

# Summary

## MAPS Clinical Studies Summary

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### **MDMA-Assisted Psychotherapy Study with War Veterans with PTSD, Charleston, South Carolina**

**Total cost: \$500,000, \$431,000 Needed**

**Clinical Investigators Michael Mithoefer, M.D., and Anne Mithoefer, B.S.N.**

On Sept. 27, 2010, MAPS began a study of MDMA-assisted psychotherapy to treat U.S. veterans with chronic, treatment-resistant PTSD. The clinical investigators will treat 16 subjects with PTSD from the Iraq, Afghanistan, and Vietnam wars. We aim to enroll equal numbers of men and women. This study uses a sophisticated randomized, triple-blind, placebo-controlled protocol. During a three-month course of psychotherapy, all subjects will receive weekly non-drug psychotherapy and three daylong MDMA-assisted psychotherapy sessions, scheduled three to five weeks apart. MAPS will test three different doses of MDMA to determine whether this design will result in a successful blind. It is hoped that the subjects, therapists, and the independent raters will be uncertain as to which subject received which dose.

### **MDMA-Assisted Psychotherapy PTSD Study, Charleston, South Carolina**

**Total cost: \$1,200,000, All Funded**

**Clinical Investigators Michael Mithoefer, M.D., and Anne Mithoefer, B.S.N.**

MAPS' flagship Phase 2 pilot study was completed in Sept. 2008 with remarkably promising results. This was the first-ever study evaluating MDMA's therapeutic applications in clinical trials conducted under an FDA Investigational New Drug Application. Like all of MAPS' psychedelic-assisted psychotherapy studies, the protocol was randomized, double-blind, and placebo-controlled. All twenty subjects had treatment-resistant PTSD as a result of sexual abuse, crime, or war. On July 19, 2010, a paper about this study was published in the *Journal of Psychopharmacology*. On July 27, 2010, data collection was completed for the long-term follow-up. The average length of time between the final experimental treatment session and the follow-up data collection was 40 months, almost three and a half years.

### **MDMA-Assisted Psychotherapy PTSD Study, Solothurn, Switzerland**

**Total Cost: \$280,000, All Funded**

**Clinical Investigators Peter Oehen, M.D., and Verena Widmer, R.N.**

On Jan. 8, 2010, researchers conducted the final MDMA session with the 12th and final subject in our Swiss MDMA/PTSD

study. The 12-month-plus follow-up will be completed in January 2011. In early 2011, the study results will be analyzed and a paper will be written for submission to a peer-reviewed journal. In this study, we used a threshold/low dose of MDMA as an active placebo instead of using an inactive placebo. This small amount of MDMA was enough to cause the researchers as well as some of the subjects to occasionally guess incorrectly whether the threshold dose or the full dose had been administered. There were no Serious Adverse Events (SAEs) and no evidence of harm to any subject. The efficacy results of this study are larger than the results in the Zolof and Paxil studies that were sufficient for their approval as prescription medicines for PTSD, though less dramatic than in our U.S. study.

### **MDMA-Assisted Psychotherapy PTSD Study, Vancouver, Canada**

**Total cost: \$290,000, \$279,000 Needed**

**Clinical Investigators Ingrid Pacey, M.D., Andrew Feldmár, M.A.**

We are in the process of obtaining final permissions for an MDMA/PTSD pilot study in Canada. This study will be the first clinical psychedelic research in Canada in about 35 years. We have approval from Health Canada and an Institutional Review Board (IRB), and are working on the import/export permits to bring in MDMA from Switzerland for the study. This study will treat 12 subjects with chronic, treatment-resistant PTSD in a cultural context similar to the U.S. The purpose of this study is to gather more information about the size of the treatment effect.

### **MDMA-Assisted Psychotherapy PTSD Study, Tel Aviv, Israel**

**Total cost: \$300,000, \$175,000 Needed**

**Clinical Investigator Moshe Kotler, M.D.**

MAPS began working in 1998 to start an MDMA/PTSD pilot study in Israel. It took until early 2007 for the first subject to be enrolled in the study, conducted under the direction of the former chief psychiatrist of the Israeli Defense Forces and director of the Beer Yaakov Mental Health Center, Israel's largest hospital for the treatment of mental illness. The study explored the safety and efficacy of two experimental sessions, and used a threshold/low-dose of MDMA as an active placebo. Five subjects with PTSD related to war and terrorism were enrolled in the study. We're currently writing up the results and are initiating a larger Israeli study with 10 subjects. This design uses two experimental sessions rather than three to help us evaluate our treatment method.

**MDMA-Assisted Psychotherapy PTSD Study,  
Amman, Jordan**

**Total cost: \$136,000, \$51,000 Needed**

**Clinical Investigator Nasser Shuriquie, M.D.**

MAPS is preparing a 12-subject MDMA/PTSD pilot study in Jordan. The clinical investigator is the former chief military psychiatrist for the Jordanian Royal Medical Services. This study is part of our effort to explore MDMA-assisted psychotherapy conducted in a range of cultures. Cultural differences require us to think even more carefully about the core elements of our therapeutic approach and how we teach our therapist teams. This study is also using a slightly higher active placebo dose (40 mg MDMA) to help us gather more data on the effectiveness of the double-blind in a range of doses.

**Psychological Effects of MDMA (Therapist Training),  
Charleston, South Carolina**

**Total cost: \$100,000, \$100,000 Needed**

**Clinical Investigators Michael Mithoefer, M.D.,  
and Anne Mithoefer, B.S.N.**

This study is a Phase I, randomized, double-blind, placebo-controlled crossover design investigating the psychological effects of MDMA when administered in a therapeutic context to healthy subjects. In this study, we will administer a single MDMA-assisted psychotherapy session to each of 20 healthy subjects and will evaluate them with a variety of measures. Subjects will be limited to those in our MDMA/PTSD therapist-training program, as an optional part of their learning to conduct MAPS' MDMA/PTSD studies.

**LSD-Assisted Psychotherapy Life Threatening Illness  
Study, Solothurn, Switzerland**

**Total cost: \$200,000, All Funded**

**Clinical Investigator Peter Gasser, M.D.**

MAPS is conducting research combining LSD with psychotherapy to treat anxiety associated with life-threatening illnesses. This study will evaluate 12 subjects suffering from clinical anxiety associated with advanced-stage cancer and other illnesses. MAPS is proud to sponsor the first study of the therapeutic use of LSD in humans in more than 35 years. The first subject was enrolled on April 23, 2008, and now eleven of twelve subjects have been enrolled.

**Ibogaine Detoxification for Opiate Dependence Study,  
Playas De Tijuana, Mexico**

**Total cost: \$30,000, All Funded**

**Principal Investigators Valerie Mojeiko  
and Thomas Brown, Ph.D.**

MAPS is collecting data from 30 opiate-dependent subjects for one year after ibogaine-assisted detoxification to evaluate the long-term outcomes of ibogaine treatment. Ibogaine is a psychedelic plant from Africa used for religious purposes that also has addiction interrupting properties. MAPS' research is taking place at Pangaea Biomedics, a treatment facility in Playas de Tijuana, Mexico.

**Investigating Marijuana as a Treatment for PTSD,  
Phoenix, AZ**

**Cost: TBD**

**Clinical Investigator Sue Sisley, M.D.**

MAPS is finalizing the study design for a controlled, randomized, dose-response, triple-blind investigation of five different doses of marijuana, smoked or vaporized, in 50 veterans with chronic, treatment-resistant PTSD. The subjects will receive marijuana for four weeks, then go through a two-week period of cessation, then randomly receive another batch of marijuana for four more weeks of medication, then two weeks of cessation. Currently, numerous anecdotal reports of PTSD survivors self-medicating with marijuana suggest that marijuana as a medicine treats symptoms (especially nightmares) and requires regular administration. In contrast, MDMA-assisted psychotherapy addresses the core problem and is only used a few times, yet is more expensive and time-consuming. As a key part of our study design, we are requesting that NIDA provide us with a strain of marijuana that contains significant amounts (6%) of cannabidiol (CBD) in addition to significant amounts of THC (6%). CBD has been found to reduce anxiety but has yet to be explored in PTSD subjects. Currently, NIDA does not produce marijuana with CBD, highlighting another reason why NIDA's monopoly obstructs or delays research and should be ended.