

# Research News

## Treating PTSD with MDMA-Assisted Psychotherapy

[mdmaptsd.org](http://mdmaptsd.org)

### 19 of 24 Subjects Treated in Veterans Study; Legalizing Psychedelic Therapy Campaign Seeks to Complete Funding *Ongoing study*

**Location:** Charleston, South Carolina

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

**Estimated study budget:** \$1,380,000

**Already raised:** \$1,330,000

**Needed to complete this study:** \$50,000

Make a donation today to help us complete this study at [legalizepsychedelictherapy.org](http://legalizepsychedelictherapy.org).

On June 17, 2014, the 19th subject began treatment 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. The 18th subject was treated on May 23. On May 7, the 11th subject completed their one-year follow-up evaluation. Six subjects have also enrolled in our ongoing sub-study of the physiological effects of MDMA-assisted psychotherapy, which will examine heart rate variability (HRV) and functional magnetic resonance imaging (fMRI) and explore correlations with clinical outcomes. Virgil Huston, and Iraq veteran who participated in the study, wrote to MAPS after completing the study. “As a patient



Study participant and retired Marine Nicholas Blackston is featured in Tom Schroder's new book *Acid Test*. “I found the healing that I needed for the combat experiences I went through in my very first MDMA-assisted psychotherapy session.”

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 dou-

ble-blind; and (3) increasing awareness and support for our work by assisting a population with mainstream public recognition.

### Four More Subjects Treated in Boulder Study; Study Size Increased to 23 Subjects

*Ongoing study*

**Location:** Boulder, Colorado

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

**Estimated study budget:** \$711,000

**Already raised:** \$213,000

**Needed to complete this study:** \$498,000

From June 20 through July 6, 2014, the seventh, eighth, ninth, and 10th subjects were treated in our ongoing study of MDMA-assisted psychotherapy for PTSD 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. We have increased the



“Since I completed the MDMA-assisted psychotherapy, the world feels like a friendlier, more loving place.” —Study participant Elizabeth Matthews

size of this study in order to get a better sense of the range of outcomes from different co-therapist teams—important data for calculating the size of our Phase 3 studies—and to compare the effectiveness of different doses of MDMA combined with psychotherapy for treating PTSD.

“I feel so blessed to have been in this study,” reported one female participant in an email. “I feel like I have access to much more of myself and the part of me that is healthy has become stronger.”

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 ability 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.

## Fourth Subject Treated in Israeli Study

*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 was treated in our ongoing Israeli study of MDMA-assisted psychotherapy for chronic, treatment-resistant PTSD. This study will enroll 10 subjects, some of whom will be soldiers with war-related PTSD



*Our Israeli study will compare different doses of MDMA for therapeutic effectiveness.*

ferred by the Israeli Defense Forces. Led by Clinical Investigator Moshe Kotler, M.D., this study is taking place at Beer Yaakov Mental Hospital. Recent and ongoing violence in Israel has called renewed attention to the importance of conducting research for PTSD in Israel. In an email to MAPS Executive Director Rick Doblin, Ph.D., Israeli study coordinator Dafna Bornstein-Lavi reported, "Again I'm under

the table in Beer Yaakov with missiles flying over my head."

the table in Beer Yaakov with missiles flying over my head."

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.

## Canadian Study: IRB Approves Protocol Amendments, MAPS Canada Receives Charity Status

*Study screening subjects*

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

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

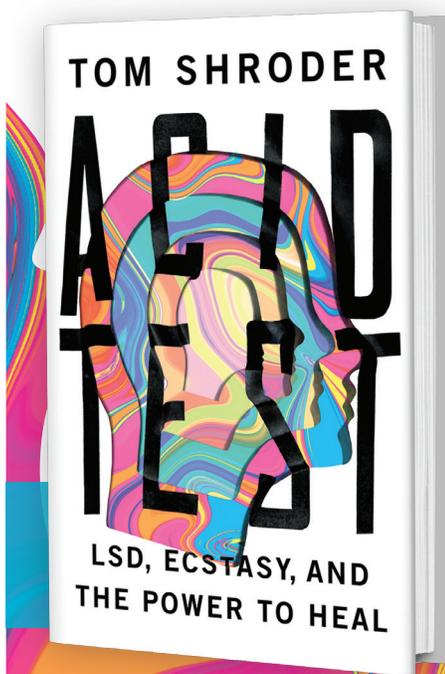
**Estimated study budget:** \$419,000

**Already raised:** \$44,000 raised + \$3,500 raised by partners

**Needed to complete this study:** \$371,500

From August 1–5, 2014, Michael Mithoefer, M.D., and Annie Mithoefer, B.S.N., led a two-and-a-half day training in Vancouver, BC, for the newly added co-investigators in our upcoming Canadian study of MDMA-assisted psychotherapy for PTSD, Donna Dryer, M.D., and Richard Yensen, Ph.D. Also participating in the training were Phil Wolfson, M.D., Julane Andries, Cody Swift, Linnae Ponté, and Shannon Petitt who

**A transformative book about the therapeutic powers of psychedelic drugs, particularly in the treatment of PTSD, and the scientific, political, and legal controversy their use has ignited, by award-winning journalist Tom Shroder.**



"Acid Test is a superb book...What any open-minded reader will feel: In a world of hurt, here is a new version of hope."

– David Finkel, author of *The Good Soldiers*

"Tom Shroder's fascinating, well-researched, and clearly written account of psychedelic history, from the discovery of LSD to the current worldwide renaissance of interest in these remarkable substances and revival of research in this area, is a *tour de force*." – Stanislav Grof, M.D., author of *LSD Psychotherapy*, *The Ultimate Journey*, and *Psychology of the Future*

"Read this riveting and important book. It's the fascinating story of how LSD and MDMA can, with controlled use, bring near-miraculous benefits to people suffering from mental trauma." – Dave Barry

Download an excerpt at [bit.ly/VTcsnF](http://bit.ly/VTcsnF)  
ON SALE SEPTEMBER 9, 2014

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will each be co-conducting experimental sessions in our upcoming study of MDMA-assisted psychotherapy for anxiety associated with advanced-stage illness. On July 22, MAPS Director of Clinical Research Amy Emerson and Clinical Research Scientist Berra Yazar-Klosinski, Ph.D., conducted the study initiation visit via remote teleconference to prepare study staff and trial documentation to begin screening and enrolling subjects. An amended protocol, which includes changes to the MDMA dose condition, was approved by the Institutional Review Board and submitted to Health Canada for review on February 14, and to the U.S. Food and Drug Administration on February 6. 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. Canadian citizens can make a tax-deductible donation to MAPS Canada by sending a check made out to MAPS Canada to MAPS Canada, c/o Mark Haden, 3155 W. 6th Avenue, Vancouver, BC V6K 1X5.

**Therapists Receive MDMA-Assisted Psychotherapy in Training Protocol** *Ongoing study*

**Location:** Charleston, South Carolina  
**Principal Investigator:** Michael Mithoefer, M.D., with co-therapist Annie Mithoefer, B.S.N.  
**Estimated study budget:** \$452,000  
**Already raised:** \$34,000  
**Needed to complete this study:** \$418,000

Between March 24 and April 4, 2014, four additional subjects received MDMA-assisted psychotherapy in our ongoing therapist training study in Charleston, SC. This protocol is a Phase 1 study of the safety and psychological effects of MDMA-assisted psychotherapy in healthy volunteers, with subjects limited to therapists in training to work on a MAPS-sponsored MDMA-assisted psychotherapy study. Two of the subjects enrolled are therapists in our ongoing study in Boulder, Colorado, and two are affiliates of the U.S. Veterans Affairs National Center

for PTSD Research training for a possible collaborative VA/MAPS study, with funding offered from MAPS. During these sessions, an additional night attendant affiliated with the VA was also trained.

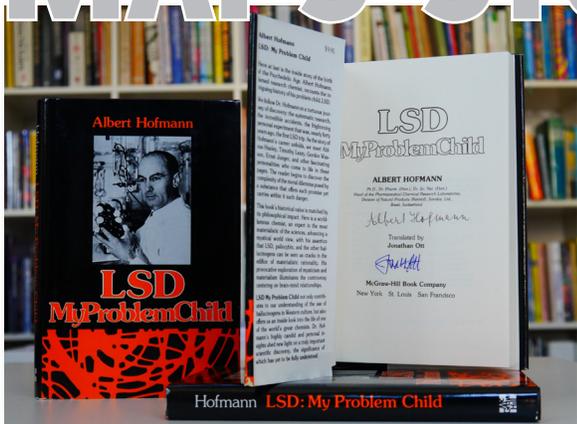
Goals for this study include (1) providing therapists with direct experience of MDMA when taken in a therapeutic context to enhance their ability to conduct effective MDMA-assisted psychotherapy, and (2) collecting additional data on the safety of MDMA-assisted psychotherapy in healthy volunteers taking MDMA in a therapeutic context.

**UK Brain Imaging Study to Explore MDMA's Effects on PTSD without Therapy**

*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 Wises’ 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.

# MAPS STORE



Shop for rare books like this signed, original hardcover edition of *LSD: My Problem Child* by Albert Hofmann, Ph.D.

[maps.org/store](http://maps.org/store)

# MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

## First Three Subjects Enrolled;

## New Website Launched *Ongoing study*

**Location:** Los Angeles, California

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

**Estimated study budget:** \$452,000

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

**Needed to complete this study:** \$418,000

On July 18, 2014, the third subject was enrolled in our new study of MDMA-assisted therapy for social anxiety in adults on the autism spectrum. The first and second subjects were enrolled on May 17 and June 20, respectively. The first treatments are scheduled to take place in August. On March 26, we officially launched **mdma-autism.org**, with background on the goals of the study, plus educational resources about autism, social anxiety, and MDMA-assisted therapy. Based on the known effects of MDMA, as well as individual reports, this exploratory pilot study in 12 subjects will focus on enhancing functional skills and quality of life in autistic adults with social anxiety.



*Principal Investigators Alicia Danforth, Ph.D., and Charles Grob, M.D. in the treatment room.*

“We’re looking for something to facilitate positive, ongoing change,” Principal Investigator Charles Grob, M.D., told the *Los Angeles Daily News* on August 2. “You can’t take an autistic person and make them un-autistic, but you can treat the overwhelming social anxiety.” This study

is being conducted in affiliation with the Los Angeles Biomedical Research Institute.

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.

*“You can’t take an autistic person and make them un-autistic, but you can treat the overwhelming social anxiety.”*

—Principal Investigator Charles Grob, M.D.

# LSD-Assisted Therapy for Anxiety

## LSD Annual Report Submitted to FDA

*Study completed*

**Location:** Solothurn, Switzerland

**Principal Investigator:** Peter Gasser, M.D.

This study is complete and has been fully funded.

On May 16, 2014, the annual report for LSD-assisted psychotherapy for anxiety associated with advanced-stage illness was submitted to the U.S. Food and Drug Administration. The required report provides an overview of the clinical and study methodology issues related to our Swiss LSD-assisted psychotherapy research from February 2013 through February 2014. Our completed study of LSD-assisted psychotherapy was published in the *Journal of Nervous and Mental Disease* on March 4, 2014. That same day, *The New York Times* reported on the study and explained how results like these are helping bring psychedelic research “back into the fold of mainstream psychiatry.”

This was the first study of the therapeutic use of LSD in humans in over 40 years. The double-blind, placebo-controlled pilot study in 12 subjects found statistically significant reductions in trait anxiety following two LSD-assisted psychotherapy sessions. The results also indicate that LSD-assisted psychotherapy can be safely administered in these subjects, and justify further research. Eleven of the 12 subjects had never used LSD previously. “The study was a success in the sense that we did not have any noteworthy adverse effects,” reports Principal Investigator Peter Gasser, M.D. “All participants reported a personal benefit from the treatment, and the effects were stable over time.”

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 in 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](http://maps.org/ayahuasca).

# Ibogaine-Assisted Therapy for Drug Addiction

## 14th and 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.

On April 27, 2014, the 14th and final subject was enrolled in our ongoing observational study of ibogaine-assisted treatment for opioid dependence in New Zealand. Since July 2012, Principal Investigator Geoff Noller, Ph.D., has been collecting follow-up data from subjects undergoing treatment at an independent ibogaine center in New Zealand. Eight participants have finished their long-term follow-up and the study is likely to be completed in Spring 2015. 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.

## Data Entry Completed in Mexico Ibogaine Study *Study completed*

**Location:** Mexico

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

This study is complete and has been fully funded.

On April 11, 2014, data entry was completed for our observational study of ibogaine-assisted therapy for opioid dependence in Mexico. 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.



# Developing MDMA into a prescription medicine



## Phase 1 trials

Small studies in healthy subjects to collect basic safety data.

COMPLETED



## 2014

### Phase 2 trials

Medium-sized studies to collect preliminary data about whether MDMA-assisted psychotherapy helps people with PTSD.

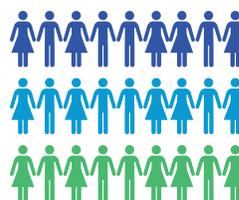
ESTIMATED COMPLETION: SEPTEMBER 2015



### End-of-Phase 2 meeting

MAPS meets with the FDA to come to an agreement on how Phase 3 studies will be conducted.

ESTIMATED DATE: MAY 2016



## 2016

### Phase 3 trials

Large, multi-site studies of hundreds of subjects to gather more information about the safety and efficacy of MDMA-assisted psychotherapy, and to compare the results in different populations.

ESTIMATED COMPLETION: SEPTEMBER 2021



## 2021

### New Drug Application

MAPS files a request with the FDA for MDMA-assisted psychotherapy to be approved for marketing in the United States.

ESTIMATED DECISION: NOVEMBER 2021

# Medical Marijuana

## Petition Receives 100,000 Signatures (and Counting) for Medical Marijuana Research in Arizona

*Study pending*

**Location:** Pending

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

**Estimated study budget:** \$876,000

**Already raised:** \$11,000

**Needed to complete this study:** \$865,000

A petition launched on Change.org by Arizona veteran Ricardo Pereyda has gathered over 105,000 signatures in support of MAPS and Dr. Sue Sisley's efforts to initiate medical marijuana research in Arizona. Launched on July 10, the petition reached 100,000 signatures in just 21 days.

The public outcry against Dr. Sisley's dismissal from the University of Arizona has reached a national audience. On June 27, the University of Arizona notified Dr. Sisley that her university appointments would be terminated as of September 26. On July 28, the University of Arizona expectedly denied Dr. Sisley's appeal for reinstatement, forcing Dr. Sisley to seek a new location for the study. On July 30, the University of Arizona proposed a replacement investigator, ignoring MAPS' repeated public statements that we will stand behind Dr. Sisley wherever the study is ultimately conducted.

MAPS and Dr. Sisley are seeking a new location for the study within Arizona with reinstatement at the University of Arizona no longer a possibility. Multiple universities outside Arizona have already offered to host the study.



*Clinical Investigator Sue Sisley, M.D. is interviewed by CNN's Dr. Sanjay Gupta on July 12, 2014.*

On July 22, Dr. Andrew Weil, founder of the Arizona Center for Integrative Medicine at the University of Arizona, wrote a letter to University of Arizona President Dr. Ann Weaver Hart expressing his support for Dr. Sisley's work.

"Dr. Sisley has passionately chosen her professional obligation to patients over political pressure; she has chosen science over dogma; and has chosen integrity over censorship. This is the type of individual any University should want on their faculty."

Dr. Sisley has been working with MAPS since 2010 to initiate a study of the safety and effectiveness of whole plant marijuana, smoked or vaporized, in 70 U.S. veterans with chronic, treatment-resistant posttraumatic stress disorder (PTSD).



**University Drops Marijuana Researcher**  
by Sanjay Gupta, M.D.  
July 12, 2014



**Vets Rally Behind Pot Researcher Set To Be Fired by the UofA**  
by Steve Krafft  
July 22, 2014



**Pot Researcher Firing Unleashes Rising Veteran Backlash**  
by Bill Briggs  
July 29, 2014



**Pot-for-PTSD Researcher Denied Reinstatement**  
by Patricia Kime  
July 29, 2014



**Reefer Research Madness**  
by Mari Herrerias  
Front page: July 17, 2014



**Medical Marijuana Research Hits Wall of U.S. Law**  
by Serge F. Kovalski  
August 10, 2014