

MDMA-Assisted Psychotherapy in the Treatment of Posttraumatic Stress Disorder (PTSD): Eleventh Update on Study Progress



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HERE IS A SUMMARY of where we stand with subject enrollment and completion:

- Sixteen subjects have now completed the double blind protocol (Stage 1). One of these subjects, who received placebo during Stage 1, is now enrolled in the Stage 2 open label protocol in which she will have three MDMA sessions accompanied by nine non-drug therapy sessions for integration. She is now more than halfway through Stage 2.
- Three other subjects are currently enrolled, bringing the total to 19. Two of these subjects are nearing completion of Stage 1. The third is our first subject to be enrolled with war-related PTSD. His trauma occurred during combat in Iraq. He will have his first MDMA or placebo session in early December.
- We are awaiting screening results that are likely to allow us to complete enrollment of the 20th and last subject we need to complete the study.
- On August 28th I wrote to the FDA asking permission to enroll a 21st subject. This would allow us to include an additional Iraq veteran with war-related PTSD, and we asked that the requirement for prior treatment be waived for this subject. We need FDA and IRB permission to deviate from our inclusion criteria that requires all PTSD subjects to be treatment-failures from both drug and non-drug treatments. The request to include a subject who is not a treatment-failure is due to the unfortunate fact that this veteran, like several others with whom we have spoken, has been diagnosed with PTSD but has never been offered individual treatment by the military. As of September 27 the FDA is allowing us to move forward. We have now submitted the same request to our institutional review board (IRB) and expect to hear from them in October. We have screened a veteran who is

interested in participating as the 21st subject if we do get IRB approval. We believe that it would be worthwhile to study this individual in order to provide more experience working with veterans in this Phase 2 study, before we go on to designing a larger, Phase 3 trial that will include veterans. Adding another male subject would also be desirable because only two men have completed the study thus far and one is currently enrolled. In support of this request we sent the FDA and the IRB our outcome and neuropsychological data on the first 15 subjects. The data continues to show promising results in decreasing PTSD symptoms and no evidence of decline in neuropsychological functioning. In fact, there is a non-significant trend toward improvement in neuropsychological test scores after MDMA, which may be related to the lessening of PTSD symptoms that can interfere with cognitive functioning.

International Interest

Although we have not yet completed the study, there has been considerable interest in this research throughout the international academic community. In June, 2007, I presented at the European Conference on Traumatic Stress in Opatija, Croatia, on a panel with Swiss researchers Peter Oehen, MD, and Franz Vollenweider, MD. As *Bulletin* readers know, Peter and his wife Verena are conducting the ongoing MAPS-sponsored Swiss MDMA/PTSD study, while Franz has been an international leader in brain imaging and other Phase 1 human research with MDMA and other psychedelics. Dr. Christian Schopper, who works with Franz Vollenweider, also presented at the conference. They are now doing fascinating work investigating altered psychophysiological parameters in PTSD patients and the possible effects of treatment on these parameters, including treatment with MDMA-assisted therapy administered in Peter's study.

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It was really enjoyable and extremely useful for me and Annie to spend time with these fellow researchers and friends, and to share our experiences and ideas about current and future research. In July, Annie Mithoefer, BSN, my beloved wife and co-therapist/investigator in our study, joined Valerie Mojeko, June May Ruse and Amy Emerson to present¹ on MDMA research at the Women's Visionary Congress, which was co-sponsored by MAPS and the Women's Visionary Council. It was a wonderful conference and another chance to spend time and share ideas with other people interested in psychedelic research. At the time of this writing, I am about to leave for Vienna to speak at the annual Congress of the European College of Neuropsychopharmacology. My talk will be part of a

symposium I will be co-chairing titled, "Drugs facilitation of psychotherapy in anxiety related disorders." I'm looking forward to interesting discussions with other researchers who are exploring the model of using drugs intermittently as catalysts to psychotherapy rather than daily as direct treatment of symptoms. This is a small but growing area of psychiatric research, both with non-psychedelic compounds such as d-cycloserine and with psychedelics such as MDMA, psilocybin and LSD. •

1. This presentation, and others from the Visionary Congress, are available in mp3 format on the MAPS Web site: maps.org/avarchive/wvc_audio.html