

# Research News

## Treating PTSD with MDMA-Assisted Psychotherapy

mdmmaps.org

### 17 of 24 Subjects Complete Long-Term Follow-Up in U.S. Veterans Study *Ongoing study*

**Location:** Charleston, South Carolina

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

**Estimated study budget:** \$1,429,000

**Already raised:** \$1,429,000

This study has been fully funded.

As of September 23, 2015, 17 of 24 subjects have completed 12-month follow-up interviews in our nearly completed study of MDMA-assisted psychotherapy for U.S. veterans, firefighters, and police officers with chronic, treatment-resistant PTSD. Led by Principal Investigator Michael Mithoefer, M.D., and Co-therapist Annie Mithoefer, B.S.N., the data from this study are now being prepared for analysis and publication in a peer-reviewed scientific journal. "Over 900 people have contacted us about wanting to participate in our most recent study that had room for only 24 participants," writes Dr. Mithoefer in his *MAPS Bulletin* article, page 24. "Annie and I deeply appreciate the willingness of study participants to volunteer for our clinical trials, and to allow us to support them in their profound and challenging processes of healing."

Approximately half of the 24 subjects have also enrolled in our ongoing sub-study, in collaboration with researchers at the Medical University of South Carolina (MUSC), of the physiological effects of MDMA-assisted psychotherapy. This sub-study is using heart rate variability (HRV) and functional magnetic resonance imaging (fMRI) to explore correlations with clinical outcomes.

We anticipate that the results will be published in early 2016, after the data from this study and all of our other international Phase 2 pilot studies is submitted to the U.S. Food and Drug Administration for consideration of Breakthrough Therapy status.

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.

### Final Two Subjects Treated in Boulder Study

*Ongoing study*

**Location:** Boulder, Colorado

**Principal Investigator:** Marcela Ot'abora, M.A., L.P.C.

**Estimated study budget:** \$771,000

**Already raised:** \$727,000

**Needed to complete this study:** \$44,000

On October 2 and 9, 2015, the last two subjects were treated in our ongoing study of MDMA-assisted psychotherapy for 23 subjects with PTSD from sexual assault, violent crime, war, natural disasters, or any other cause, taking place in Boulder, Colorado. This will be the second-largest study ever conducted of MDMA-assisted psychotherapy for PTSD, having enrolled 19 women and nine men, with five subjects dropped out or excluded for not meeting study criteria, and 23 subjects to be included in a final analysis (all 29 will be included in our intent-to-treat analysis, a more conservative approach that analyzes data from all subjects enrolled in the study).

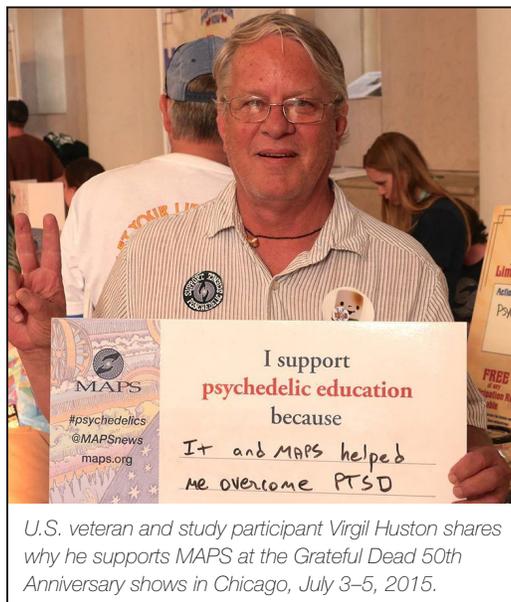
The September 2015 issue of *Marie Claire* includes an in-depth feature article about the experiences of three women who benefited from MDMA-assisted psychotherapy for PTSD, including two from this study. On September 13, NPR broadcast a special report including an interview with Brenda, a woman who overcame PTSD after participating in this study.

Brenda shares how her life and relationships have changed after she received MDMA-assisted psychotherapy, and journalist Kelley McMillan speaks about what she learned during her investigative report on MDMA research. "Now, life is good," Brenda told NPR. "Spending 35+ years suicidal was something I don't wish on anyone. After six months in that study, I am not suicidal. I want to live."

Primary outcome data is anticipated to be available in December 2015. The final results will begin to be prepared for publication in early 2016, with publication expected in late 2016. In addition to obtaining Phase 2 data on the safety and effectiveness of MDMA-assisted psychotherapy for

PTSD, this study is also comparing outcomes between different combinations of male/female co-therapist teams.

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-



*U.S. veteran and study participant Virgil Huston shares why he supports MAPS at the Grateful Dead 50th Anniversary shows in Chicago, July 3–5, 2015.*

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.

**Eighth Subject Treated in Israeli Study** *Ongoing study*

**Location:** Beer Yaakov, Israel

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

**Estimated study budget:** \$509,000

**Already raised:** \$92,000

**Needed to complete this study:** \$417,000

On October 6, 2015, the eighth subject was treated in our ongoing Israeli study of MDMA-assisted psychotherapy for PTSD. Led by Principal Investigator Moshe Kotler, M.D., this Phase 2 study will treat up to 10 subjects with chronic, treatment-resistant PTSD from any cause. The Israeli team will seek to enroll the final two subjects in November, when we will close enrollment in order to gather the data for submission to the U.S. Food and Drug Administration as part of our End-of-Phase 2 meeting, in preparation for Phase 3. This study is actively seeking Israeli participants (learn more at [maps.org/israel](http://maps.org/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.

**Fifth and Sixth Subjects Treated**

**in Canadian Study** *Ongoing study*

**Location:** Vancouver, British Columbia, Canada

**Principal Investigators:** Ingrid Pacey, M.D.

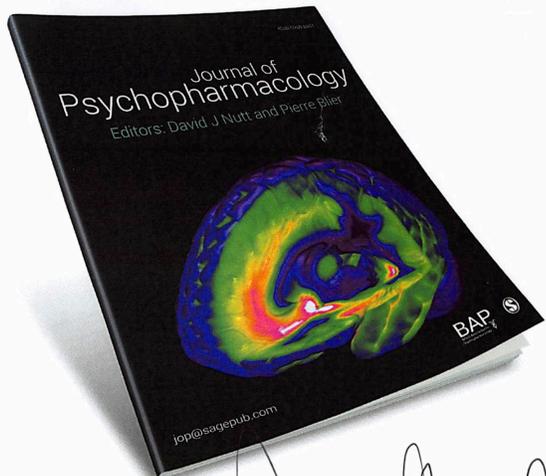
**Estimated study budget:** \$470,000

**Already raised:** \$46,000 + \$69,000 raised by partners

**Needed to complete this study:** \$355,000

On June 26 and July 3, 2015, the fifth and sixth subjects were treated in our ongoing Canadian study of MDMA-assisted psychotherapy for PTSD. The sixth subject was enrolled on June 29. Led by Principal Investigator Ingrid Pacey, M.D., in Vancouver, B.C., this Phase 2 study is treating up to 12 subjects with chronic, treatment-resistant PTSD from sexual assault, violent crime, military service, or any other cause. Mark Haden, Chair of the Board of Directors of MAPS Canada, reflected on the media attention the study has been receiving: "We had 15 minutes on CBC national radio, a feature article in *Macleans*' (Canada's most prominent weekly magazine), and CBC's high-profile show *Ideas* is producing two new shows dedicated to psychedelics," Haden writes. "MAPS Canada is not just developing a better treatment for PTSD, but also having an impact on public perception of the vast potential of psychedelic medicine."

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.



David Nutt, Editor-in-Chief  
Journal of Psychopharmacology



# 2015 Most Cited Paper Prize

Presented to

**Mithoefer MC, Wagner MT, Mithoefer AT,  
Jerome L, Doblin R**

Authors of

**The safety and efficacy of  
{+/-}3,4-methylenedioxymethamphetamine-  
assisted psychotherapy in subjects with  
chronic, treatment-resistant posttraumatic  
stress disorder: the first randomized  
controlled pilot study**

J Psychopharmacol. 2011 Apr;25(4):439-52

This paper represents a significant and proven contribution to both the journal and the field.

Times Cited: 60\*

\*Information correct at time of award, July 2015 - Thomson Reuters Journal Citation Reports®

## MAPS Leads Seven-Day MDMA Therapist Training in South Carolina

From October 4–11, 2015, MAPS hosted a seven-day training in Charleston, South Carolina, for therapeutic professionals interested in working on MAPS’ future clinical trials of MDMA-assisted psychotherapy for PTSD. The training was led by Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., along with Marcela Ot’alora, M.A., L.P.C., Principal Investigator of our ongoing study in Boulder. The weeklong training included 16 participants reviewing videos of MDMA-assisted psychotherapy sessions and discussing therapeutic techniques. Participants also completed a five-hour online training via our new online Training Portal prior to attending in person. The goals for this training were to educate therapists and potential researchers about MDMA-assisted psychotherapy methods, and to test our new educational model by conducting a pilot run of our expanded therapist training program (seven days instead of five).

Are you interested in learning more about being a Phase 3 MDMA-assisted psychotherapy for PTSD researcher? Contact us at [askMAPS@maps.org](mailto:askMAPS@maps.org).

## MPBC Purchases GMP MDMA Supply for Phase 3 Trials

On September 28, 2015, the MAPS Public Benefit Corporation initiated the purchase of one kilogram of 3,4-methylenedioxymethamphetamine (MDMA) certified under current Good Manufacturing Practices (GMP), from the UK pharmaceutical drug manufacturer Shasun. This supply will be used for our upcoming Phase 3 trials of MDMA-assisted psychotherapy for PTSD, which will begin in 2017. The GMP MDMA will not be any purer than our existing supply, but has been created with complete documentation and validation of all manufacturing procedures as required by the FDA and the European Medicines Agency (EMA) for use in Phase 3 trials.

The MDMA used in our current and completed U.S. Phase 1 and 2 trials was originally manufactured in 1985 by pharmacologist David Nichols, Ph.D., at Purdue University’s Department of Medicinal Chemistry, under contract to Earth Metabolic Design Lab, the non-profit that Rick Doblin started before MAPS. The original 1 kilogram supply cost \$4000, or \$4 per gram (the actual cost was lower since Nichols had an excellent yield and produced more than 1 kilogram). Approximately 960 grams of the original batch still remains. Our ongoing Israeli and Canadian studies, and our completed Swiss study, have used a different batch of MDMA manufactured in Switzerland by Lipomed, which no longer manufactures MDMA for clinical research. The new GMP MDMA will cost almost 100 times the cost of our original supply.

Begin with the end in mind  
 then work backward to plan for reaching ambitious goals  
 —Ashawna Hailey, who left \$5.5 million to MAPS in her will

Help create a world where psychedelics are integrated into society by including MAPS in your end of life plans. If you tell us about your plans, you can join our *Next Horizon Society*, and we will invite you to receptions, learning opportunities, and other special events.

Please contact MAPS Major Gifts Officer  
 Jade Netanya Ullmann to discuss your plans.  
[jade@maps.org](mailto:jade@maps.org)  
 831.429.6362 x111



## MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

### **Ninth Subject Treated** *Ongoing study*

**Location:** Los Angeles, California

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

**Estimated study budget:** \$336,000

**Already raised:** \$12,000 + \$15,000 raised by partners

**Needed to complete this study:** \$309,000

On September 26, the ninth subject was treated in our ongoing study of MDMA-assisted therapy for social anxiety in 12 adults on the autism spectrum. Sponsored by MAPS, this is a collaborative study between MAPS and the Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, with blood plasma biomarker analysis being conducted by researchers at Stanford University. “No Serious Adverse Events



*Alicia Danforth, Ph.D., gave a presentation on MDMA-assisted therapy for social anxiety in autistic adults at Breaking Convention in London, July 10–12, 2015.*

have occurred, and the study has received 228 screening inquiries from across the United States and several other countries,” reports study Co-Investigator Alicia Danforth, Ph.D. “One of the key factors contributing to this study running smoothly since the launch was early and ongoing consultation with members of the autism community.”

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.

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

### **Fifth Subject Treated in Marin Study** *Ongoing study*

**Location:** Marin, California

**Principal Investigator:** Phil Wolfson, M.D.

**Estimated study budget:** \$627,000

**Already raised:** \$194,000

**Needed to complete this study:** \$433,000

On September 21, 2015 the fifth subject received their first experimental session in our ongoing study of MDMA-assisted psychotherapy for anxiety associated with life-threatening illness. Led by Principal Investigator Phil Wolfson, M.D., with co-therapist Julane Andries, LMFT, in Marin, Calif., this study will treat 18 subjects suffering from anxiety related to a life-threatening disease that is either ongoing or in remission with a possibility of recurrence. “We’re very excited to see the results from the first group of participants in this study,” says Ben Shechet, Clinical Research Associate for MAPS Public Benefit Corporation. “The reports from the study therapists regarding these subjects’ experimental sessions have been extremely positive, and we look forward to seeing how those experiences will be reflected in the data now coming in.” We currently expect all experimental sessions in this study will be completed by late 2016.

Goals for this study include (1) gathering data on the safety and effectiveness of MDMA-assisted psychotherapy for subjects with anxiety associated with life-threatening illness; (2) determining if additional studies are warranted; and (3) initiating MDMA-assisted psychotherapy research for a new clinical indication.

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

Learn more at [mdma-autism.org](http://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](http://mdma-autism.org/donate)

# Ibogaine-Assisted Therapy for Drug Addiction

## Final Subject Enrolled in 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 subjects undergoing treatment at an independent ibogaine center in New Zealand. Data from this study 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: Paper Prepared for Submission to Peer-Reviewed Journal

*Study completed*

**Location:** Mexico

**Principal Investigator:** Thomas Kingsley Brown, Ph.D.

This study is complete and has been fully funded.

The results of our completed study of ibogaine-assisted therapy for addiction in Mexico will be submitted for publication in a peer-reviewed scientific journal in December 2015. 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.

“Stories about recovery and reconciliation have great power to convince people of the efficacy of ibogaine treatment,” writes Brown in his MAPS *Bulletin* article, page 36. “However, the primary aim of the study was to produce good quantitative evidence—the kind that can get the attention of scientists and medical professionals. I’m pleased to say that despite the shortcomings of the study, namely the low number of participants and the lack of a control group, we have some strong evidence that ibogaine is helping people.”



## COVER ARTIST: CHOR BOOGIE



Chor Boogie

**Front cover:** *The Love Dance*  
spray paint on canvas  
48 x 72 in

**Back cover:** *Love Land*  
detail of public mural  
Crans Montana, Switzerland

*The Love Dance* is inspired by the loving intelligence and healing powers of the iboga medicine. Two years ago, the artist Chor Boogie suffered from a brief, but serious opiate relapse and pursued treatment with the total alkaloid iboga medicine, administered by a lineage Bwiti shaman. The

medicine, along with the shaman’s skillful guidance, cleared his body of the physical and psychological addiction within days and offered teachings for a healthier and more meaningful path. *The Love Dance* will grace the cover of a memoir about iboga, *Heart Medicine: A True Love Story*, written by the artist’s wife, Elizabeth Bast, to be released late 2015 (information at [ebast.net](http://ebast.net)).

*Love Land* is also inspired by iboga. This piece is dedicated to the artist’s grandmother, Patricia Demeo, who passed away just before his journey to Switzerland. This is the artist’s rendition of her soul reaching the universal love, along with spirit animals that crossed his path during Bwiti ceremony: the king snake (not shown), a protector snake the eats poisonous snakes, and the butterfly, a symbol of transformation and rebirth.

Chor Boogie, a.k.a. Joaquin Lamar Hailey, is a critically acclaimed spray paint artist whose visionary murals and art exhibitions have appeared all over the globe. He was recently honored by Societe Perrier as being number three among the Top Ten U.S. Street Artists of 2014. He approaches his use of color as a form of therapy and visual medicine, and has been dubbed “the color shaman” by comrades and fans.

Chor Boogie is recognized for having achieved a profound level of technical and emotional virtuosity in the medium of spray paint. He was first nurtured by the world of street art and is primarily a self-taught artist. He draws inspiration from artists such as Michelangelo, Da Vinci, Rembrandt, Klimt, Van Gogh, Dali along with his personal spray paint mentors Phase2, Vulcan, and Riff170 who were among the first notable creators in the street art and hip hop cultural movements. Through his dynamic range of artistic styles, Chor addresses issues of race, class, gender, neo-imperialism, corporate corruption, substance abuse, health care, drug policy reform, and the rights of indigenous peoples. Chor uses his voice as an artist and public figure to raise awareness about indigenous African wisdom traditions.

He has resided in the San Francisco Bay Area since 2007 where he has been an active member of the street art community and has painted several notable commissioned public murals including *The Eyes of San Francisco*, *Purgatory*, and *Opium Horizons*.

[chorboogie.com](http://chorboogie.com)

[facebook.com/chorboogie01](https://www.facebook.com/chorboogie01)

[instagram.com/choreboogie](https://www.instagram.com/choreboogie)

## Medical Marijuana Research

### Johns Hopkins IRB Approves Protocol Design; Phoenix Site Identified; Sue Sisley Presents Lecture at Walter Reed Research in Arizona

*Study in development*

**Location:** Baltimore, Md., and Phoenix, Ariz.

**Coordinating Principal Investigator:**

Marcel Bonn-Miller, Ph.D. (University of Pennsylvania)

**Co-Investigators/Site Principal Investigators:**

Sue Sisley, M.D. (private practice) and

Ryan Vandrey, Ph.D. (Johns Hopkins University)

**Co-Investigator:** Paula Riggs, M.D. (University of Colorado)

**Estimated study budget:** \$2,156,000

**Already raised:** \$2,156,000 grant awarded by the State of Colorado

On September 25, 2015, the Institutional Review Board (IRB) at Johns Hopkins University approved the protocol design for our upcoming study of smoked marijuana for symptoms of PTSD in 76 U.S. military veterans. On September 14, 2015, researchers and study staff completed an all-day pre-study visit at the Johns Hopkins University Behavioral Pharmacology Research Unit (BPRU) to prepare for our upcoming study of smoked marijuana for symptoms of PTSD in U.S. veterans. The study team reviewed the clinical trial protocol, standardized the methods used at both study sites, and inspected the site facilities.

The Principal Investigator for this study is Marcel Bonn-Miller, Ph.D., of the University of Pennsylvania (see his article on page 32). Paula Riggs, M.D., of the University of Colorado, is serving as an additional Co-Investigator to help ensure the study's scientific integrity.

On September 4, the U.S. Drug Enforcement Administration inspected the proposed Phoenix, Arizona, study site which will be led by Co-Investigator/Site Principal Investigator (PI) Sue Sisley, M.D. Half of the study's 76 subjects will be treated at the Phoenix site, with the other half treated at Johns Hopkins by Co-Investigator/Site PI Ryan Vandrey, Ph.D. The IRB will issue final approval for the study after the U.S. Drug Enforcement Administration (DEA) grants the Schedule I license for the study site in Phoenix, Ariz., and the study is listed on [clinicaltrials.gov](http://clinicaltrials.gov). The DEA will review the Phoenix study site when construction of the site is complete, and has already approved the specific refrigeration and security systems that we will use to store the study marijuana at the Phoenix site.

On September 15, Dr. Sisley presented a clinical lecture at the 5th Annual Pain Care Skills Training event at Walter Reed National Military Center about our upcoming study. "The military has historically been a leader in adopting new medical practices far ahead of the larger medical community," said Sisley. "It's an honor to be able to help educate these highly dedicated medical professionals about medical cannabis and PTSD."



### Study in Development: Ayahuasca-Assisted Treatment for PTSD

MAPS is sponsoring an observational study investigating the safety and effectiveness of ayahuasca-assisted treatment for PTSD in 12 U.S. veterans. Led by retired Marine Lance Cpl. Ryan LeCompte, the study is set to begin with a 10-day retreat to Peru in early 2016 and will include measurements of PTSD symptoms prior to treatment, and with three, six, and 12-month follow-up evaluations. The follow-ups will be conducted at Naropa University in Boulder, Colorado.

LeCompte is the founder of the non-profit organization Veterans for Entheogenic Therapy (VET), whose mission is to provide veterans suffering from service-connected PTSD with the opportunity to find their own path of healing. On October 26, 2014, CNN aired an episode of *This is Life with Lisa Ling* titled "Jungle Fix," featuring VET and a group of military veterans as they traveled to Peru and participated in ayahuasca ceremonies as a possible treatment for PTSD and other emotional and mental trauma suffered in combat.

"Ayahuasca is a way to give relief to those who are suffering," says LeCompte, who says many veterans are not satisfied with the PTSD treatment they receive when they return from deployment. "I've seen how ayahuasca has the ability to mimic the mechanics utilized in exposure therapy, a kind of psychotherapy used at the VA for PTSD. It allows a complete catharsis, one that opens the doors of perception to how we are seeing our own trauma. Once this shift in perspective happened, there was a letting go or release of the traumatic memory."



*LeCompte speaks with a veteran seeking ayahuasca-assisted treatment for PTSD.  
Image: CNN*