

## Swiss MDMA-assisted Psychotherapy Study: Update on Study Progress



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THE first half of the MAPS-sponsored Swiss MDMA/PTSD study has been completed. So far, six subjects have completed the MDMA-assisted psychotherapy study protocol--which involves twelve subjects who suffer from treatment-resistant posttraumatic stress disorder (PTSD)--and are now in the follow-up phase of the protocol. Subjects will be evaluated several times during the year after their third and last MDMA-assisted session.

Two subjects have dropped out of the study. They both decided to discontinue participation in the study after their first MDMA-assisted sessions. One of the subjects received the full dose of MDMA and felt unable to face and endure reliving the trauma--as well as its emotional sequelae--under the influence of the MDMA. After a disturbing first week following the MDMA experience, he stabilized and eventually returned to his usual state of mind. This demonstrated to us that even in a very difficult situation--which we assessed as an expected adverse event--the MDMA experience can be handled safely.

The other subject who dropped out of the study had received an active placebo. This is a low dose of MDMA (25 milligrams), followed by booster dose of 12.5 milligrams of MDMA two and a half hours later. This subject had to face previously suppressed, traumatic memories during the active placebo session--intensely reliving the trauma, but without receiving specific support from the MDMA. This also proved to be a very trying situation for both the subject, as well as the therapists, and required additional support for the integration of the experience in the following two to three weeks after the subject had decided to drop out.

A few months later we experienced a similar situation with another subject, who also received an active placebo. This situation helped to highlight the question of how the active placebo was "more active than a placebo." This low dose of 25 milligrams is distinctly below the commonly accepted threshold dose of 80 milligrams, and it can actually activate PTSD symptoms in some sensitive subjects. This is an important ques-

tion to look into with regard to developing future MDMA studies.

Two of the subjects who finished the protocol were evaluated as "non-responders." This means that they did not improve significantly after the MDMA-assisted psychotherapy, with the full dose of MDMA, as assessed by the main outcome measure and by the principal investigator's clinical judgment. Both subjects reported that the MDMA-assisted psychotherapy had helped them to some degree, and both felt that additional MDMA sessions could help assist them further on their way to healing from PTSD. We therefore applied for two additional MDMA sessions, with the possibility of administering a twenty percent higher MDMA dose. Final approval from the Swiss health authorities was obtained for this at the end of April 2008.

The first of the "non-responders" has completed the two additional sessions--with the higher MDMA dose of 150 milligrams, followed by a booster dose of 75 milligrams. This was well tolerated in both sessions, and did not lead to any significant rise in blood pressure, temperature, or any increase of typical MDMA side-effects. The follow-up measurements have yet to be performed, but the subject reported feeling further improvement. We have not yet been able to tell if this improvement is due to the additional sessions or the higher dose of MDMA. The other "non-responder" subject will go through the two additional sessions soon.

Along with Michael and Annie Mithoefer, we were able to present the preliminary results of our U.S. and Swiss MDMA/PTSD pilot studies at the World Psychedelic Forum conference in Basel, Switzerland in March 2008. Our work received a lot of positive attention from conference participants--and from the media, which is now helping us to recruit additional subjects for the Swiss study. With the help of the media, we have now received inquiries from another six potential subjects. If recruitment continues to be as promising as it is at the moment, then we hope to be able to finish the study within a year.