

A Pilot Process-Outcome Study of Change During MDMA-Assisted Psychotherapy for the Treatment of PTSD

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This present study will analyze audio and video recordings of therapy sessions from the ongoing MDMA-assisted psychotherapy study in the treatment of clients with post-traumatic stress disorder (PTSD) from the site of MAPS-sponsored research conducted by Michael Mithoefer, M.D. in South Carolina. The dataset that Dr. Mithoefer and MAPS have generously made available provides an invaluable opportunity to study the MDMA-assisted psychotherapeutic process in depth. This pilot project will be conducted at the Norwegian University of Science and Technology (NTNU) in close cooperation with MAPS President Rick Doblin, Ph.D., Dr. Mithoefer, and John Halpern, M.D. The objective of this study is to provide empirical evidence on how MDMA influences behavior in the context of psychotherapy, to understand how MDMA might facilitate the therapeutic process, and finally to empirically inform the development of a standardized treatment manual for MDMA-assisted psychotherapy.

Defenses are coping strategies, often unconscious, that diffuse conflict and minimize stress. As an example, in the less adaptive defensive behavior of dissociation, which we expect to be frequent among the PTSD patients, both the uncomfortable idea and the associated emotion are kept out of awareness but are expressed by an alteration in consciousness. The subject usually comments that something “weird” or unusual takes place at such times. In the therapy session dissociation might be occurring when the client frequently expresses clouding of consciousness in response to talking about emotional trauma, e.g. “I suddenly feel confused and can’t think.”

A person’s characteristic defensive behaviors are more enduring and trait-like than many of the more state- or mood-dependent psychiatric self-report tests. Longitudinal studies have shown that people continue to use the same pattern of defenses over decades. Thus any change in defensive behavior during treatment is likely to indicate lasting change in a PTSD patient beyond the remission of the current episode of distress.

Experiential avoidance occurs when a person is unwilling to remain in contact with particular experiences in the form of bodily sensations, emotions, thoughts, memories, or behavioral dispositions. Experiential avoidance mani-

fest itself in the therapy session as defensive behavior. The converse of experiential avoidance is emotional experiencing, something that MDMA is reported to increase. Experiential avoidance is recognized as an important concept in all the major systems of psychotherapy. Exposure to emotional experiences or memories is a central therapeutic intervention, particularly for anxiety disorders and PTSD.

In this pilot study we will quantitatively measure the frequency and relative adaptivity of defensive behavior and the degree of emotional experiencing. Defensive behavior and emotional experiencing are closely related and have previously been linked to therapy outcome. Change in defensive behavior is also regularly found to predict symptomatic change for anxiety, depressive, and personality disorders.

Anecdotal accounts, reports of subjective effects of MDMA in Phase I studies, and results of neuropsychological studies all suggest that MDMA belongs to a new class of psychoactive agents called *entactogens* that produce feelings of closeness to others, empathy, well-being, and insightfulness, with little perceived loss of control, and increased recall of emotional material. These findings are consistent with reports of decreased defensive behavior and increased emotional experiencing in previous accounts of MDMA-assisted psychotherapy.

The Defense Mechanism Rating Scales (DMRS), 5th edition, developed by Christopher Perry, M.D. at Cambridge Hospital (1990) provides an observer-rated system for measuring defensive behavior. The DMRS is a manual for quantitatively identifying the use of 28 specific defensive behaviors, similar to the proposed Defense Axis in Appendix B of the Diagnostic and Statistical Manual IV by the American Psychiatric Association, 1994.

The DMRS groups defenses into a hierarchical structure of seven levels (mature, obsessional, other neurotic, minor image-distorting, disavowal, major image distorting, and action defenses) that has been consistently empirically validated. Overall defensive functioning (ODF) is a weighted average of the observed defenses, ranging from 1 (least adaptive) to 7 (most adaptive). Trained coders can achieve high reliability. Inter-rater reliability for the ODF has yielded a high median intra-class R of .875 (range from

.83 to .90) across seven studies. One of the investigators of this study has had extensive experience in the identification of defensive behavior, has received supervision by the author of the DMRS scale at the Austin Riggs Center, and is a co-investigator at the current defense mechanism project at the Harvard Study of Adult Development. When using the DMRS, coders individually mark each defense with a timecode, a clinical vignette, and a reason for each rating.

Of relevance for the current study, the DMRS scale also includes defensive behavior characteristic of highly adaptive and optimally functioning people. Some highly adaptive defenses we expect to be more frequent during the MDMA experimental sessions and the sessions following include: humor, sublimation, anticipation, self-observation, self-assertion, and affiliation. We expect the change toward a more adaptive defensive style under and following the MDMA experimental sessions will be accompanied by more intense, better modulated, and more integrated emotional expression.

The emotional experiencing sub-scale of the Assimilation of Therapeutic Objectives Scale (ATOS), developed by Leigh McCullough, Ph.D. at the Harvard Psychotherapy Research Program, provides a system for quantitatively measuring experiential avoidance. In the present study, the peak expression of anger and sadness in each ten minute segment from the therapy sessions will be rated, according to the ATOS, on a 1–100 scale based on the intensity, duration, and modulation of the emotional expression. The ATOS has undergone five reliability studies and has been clarified and improved with each successive examination.

We plan to analyze at least 40 minutes from each of sessions 3, 5, 8, 11, and 14 from all of the 20 subjects (for a total of 100 sessions) across the range of outcomes in both the MDMA and the placebo conditions. Sessions 5 and 11 are the experimental (MDMA or placebo) sessions. Eight to ten graduate students in the clinical program at the Norwegian University of Science and Technology will participate in the coding process.

We expect that the MDMA will facilitate a bearable re-experiencing of the trauma while increasing the relative adaptivity of defensive behaviors and enabling a more effective emotional processing of the trauma. Based on the previous empirical evidence from multidisciplinary research into MDMA and clinical research into experiential avoidance, we will examine the role of defensive behavior and emotional experiencing with the following main hypotheses:

1. Overall Defensive Functioning (ODF) score will increase to a more adaptive level from pre-treatment to therapy session 14, in both the MDMA and the placebo therapy conditions.
2. There will be both a higher relative ODF score and a higher degree of emotional experiencing in the MDMA compared to the placebo condition.
3. The change in ODF and emotional experiencing separately and in combination will predict outcome in both conditions, both at the end of treatment and at the three month follow-up.

This pilot study is unique since it is the first well-controlled study of how MDMA influences behavior within psychotherapy. It will evaluate the degree to which MDMA facilitates emotional experiencing through a relative increase in Overall Defensive Functioning, and it will examine if this predicts outcome. We are well aware of the limitations of our quantitative approach, so we hope to be able to supplement our results with illustrative and in-depth qualitative case studies.

Our long-term goal is to extend this study to the other MDMA-assisted studies that are starting up through MAPS and also to examine the effects of specific therapist interventions on specific defense mechanisms. Since defensive behavior is discrete and relatively frequent within therapy sessions (about 20–80 defensive behaviors are recorded in each session), they are well suited for quantitative studies of interactions with therapist interventions. Our hope is that, in cooperation with other psychotherapy process researchers, we can examine the effects of specific psychotherapy interventions before and after the defensive behaviors, and before and after the peaks of emotional experiencing, to see whether they lead to emotional processing. For instance, should therapists ignore, clarify, confront or validate defenses? By identifying interventions that lead to emotional experiencing and more adaptive overall defensive functioning we can supplement clinical experience and develop empirically informed training tools, treatment manuals, and systems for monitoring therapist adherence and competence for MDMA-assisted psychotherapy, and thus pave the way for well-controlled larger multi-site studies down the road.

We are grateful that MAPS has provided \$5000 for this pilot study to fund graduate student coders and project acquisition. However we are in urgent need of further support in this initial stage of the study. Please contact MAPS if you would like to contribute funds toward this project.