

Canadian MDMA/PTSD Study Gains Institutional Affiliation

On July 19, 2010, Health Canada informed principal investigator Ingrid Pacey, M.D. that they would accept a letter from the director of the University of Victoria's (UVic) Center for Addiction Research of British Columbia (CARBC) as proof of affiliation with UVic/CARBC. This was a major hurdle in getting the Canadian MDMA/PTSD study started. In Switzerland and the U.S., we have been able to conduct our research without any outside institutional affiliation, but Health Canada required affiliation with a Canadian institute before we could import MDMA for the study. We had obtained approval for the actual protocol from both Health Canada and a Canadian Institutional Review Board (IRB) by March 2009, so this delay for institutional affiliation has been especially prolonged and frustrating. Fortunately, we were not deterred from continuing to strive for full approval for what will become the first psychedelic research study to take place in Canada in almost 40 years.

On July 22, 2010, Tim Stockwell, Ph.D. the Director of CARBC, sent a letter to Health Canada confirming CARBC's support and affiliation with Dr. Pacey. In the letter, Stockwell wrote, "I have reviewed the paper about the results of the [MAPS-sponsored] U.S. MDMA/PTSD study... As a result, I found the results to be promising and think it is of significant scientific importance that a Canadian MDMA/PTSD study is conducted to see if the results can be replicated with a new co-therapist team in a new location."

Switzerland MDMA/PTSD One-Year Follow-Up Study Proceeds

On January 8, 2010, the last of the experimental treatments were completed in the Swiss MDMA/PTSD study. The study, led by Principal Investigator Peter Oehen, M.D., with Co-Investigator Verena Widmer, R.N., treated 12 subjects with chronic, treatment-resistant PTSD. The investigators are currently collecting data for the one-year, long-term follow-up phase of the study. Eight subjects have already completed the long-term follow-up, three subjects have not yet done so, and sadly, one subject has died from an unrelated cause.

On June 14, 2010, at our office in Santa Cruz, CA, volunteer clinical research intern Tim Whalen finished building and validating the database for this study. On July 19, volunteer research intern Audrey Redfield, Ph.D. candidate (Institute of Transpersonal Psychology) finished entering the preliminary data into the database. Katharina Kirchner, M.A., who is assisting our Swiss end-of-life anxiety study, will also assist the investigators of this study with resolving data queries. The final analysis is scheduled for completion in January 2011, after the last measurements are collected from the final subject. We anticipate that the results will be submitted for publication in Spring 2011.

Jordanian MDMA/PTSD Research Team Visited U.S. for Training

From April 7-12, 2010, our Jordanian MDMA/PTSD team, led by Nasser Shuriquie, M.D., participated in a six-day therapist-training program conducted by the Mithoefers in Charleston, SC. The Jordanian team consisted of Tayseer Shawash, Ph.D., Mona Abdulhamid Alnsour, Ph.D., and licensed social worker Rodina Abubaker. The training included a review of our treatment manual in order to learn how to conduct therapy in accordance with our treatment method. A major portion of the training was viewing videos from our first U.S. MDMA/PTSD study. Now that the team has participated in the non-drug training, each team member has the option to experience MDMA by participating in our Phase I study of the psychological effects of MDMA administered in a therapeutic setting to healthy volunteers.

On April 13, 2010, the Jordanian team traveled from Charleston, SC, to San Jose, CA, to attend our conference, Psychedelic Science in the 21st Century, and a post-conference workshop led by Stan Grof, M.D.

MDMA/PTSD Study in Israel Paused; Prospect of Revised Israeli Study Being Investigated

On March 26, 2010, we closed our Israeli MDMA/PTSD study to new subjects in order to provide more training to the therapeutic teams and to our independent rater, to improve our data collection processes, and to make several improvements to the protocol. There were no Serious Adverse Events (SAEs) and all patients had been treated without evidence of harm. We have conducted preliminary analysis of the data from the five subjects who were treated and found self-reports of healing, but quantitative measures did not correspond. Rick will visit Israel in October to discuss procedures for restarting the study with Principal Investigator Moshe Kotler, M.D. Though recruitment had been slow, an official at the Israeli Defense Forces indicated a willingness to refer soldiers with war-related PTSD once we restart the study. We have learned from the Israeli study that we need to provide all of our therapist teams with enhanced training about MDMA-assisted psychotherapy, protocol adherence, and data collection, prior to a study's initiation. We also have learned that we need a single, dedicated research coordinator for each site.

The screenshot shows the WebMD website interface. At the top, there are navigation tabs for Home & News, Health A-Z, Drugs & Supplements, Healthy Living, Eating & Diet, and Parents. Below the navigation is a search bar with the text "WebMD Better Information. Better Health." and a search button. The main content area displays a search result for "Ecstasy May Ease PTSD Symptoms" under the "Mental Health" category. The article title is "Designer Drug Ecstasy Combined With Therapy Successfully Treats Posttraumatic Stress Disorder, Study Says (continued)". The text below the title discusses the findings of a study, mentioning that MDMA appears to be a promising treatment for PTSD symptoms.

The screenshot shows the Fox News website. The main headline is "Study: Ecstasy Can Help Traumatized Soldiers" with a sub-headline "The illegal party drug ecstasy is a potentially safe way of treating patients with post-traumatic stress disorder, according to a study published Monday in the Journal of Psychopharmacology." The article text states that the drug, also known as MDMA, is used to reduce fear among long-term patients and is being tested in a clinical trial. It mentions that the study was funded by the Multidisciplinary Association for Psychedelic Studies (MAPS) in Santa Cruz, California.

The screenshot shows the Military.com website. The main headline is "Study: Ecstasy Treats PTSD" with a sub-headline "The drug Ecstasy shows positive results in the majority of patients when used to treat post-traumatic stress disorder, according to a report coming out Monday in the Journal of Psychopharmacology." The article text mentions that the study, which focuses on 20 patients for whom previous drug and psychotherapy treatments were unsuccessful, is the first of its kind and a stepping stone for a follow-up that will focus entirely on U.S. military veterans.

The screenshot shows the TIME magazine website. The main headline is "Ecstasy Shows Promise in Relieving PTSD" with a sub-headline "As Army Troops Cope with PTSD". The article text discusses the findings of a study, stating that the drug Ecstasy shows promise in relieving PTSD symptoms. It mentions that the study was conducted by researchers at the University of California, San Diego, and the Multidisciplinary Association for Psychedelic Studies (MAPS).