

# mdma research news updates

## **Journal of Psychopharmacology Publishes Paper about MAPS' U.S. MDMA/PTSD Pilot Study**

On July 19, 2010, the Journal of Psychopharmacology published a paper about the MAPS-sponsored U.S. MDMA/PTSD pilot study. The paper is titled "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," and is authored by Michael Mithoefer, M.D., Mark Wagner, Ph.D., Ann Mithoefer, B.S.N., Lisa Jerome, Ph.D., and Rick Doblin, Ph.D. This is cause for major celebration since this is the first paper ever published about a completed study of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD).

Our drug development efforts do not require our research to be published in peer-reviewed scientific journals, but this greatly enhances our public education efforts. Since the publication was released, there have been more than 150 news reports around the globe about the study, some as far away as Pakistan and Australia. Many of these news reports were in major media outlets such as Time.com, New Scientist, the Boston Globe, and Fox News. Media reports also appeared in significant medical resources such as Medscape, WebMD, and Nursing Times. Even Military.com, whose ten million members make it the most active online news source for persons associated with the U.S. military, reported positively about the study. This article will help us gain support for our upcoming study in veterans with war-related PTSD. We have reposted many of these reports on our website at: [www.maps.org/media](http://www.maps.org/media)

The full text of the journal article can be found at: [www.maps.org/mdma/ptsdpaper.pdf](http://www.maps.org/mdma/ptsdpaper.pdf)

## **Long-term Follow-up of U.S. MDMA/PTSD Pilot Study is Complete**

On July 27, 2010, MAPS Deputy Director Valerie Mojeiko and Clinical Research Associate Berra Yazar-Klosinski, Ph.D. completed data collection for the long-term follow-up to our flagship U.S. MDMA-assisted psychotherapy for PTSD study led by Principal Investigator Michael Mithoefer, M.D. and Co-Investigator Ann Mithoefer, B.S.N. in Charleston, SC. Independent rater Mark Wagner, Ph.D., from the College of Medicine, Department of Neurology, collected Clinician-Administered PTSD Scale (CAPS) measurements from 17 of the 20 subjects who received treatment. All 20 subjects filled out a questionnaire developed internally to assess long-term effects. The average length of time between the final experimental treatment session and the follow-up data collection was three and a half years. Preliminary analysis of the results suggests the benefits of the treatment were maintained. MAPS' clinical research volunteers are inputting data into a validated database at the MAPS office in Santa Cruz, CA. After the data is analyzed, Dr. Mithoefer, et al, will write a new paper for submission to a scientific journal around the end of 2010.

## **Mithoefer Receives DEA License for Phase 1 Psychological Effects/Therapist Training Study; License for U.S. MDMA/PTSD Veterans Study Coming Soon**

On August 9, Michael Mithoefer, M.D., received a Schedule I license from the Drug Enforcement Administration (DEA) to administer MDMA in our Phase 1 study to investigate the effects of MDMA on healthy volunteers (limited to therapists enrolled in our therapist-training program). He waited approximately seven months to receive the license. This is a relatively short period compared with 19 months last time he was licensed. The DEA also told Dr. Mithoefer to expect his license for our Veterans study soon, which would be only 4 months from the time of application. The FDA and Institutional Review Board (IRB) approved both of these studies months ago, so we've just been waiting on the DEA's Office of Drug and Chemical Evaluation (ODE) to issue the licenses. The studies are co-lead by Ann Mithoefer, B.S.N.

## **Psychological Effects on Healthy Volunteers/Therapist-Training Study**

On October 3, 2009, the FDA approved our protocol for studying the effects of MDMA on healthy volunteers. On December 21, 2009, the protocol was approved by the IRB. In this study the Mithoefers will administer MDMA to healthy volunteers who are part of our therapist-training program. The goal of this study is two-fold: (1) the study will allow us to learn more about the psychological effects of MDMA-assisted psychotherapy in healthy individuals; and (2) the therapists in our training program will have the opportunity to have a first-hand experience with MDMA, which we suspect will enable them to be better therapists in our future studies.

We are anticipating we will need 20–30 therapist teams in approximately three years for our two large-scale, multi-site, Phase 3 studies. Since the training program can take a long time, we are currently soliciting more applications from qualified therapists interested in conducting clinical research with MAPS. Applications are encouraged from therapists with some or all of the following qualifications: 1) treated patients with PTSD, 2) worked with non-ordinary states of consciousness, and/or 3) conducted clinical research. Applications from male/female teams are highly encouraged. If interested, please contact Berra Yazar-Klosinski, Ph.D. at: [berra@maps.org](mailto:berra@maps.org)

## **Veterans Study**

We are in the process of recruiting subjects for our MDMA-assisted psychotherapy study for veterans with war-related PTSD. We are recruiting subjects primarily from Charleston, SC, to save approximately \$5,600 in travel expenses for each out-of-town subject. We are mostly seeking veterans from the Iraq and Afghanistan wars, but subjects with PTSD from the Vietnam War are eligible. We are trying to recruit equal numbers of men and women.

The study will be our second MDMA/PTSD study to take place in Charleston, SC. Subjects in the Mithoefers' previous study primarily had PTSD brought on by sexual assault, abuse and violent crime, with just two veterans with war-related PTSD. This new study will only enroll veterans, so that we can evaluate if the treatment for war-related PTSD is the same or different than the treatment for the aforementioned causes.

We will also be able to enroll subjects with the previously excluded risk factors of Hepatitis C and controlled hypertension, with additional screening evaluations and safety measures for these subjects.