

Research News

Treating PTSD with MDMA-Assisted Psychotherapy

mdmaptsd.org

20th Subject Treated in Ongoing Veterans Study; Study Fully Funded *Ongoing study*

Location: Charleston, South Carolina

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

Estimated study budget: \$1,382,000

Already raised: \$1,382,000

This study has been fully funded.

On August 26, 2014, the 20th subject was treated in our ongoing study of MDMA-assisted psychotherapy for 24 U.S. veterans, firefighters, and police officers with service-related PTSD, led by Principal Investigator Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N. This subject is the first police officer enrolled in the study.

In just 16 days, over 800 funders helped us reach our \$50,000 goal for our Legalizing Psychedelic Therapy crowdfunding campaign, completing our multi-year, \$1.38 million fundraising effort for this study. “I really did find the healing that I needed for the combat experiences that I went through during my very first session,” says Iraq veteran and study participant Nicholas Blackston. “It just helped me go so much deeper within my consciousness. I accepted that part of myself that I had cut off.”

Seven subjects have also enrolled in our ongoing sub-study of the physiological effects of MDMA-assisted psychotherapy, which will use heart rate variability (HRV) and functional magnetic resonance imaging (fMRI) to explore correlations with clinical outcomes.

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.



Our phase 2 studies are a step toward legalizing MDMA-assisted psychotherapy by 2021.

16th Subject Enrolled in Boulder Study; Protocol Amendment Approved by IRB *Ongoing study*

Location: Boulder, Colorado

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

Estimated study budget: \$711,000

Already raised: \$309,000

Needed to complete this study: \$402,000

On September 30, 2014, the 16th subject was enrolled in our ongoing study of MDMA-assisted psychotherapy for PTSD in 23 subjects with PTSD from sexual assault, violent crime, war, natural disasters, or any other cause, taking place in Boulder, Colorado. Led by Clinical Investigator Marcela Ot'alara, 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.

As of November 12, 11 subjects have completed their primary endpoint interviews, including the Clinician Administered PTSD Scale (CAPS) and other assessments, after receiving two experimental sessions. “A good way to describe it is that I felt like I was in a cave, trying to get out, but I didn't have any light,” James, a study participant, recently told the CU Independent. “So I was just feeling around the walls, getting turned around, and getting even more lost. But with the MDMA sessions, it was like the therapist was my guide and the MDMA was a flashlight. With those resources, I could get out of the cave I'd been lost in for so long.”

Our Legalizing Psychedelic Therapy crowdfunding campaign raised \$141,888, with all funds raised above \$50,000 going towards costs associated with this study. These funds will pay for therapist training and supervision, MDMA storage and preparation, setting up the treatment room, plus all remaining experimental sessions in the Boulder study.

On August 28, the Institutional Review Board approved an amendment to the study protocol, adding greater variability in dosing options for subjects' unblinded sessions, giving subjects randomly assigned to the 100mg condition for their first two sessions the option of requesting either a 100mg or 125mg dose for their third experimental session. “The first two treatments with 100mg felt like I helped the medicine help me,” reported one participant. “With the 125mg, the medicine was right there to help and hold me. It held me and supported me doing my work.”

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 abil-

ity 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.

“The Boulder study is at its halfway point and the results have been encouraging and significant,” reports study Principal Investigator Marcela Ot’alora. “We have witnessed people change in ways they did not think possible. I am continuously amazed by our participants’ willingness to embark on a journey they know little about, while having their world disrupted and ultimately doing tremendous work.”

Fourth Subject Treated in Israeli Study; Israeli TV to Fund Upcoming Documentary

Ongoing study

Location: Beer Yaakov, Israel

Clinical Investigator: Moshe Kotler, M.D.

Estimated study budget: \$493,000

Already raised: \$83,000

Needed to complete this study: \$410,000

On June 15, 2014, the fourth subject out of 10 was treated in our ongoing Israeli study of MDMA-assisted psychotherapy for chronic, treatment-resistant PTSD. On October 28, the quality monitoring visit was completed by Kamila Novak of Antaea Medical Services, our Israeli contract research organization, to check the quality of the study site, study forms and documents, and review the data collected from the first four subjects. Additionally, Israel’s Channel 1 has committed funding for an upcoming documentary on the study. Led by Clinical Investigator Moshe Kotler, M.D., this study is taking place at Beer Yaakov Mental Hospital.

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.

Subject Screening Begins in Canadian Study; New Co-Investigators Participate in Therapist Training

Study pending initiation

Location: Vancouver, British Columbia, Canada

Principal Investigators: Ingrid Pacey, M.D.

Estimated study budget: \$419,000

Already raised: \$50,000 raised + \$3,500 raised by partners

Needed to complete this study: \$365,500

On September 2, 2014, the first potential subjects were screened for our Canadian study of MDMA-assisted psychotherapy for PTSD. Led by Principal Investigator Ingrid Pacey, M.D., in Vancouver, B.C., this study will treat up to 12 subjects with chronic, treatment-resistant PTSD from any cause. From

August 1–5, 2014, the study’s new co-investigators, Donna Dryer, M.D., and Richard Yensen, Ph.D. participated in a two-and-a-half day therapist training led by Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., in Vancouver.

MAPS is sponsoring this study in association with MAPS Canada, the first and only Canadian organization dedicated to psychedelic research and education, now able to receive tax-deductible contributions in Canada. “After an incredibly long process of study approval and start-up, it is wonderful to see all of our hard work come to fruition,” said Amy Emerson, MAPS Director of Clinical Research. “The addition of this study team will give us experience with a new therapy team and a chance to compare with results from our other studies.”

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.

MAPS and UK Researchers Plan Brain Imaging Study of MDMA and PTSD

Upcoming study

Location: Cardiff University, UK

Principal Investigator: Prof. Jon Bisson

Study Lead: Ben Sessa, M.D.

Funded in part by MAPS.

“Hooking up with the neuroimaging expertise of Robin Carhart-Harris, Ph.D., and Dr. David Nutt at Imperial College London and Richard Wisnes’ fMRI department at Cardiff University, we designed a study that looks primarily at the neurobiological mechanisms behind MDMA’s effects on the core features of PTSD. There have already been neuroimaging studies on patients with PTSD and on healthy people taking MDMA, but ours will be the first time fMRI has looked specifically at patients with PTSD under the direct effect of MDMA. This study will be funded by MAPS, Beckley Foundation, and an anonymous donor. There is no therapeutic component to the study, but subjects will be able to request therapeutic support if they feel it is necessary since for most of their MDMA experience they will not be in the scanner. This study will also explore MDMA’s potential beneficial effects without delivering formal therapy.” —Dr. Ben Sessa MBBS (MD) BSc MRCPsych, Consultant Child and Adolescent Psychiatrist in Substance Misuse and Psychedelic Researcher, Bristol and Cardiff, UK.

MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

Fifth Subject Enrolled *Ongoing study*

Location: Los Angeles, California

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

Estimated study budget: \$320,000

Already raised: \$1,000 raised + \$15,000 raised by partners

Needed to complete this study: \$304,000

On October 24, 2014, the fifth subject of 12 was enrolled in our ongoing study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum. This exploratory pilot study is exploring whether MDMA combined with therapy can enhance functional skills and quality of life in autistic adults with social anxiety, and is being conducted in affiliation with Harbor-UCLA Medical Center and the Los Angeles Biomedical Research Institute. Comparative studies suggest that autistic adults are at greater risk for lifetime and current psychological disorders, especially social anxiety.

“When the study began, we were optimistic that individuals with social phobias would find the courage to call the hotline, send an e-mail, or contact us through other means,” reports co-Principal Investigator Alicia Danforth, Ph.D. “We are happy to report that we already have received over 80 screening inquiries from men and women from all over the United States and several from overseas. We are on track to enroll at least one more participant by the end of the year, which will keep us on schedule.”

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.



Alicia Danforth, Ph.D., and Charles Grob, M.D., in the treatment room at Harbor-UCLA Medical Center.

MDMA-Assisted Psychotherapy for Anxiety Associated with Life-Threatening Illness

FDA and IRB Approved Protocol *Upcoming study*

Location: Marin, California

Principal Investigators: Phil Wolfson, M.D.

Estimated study budget: \$582,000

Already raised: \$121,500

Needed to complete this study: \$460,500

On November 13, 2014, the U.S. Food and Drug Administration (FDA) approved the protocol for our upcoming study of MDMA-assisted psychotherapy for anxiety associated with life-threatening illness. This randomized, double-blind, placebo-controlled Phase 2 study, to be conducted in Marin, Calif., will gather preliminary data about the safety and efficacy of MDMA-assisted psychotherapy for anxiety in 18 subjects diagnosed with a life-threatening illness. Principal Investigator Phil Wolfson, M.D., brings to the study his substantial experience using MDMA in psychotherapy before MDMA was criminalized in 1985.

The study was approved by the Institutional Review Board (IRB) on September 16. On November 19, the Research Advisory Panel of California (RAP-C) is scheduled to review our responses to their request for several changes to the protocol and Informed Consent form, as California is the only U.S. state with a separate review process for Schedule I drug research. The study will also require approval from the U.S. Drug Enforcement Administration before we can begin screening subjects.

Anecdotal reports indicate that MDMA may be helpful in reducing social anxiety in autistic adults.

Learn more at
mdma-autism.org



Please support our clinical study testing the safety and efficacy of MDMA-assisted therapy in the treatment of social anxiety in adults on the autism spectrum.

mdma-autism.org/donate

LSD-Assisted Psychotherapy for Anxiety Associated with Life-Threatening Illness

Switzerland: Qualitative Results Published, Showing Lasting Benefits

Study completed

Location: Solothurn, Switzerland

Principal Investigator: Peter Gasser, M.D.

This study is complete and has been fully funded.

On November 11, 2014, the peer-reviewed *Journal of Psychopharmacology* published a paper describing the results of a qualitative study of subjects in our completed Swiss Phase 2 pilot study of LSD-assisted psychotherapy for 12 subjects with anxiety associated with advanced-stage illness. A March 2014 paper in the *Journal of Mental and Nervous Disease* about our completed pilot study found positive trends in the reduction of anxiety following two LSD-assisted psychotherapy sessions, and indicated that LSD-assisted psychotherapy can be safely administered in these subjects. The long-term results, showed lasting reductions in anxiety and increases in quality life for participants one year after receiving two LSD-assisted psychotherapy sessions. "I was very very sad, I cried, never desperate, but a lot of sad things came up," one subject recalled of their experience in the study. "Quality of life changed extremely insofar as I became calmer, that I take things easier," wrote one study participant. "It makes a difference if I look upon death with stress or with equanimity. I believe that is an enormous difference in quality of life."

This is the first study of the therapeutic use 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. Eleven of the 12 subjects in the double-blind, placebo-controlled pilot study had never used LSD previously. 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.



MAPS supports research into the safety and effectiveness of **ayahuasca-assisted treatment for drug addiction**. We also support conferences, meetings, and publications about the scientific, therapeutic, sustainable, and spiritual uses of ayahuasca. Learn more at maps.org/ayahuasca.

Ibogaine-Assisted Therapy for Drug Addiction

New Zealand Ibogaine Study

Ongoing study

Location: New Zealand

Principal Investigator: Geoff Noller, Ph.D.

Donations are needed to support ibogaine research.

Investigator Geoff Noller, Ph.D., has collected follow-up data from eight participants who underwent treatment at an independent ibogaine center in New Zealand. Data from this study, which is expected to be complete in Spring 2015, will be compared to the results of our completed observational study in Mexico.

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.

Mexico Ibogaine Study

Study completed

Location: Mexico

Principal Investigator: Thomas Kingsley Brown, Ph.D.

This study is complete and has been fully funded.

Data cleanup has begun in preparation for submitting the results for publication in a peer-reviewed scientific journal. In this study, Principal Investigator Thomas Kingsley Brown, Ph.D., observed the long-term effects of ibogaine treatment for individuals undergoing treatment for opioid dependence at an independent clinic in Mexico.



Medical Marijuana Research

\$2 Million Grant Proposal Submitted to State of Colorado for Multi-Site Study

Research in Arizona *Study pending*

Location: Arizona and TBD

Clinical Investigator: Sue Sisley, M.D.

Estimated study budget: \$2,000,000

Already raised: \$33,000

Needed to complete this study: \$1,967,000

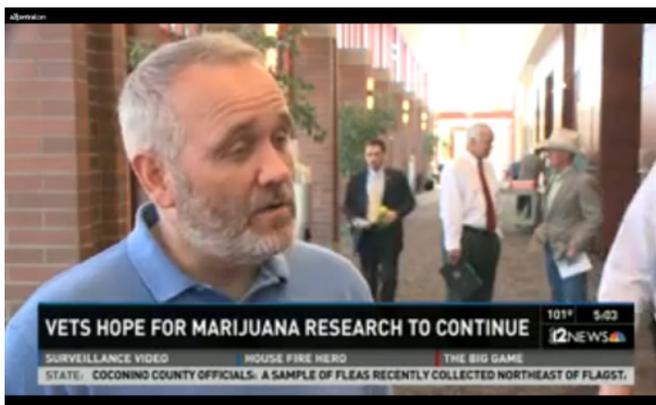
On October 14, 2014, MAPS submitted a proposal to the Colorado Department of Public Health and Environment requesting \$2 million for our planned study of marijuana for symptoms of PTSD in 76 U.S. veterans. The State of Colorado has \$9 million available for marijuana research, and the response to our submission is expected in late November or December. The National Institute on Drug Abuse (NIDA) estimates that they will be able to provide the marijuana for our study in January 2015. The study is the first randomized controlled trial (RCT) to test the therapeutic potential of smoked marijuana and its components as a treatment for PTSD.

This will be a two-site study led by Principal Investigator Sue Sisley, M.D., who will conduct her portion of the study in her private practice office in Arizona or at Arizona State University, and a second Principal Investigator, Ryan Vandrey, Ph.D., who will conduct his portion of the study at Johns Hopkins University in Baltimore, MD. On September 25, veterans and medical marijuana advocates spoke to the Arizona Board of Regents in favor of Dr. Sisley, encouraging ASU to host part of the study there. Dr. Sisley is currently in discussions with ASU about the possibility of hosting the study there.

Marcel Bonn-Miller, Ph.D., of the University of Pennsylvania will serve as Coordinating Principal Investigator, and Paula Riggs, M.D., of the University of Colorado, Denver will serve as Senior Scientific Advisor. Dr. Sisley has been working with MAPS since 2010 to initiate the study.

HHS Denies Request from 30 Members of Congress to End Obstructive Review Process

On September 22, 2014, U.S. Department of Health and Human Services Secretary Sylvia M. Burwell formally rejected a request from 30 members of Congress requesting that HHS end the obstructive Public Health Service (PHS) review process for privately funded medical marijuana research. A 1999 HHS Guidance requires an additional review process for federally regulated research with marijuana, but not for any other Schedule I drug. This additional review process makes it difficult or impossible for scientists in the U.S. to gain approval for whole-plant medical marijuana drug development research. On June 17, Rep. Earl Blumenauer (D-OR) and 29 other Congressional representatives sent a letter to HHS requesting that the PHS review process be eliminated. MAPS is now working with Rep. Blumenauer's office to prepare a letter to Sec. Burwell responding to her rejection letter, which ignores the substance of the 30 Congressional representatives' concerns and fails to justify the problematic PHS review process for medical marijuana research.



Arizona's Channel 12 News features coverage of the Arizona Board of Regents meeting on September 25, 2014, highlighting presentations from veterans and advocates who traveled from around the country to voice their support for MAPS and Dr. Sue Sisley's study of marijuana for PTSD.

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