, the study’s principal investigator.

The publication of these results received widespread media coverage in *The New York Times*, CNN, NPR, Military.com, Stars & Stripes, Care2, and many more.

“MDMA-assisted psychotherapy helped me move past that feeling of needing to be in control,” one subject reported. “I felt like me, probably for the first time. That was what I’d been looking for: the feeling that I was OK.”

U.S. Veterans Study Expanded, Local Firefighter Receives Treatment
Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D., with co-therapist Ann Mithoefer, B.S.N.
$1,260,000 estimated study cost / $526,000 still needed

As of November 2012, 11 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. Three subjects have completed the entire study, including the long-term follow-up. One subject dropped out after one successful MDMA-assisted psychotherapy session, reporting that 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 evaluation.

On February 22, 2012, the FDA accepted an amended protocol increasing the study size from 16 to 24 subjects and added the option of including firefighters and police officers suffering from PTSD as a result of their service. On October 11, the study enrolled a local firefighter with service-related PTSD; this subject was treated on October 26. 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 people suffering from PTSD, and will help reduce costs by increasing local recruitment. Nearly 300 people have joined the waiting list to be screened for participation, demonstrating the widespread need for new treatments for chronic PTSD.

Zoning Office Approves Site for New Intern Study in Boulder
Boulder, Colorado
Principal Investigator: Marcela Ot’alora, M.A., L.P.C.
$497,000 estimated study cost / $372,000 still needed

On October 25, 2012, the Zoning Office for the City of Boulder, Colorado, issued the business license for the site for our upcoming study of MDMA-assisted psychotherapy for PTSD. This license was required before the Drug Enforcement Administration would grant a Schedule I license to the study physician, and required multiple rounds of renovations and inspections as well as a complete relocation before it was approved. Needing to comply with unexpected Boulder zoning regulations delayed our estimated start date for the study by about six months, and we are hoping to start screening subjects in January 2013.

The new study will explore 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 and to train the next generation of psychedelic psychotherapists.

From September 21-23, 2012, MAPS Director of Clinical Research Amy Emerson and Lead Clinical Research Associate Berra Yazar-Klosinski, Ph.D, visited the new study site. They met with Principal Investigator Marcela Ot’alora, L.P.C., coresearchers, and other study staff to conduct a final training on the protocol and study documents, as well as to review our MDMA Investigator’s Brochure and new safety data from completed MAPS clinical trials (see inside front cover).

First Subject in Relapse Study Completes Follow-Up Evaluation after Successful Treatment Charleston, South Carolina
Clinical Investigator: Michael Mitoefer, M.D.
$55,000 still needed

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.

MAPS in the Media

Landmark Study Shows Long-Term Benefits of MDMA-Assisted Psychotherapy for PTSD
Results published in the Journal of Psychopharmacology

The New York Times
A ‘Party Drug’ May Help the Brain Cope With Trauma
by Benedict Carey
November 19, 2012
“The feeling I got was nothing at all for 45 minutes, then really bad anxiety, and I was fighting it at first,” said Anthony, the Iraq veteran, who patrolled southwest of Baghdad in 2006 and 2007 amid relentless insurgent harassment and attacks with improvised explosive devices. “And then—I don’t know how to put it, exactly—I felt O.K. and messed up at the same time. Clear. It was almost like I could go into any thought I wanted and fix it.”

PTSD Study Findings Reinforce Case for Ecstasy
by Bryant Jordan
November 20, 2012

New Study Confirms MDMA’s Effectiveness in Psychotherapy
by Jacob Sullum
November 20, 2012

Research Points to Clear Benefits of MDMA for Post-Traumatic Stress Disorder
by Craig Comstock
November 21, 2012

MDMA Keeps Severe Stress at Bay
by Arran Frood
November 20, 2012

Ecstasy Effective in Treatment of Lingering PTSD, New Study Finds
by Matthew M. Burke
November 20, 2012

Ecstasy May Help Treat Post-Traumatic Stress Disorder
by Join Together Staff
November 20, 2012

More headlines at maps.org/media
MAPS Seeks Funding From National Institute of Mental Health

On October 16, 2012, MAPS Executive Director Rick Doblin, Ph.D., and the MAPS clinical team met via teleconference with a member of the grants administration staff at the National Institute of Mental Health (NIMH) in Washington, D.C. Earlier in October, Rick Doblin contacted NIMH Director Thomas Insel about whether NIMH would be willing to review a grant application from MAPS for research into MDMA-assisted psychotherapy for PTSD. Dr. Insel responded immediately and encouraged us to apply. The MAPS clinical team will continue working with NIMH staff to develop a grant proposal with the greatest chance of success. The proposal would be due in either February or June 2013.

As far as we know, the last time NIMH funded psychedelic psychotherapy research was over 40 years ago. NIMH has recently funded research into the use of ketamine in the treatment of refractory depression; however, in this case the ketamine was not used as an adjunct to psychotherapy but rather as an independent pharmacological treatment.

Should MAPS succeed in obtaining NIMH funding for a Phase 2 study of MDMA-assisted psychotherapy for PTSD, it’s possible that NIMH might be open to a larger grant supporting Phase 3 studies. “For NIMH, multi-year grants of several millions of dollars are not unusual,” said MAPS Executive Director Rick Doblin, Ph.D. “We can always dream!”

MAPS and PRISM Work to Start Australian Study of MDMA-Assisted Psychotherapy for PTSD

Australia

$125,000 estimated study cost / $50,000 still needed

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 are still 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.

Health Canada Approves Pharmacy for New Vancouver Study

Vancouver, British Columbia, Canada

Principal Investigator: Ingrid Pacey, MD and Andrew Feldmar, PhD

$511,000 estimated study cost / $496,000 still needed

On November 8, 2012, after five inspections and over 15 months of resulting delays, an inspector from Health Canada finally approved the security measures at the Vancouver pharmacy where the MDMA will be stored for our upcoming study of MDMA-assisted psychotherapy for PTSD in Canada. New security regulations created after the initial inspection required us to make numerous expensive changes to the pharmacy, including hiding the safe with a wooden cabinet, moving the safe and cabinet to a new room with a solid (rather than glass) door, installing multiple new alarm systems, adding bulletproof polycarbonate over the windows, and placing additional warning labels on the study drug.

We have been working for 2½ years (since Health Canada approved the protocol) to obtain an import permit for the study drug. Once Health Canada grants the Controlled Substances License to the study pharmacist, we will know whether we will be able to import the MDMA into Canada and initiate the study, or if there will be further delays. We are optimistic that we will be able to initiate the study and begin enrolling subjects in early 2013.

New Israeli Study Prepares to Enroll Subjects, Threatened by War

Israel

Clinical Investigator: Moshe Kotler, M.D.

$381,000 still needed

On August 30, 2012, the official study kickoff meeting took place for our new Israeli study of MDMA-assisted psychotherapy for PTSD. Israeli CRA Mimi Peleg traveled from Israel to meet with MAPS Lead Clinical Research Associate Berra Yazar-Klosinski, Ph.D., in Turkey for training prior to the kickoff meeting in Israel. The meeting took place at Beer Yaakov Mental Health Center, where the study will be conducted.

The study will explore the safety and efficacy of two doses of MDMA as an adjunct to psychotherapy in 10 subjects with chronic, treatment-resistant PTSD. The Israeli Defense Forces will refer some subjects, allowing us to learn whether the treatment could help active duty military personnel.

We had planned to begin enrolling subjects in late 2012, and expect to complete
the study within only 12 months of initiation since we are working with three (rather than two) co-therapist teams. Sadly, as this Bulletin was going to print, we learned that some of the psychiatrists and psychotherapists involved in the study may be called into military service due to increasing conflict in the region. We hope that the conflict will be resolved quickly and that we will be able to initiate the study soon.

Swiss Study Results to be Published in Journal of Psychopharmacology
Solothurn, Switzerland
Clinical Investigator: Peter Oehen, M.D.
This study is completed and has been fully funded.

On September 21, 2012, the paper describing the results of our Swiss pilot study of MDMA-assisted psychotherapy was accepted for publication in the Journal of Psychopharmacology. 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 study demonstrated 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 small number of subjects in this preliminary pilot study contributed to the results falling just short of statistical significance. The study also demonstrated that the low dose of MDMA (25 mg with a supplemental 12.5 mg two hours later) created a successful double-blind as compared to the full dose (125 mg followed by 62.5 mg). The paper will appear in the January 2013 edition of the Journal of Psychopharmacology.

Therapist Teams Complete MDMA-Assisted Psychotherapy Training Protocol
Charleston, South Carolina
Principal Investigator: Michael Mithoefer, M.D., with co-therapist Annie Mithoefer, B.S.N.
$265,000 still needed

From April 8-11, 2012, the therapist teams for our new MDMA-assisted Psychotherapy for PTSD Study in Boulder, Colorado, completed our therapist training protocol in Charleston, South Carolina. Several co-therapists from our Israeli study have also participated. 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.

Connect with MAPS
Stay up-to-date and be a part of the growing psychedelic and medical marijuana research community.

MAPS Email Newsletter
maps.org/newsletter
Monthly research updates, events, news, multimedia, and more delivered to your inbox.

Facebook
facebook.com/mapsmdma
Learn and share breaking news as a part of our fast-growing social network community.

Twitter
@MAPSNews
Instant updates from MAPS’ world headquarters in Santa Cruz, California.

maps.org
Current research, media, student resources, psychedelic harm reduction information, free psychedelic literature, MAPS Store, and many other resources.

YouTube
youtube.com/mapsmdma
Watch and learn from leading researchers while exploring our extensive video library.
MDMA-Assisted Therapy for Adults on the Autism Spectrum

MAPS is currently developing a protocol for a 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 influence social interactions for adults on the autism spectrum. 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 June 2013.

MAPS initially seeded the study with a $10,000 award to the selected research team for protocol development. On January 25, 2012, the MAPS Board of Directors allocated $200,000 from Ashawna Hailey’s bequest to the study if we are unable to raise the funds from other sources. We have a goal of obtaining grants from leading autism advocacy groups and will seek federal funds available through the NIH, though based on fundraising history these funds are most likely to come from individual donors.

Ibogaine Research for Addiction Treatment

Last Subject Completes Follow-Up in Mexico Ibogaine Study
Mexico
Principal Investigator: Thomas Brown, Ph.D.
$41,000 estimated study cost / $6,625 still needed

On September 10, 2012, the 30th and final subject completed the 12-month follow-up in our observational study of ibogaine treatment for addiction in Mexico. This will be first long-term outcome study ever conducted with ibogaine in the treatment of addiction. In this study, Principal Investigator Thomas Kingsley Brown, Ph.D., is observing the long-term effects of ibogaine treatment for individuals undergoing treatment at an independent clinic in Mexico. Data from this study will be compared with our concurrent, ongoing study of ibogaine treatment for addiction in New Zealand. (See Thomas Kingsley Brown’s article on page 32.)

New Zealand Ibogaine Study Enrolls First Five Subjects
New Zealand
Principal Investigator: Geoff Noller, Ph.D.
$15,000 raised (additional funds provided by co-sponsor)

On November 9, 2012, the fifth participant was enrolled in our ongoing observational study of ibogaine treatment for addiction in New Zealand. All participants had been receiving methadone treatment for opiate addiction and are being treated for methadone dependence at independent ibogaine clinics in New Zealand. The study was approved by the IRB on February 22, 2012, and 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.

Medical Marijuana Research

FDA and Review Board Approves Protocol of Marijuana for Veterans with PTSD: Will NIDA Agree?
Phoenix, Arizona
Clinical Investigator: Sue Sisley, M.D.
$20,000 cost of protocol development and approval process / $10,000 still needed

On October 25, 2012, the Institutional Review Board at the University of Arizona notified Principal Investigator Sue Sisley, M.D., that they had approved the protocol for our planned study of marijuana for symptoms of PTSD in 50 U.S. veterans. The IRB approved all of the key elements of the protocol design, and added several safety procedures and measures. The Food and Drug Administration had previously approved the protocol in April 2011, though the study has been blocked by the National Institute on Drug Abuse/Public Health Service, which unanimously rejected the protocol, since September 2011. We are hoping that protocol approval from both the IRB and the FDA will help persuade the reviewers to approve the study and allow NIDA to sell us the marijuana needed for the study.

UMass Professor’s Lawsuit Against DEA Awaits Ruling
Boston, Massachusetts

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. We are expecting to receive the court’s ruling soon. Meanwhile, the DEA is succeeding in preventing our medical marijuana research from moving forward.
LSD-Assisted Psychotherapy for Anxiety Related to Advanced-Stage Illness

Solothurn, Switzerland
Principal Investigator: Peter Gasser, M.D.
This study has been completed and is fully funded.

From September 3-7, 2012, MAPS Lead Clinical Research Associate Berra Yazar-Klosinski, Ph.D., visited the study site to monitor our completed Swiss study of LSD-assisted psychotherapy for anxiety associated with advanced-stage illness. This was the final closeout meeting with Principal Investigator Peter Gasser, M.D. The last long-term follow-up interview was conducted on August 8, 2012. The results are currently being prepared for publication.

Ayahuasca Treatment for Addiction

British Columbia, Canada
Principal Investigator: Gerald Thomas, Ph.D.
This study has been completed and is fully funded.

On September 27, 2012, researchers affiliated with MAPS Canada presented the findings from their now-completed MAPS-supported study of ayahuasca-assisted therapy for addiction and dependence to the Canadian First Nations Band involved as subjects in the study. Combining Western psychotherapeutic techniques with South American shamanic healing practices, this study gathered preliminary evidence about the safety and effectiveness of ayahuasca-assisted therapy. Treatment consisted of participation in a five-day retreat in British Columbia, facilitated by a Peruvian Shaman assisted by Gabor Maté, M.D., that included ayahuasca-assisted therapy. The research team is currently working on a paper for submission to a scientific journal, and will present the study results at Psychedelic Science 2013.