MDMA-Assisted Psychotherapy for the Treatment of Posttraumatic Stress Disorder

A Revised Teaching Manual Draft
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1.0 *INTRODUCTION*

1.1 Background

The Multidisciplinary Association for Psychedelic Studies (MAPS) is sponsoring a series of Phase II clinical trials to explore the potential risks and benefits of MDMA-assisted psychotherapy in treatment-resistant posttraumatic stress disorder (PTSD) participants. This manual provides researchers with a method of MDMA-assisted psychotherapy to be used in conducting these trials.

3, 4- methylenedioxy – N – methylamphetamine (MDMA) produces an experience that has been described in terms of "inhibiting the subjective fear response to an emotional threat" (Greer & Tolbert, 1998, p. 371) and increasing the range of positive emotions toward self and others (Adamson, 1985; Cami et al, 2000; Grinspoon and Bakalar, 1986). Though promising, reports of the benefits of MDMA-assisted psychotherapy remain anecdotal (Adamson, 1985; d'Otalora, http://www.maps.org/research/mdma/moaccount.html; Gasser 1994; Greer and Tolbert 1998; Metzner and Adamson, 1988, 2001; Naranjo, 2001; Styk, 2001; Wolfson 1986) or based on an uncontrolled study (Greer and Tolbert 1986).

PTSD is clearly a serious public health problem that causes significant suffering and contributes substantially to health care costs (Foa, Keane, & Friedman, 2003). A complex biopsychosocial condition, PTSD is characterized by a combination of three types of symptoms: fear and hyperarousal, intrusive re-experiencing of traumatic experiences, and numbing and withdrawal. A combined treatment of MDMA and psychotherapy may be ideal for treating PTSD because MDMA can attenuate the fear response and decrease defensiveness without blocking access to memories or preventing a deep and genuine experience of emotion (Metzner, et al 1988,). Participants are able to experience and express fear, anger, and grief with less likelihood of feeling overwhelmed by these emotions. MDMA seems to engender an awareness that such feelings arise as an important part of the therapeutic process. In addition, feelings of empathy, love and deep appreciation often emerge, along with a clearer perspective of the trauma as a past event and with a heightened awareness of the support and safety that exist in the present. Hence, the goal of MDMA-assisted psychotherapy in treating PTSD is to enable the participant to restructure his/her intrapsychic realities and develop a wider behavioral and emotional repertoire with which to respond to anxiogenic stimuli.

PTSD is a disorder for which there are, to date, only two similarly acting FDA-approved medications, and about which there are still many unanswered questions regarding psychological and pharmacological interventions (Montgomery & Beck 1999). One pharmacological approach has been to seek drugs that will directly decrease symptoms and/or reduce the adverse effects of trauma and chronic stress on the brain. Another potential approach, as in the case of MDMA-assisted psychotherapy, is to develop drugs and/or psychotherapeutic treatments that indirectly interrupt the destructive neurobiological changes associated with PTSD by decreasing or eliminating the stress reactions to triggers and the chronic hyperarousal of PTSD. In this case the biological and the psychotherapeutic approaches act synergistically. The specific mechanisms involved are not completely understood, but MDMA is known to significantly decrease activity in the left amygdala (Gamma, et al 2000). This action is compatible with its reported reduction

in fear or defensiveness, and contrasts with the stimulation of the amygdala observed in animal models of conditioned fear, a state similar to PTSD (Charney 1997, Davis 1999). Thus, a possible result of MDMA-assisted psychotherapy is to interrupt the stress-induced neurochemical abnormalities produced by the condition. This reduction in stress-induced activation of the amygdale may be supported and enhanced by interacting with the therapists during and after the MDMA experience.

Thus the effects of MDMA are distinct from and go well beyond those of anti-anxiety drugs such as benzodiazepines. MDMA-assisted psychotherapy involves using the medicine in the context of a therapeutic session, instead of taking a daily dose of the medicine (as in the case of the benzodiazepines). Furthermore, there is no evidence that MDMA creates a physical dependency, as do the benzodiazepines.

In November 2004 the American Psychiatric Association (APA) published Practice Guidelines for the treatment of PTSD and noted: "there is a paucity of high-quality evidence-based studies of interventions for patients with treatment-resistant PTSD…." (Urasano et al). The APA practice guidelines state that the goals of PTSD treatment "include reducing the severity of … symptoms… (by) improving adaptive functioning and restoring a psychological sense of safety and trust, limiting the generalization of the danger experienced as a result of the traumatic situation(s) and protecting against relapse." Appendix A gives more detail on the therapeutic approaches recommended by the APA and compares these modalities with MDMA-assisted treatment of PTSD. As shown by the comparison, the nondirective approach of MDMA-assisted therapy often leads to the spontaneous occurrence of many of the kinds of experiences that are more directly elicited and thought to be therapeutically important in these other approaches.

1.2 Goals of this Manual

This manual provides the researcher with a method of MDMA-assisted psychotherapy to be used in conducting a scientific study of its potential risks and benefits in order to develop and test an investigational form of drug-assisted psychotherapy. Because this is research, by definition, the therapists in the studies are also investigators. In this document we refer to the experimental participants as "participants" rather than "patients."

The treatment protocol involves 13-14 sessions. Non-drug sessions range from 1 to 1.5 hours of interaction with the co-therapists, and MDMA-assisted therapy sessions range from 6 to 8 hours of interaction with the team of co-therapists. For research purposes this manual includes two additional sessions in which a baseline neuropsychological assessment and a diagnostic clinical interview are conducted. The treatment team consists of two primary therapists, preferably one female and one male.

The specific goals of this manual are 1) to delineate the core elements of MDMA-assisted psychotherapy in the psychotherapeutic treatment of PTSD and, 2) to educate therapists about the phases and steps involved in conducting this therapy. This manual is to be used as the basis for the controlled clinical trials that are required to standardize and validate this treatment approach. It outlines the inclusion and exclusion criteria, the assessment protocol and other specifics of our current research study of MDMA-assisted therapy for PTSD.

This manual one is not intended to define all interactions that occur in the therapy. Instead, it provides a structure within which the therapy is expected to include all the essential elements described in the manual and adherence measures, to avoid interactions that are proscribed by the manual and adherence measures, and to also allow individual therapist teams to include therapeutic interventions based on their own training, experience, intuition and clinical judgment, provided the interventions are compatible with the tenor of the method and appropriate to the participant's unfolding experience.

The basic premise of this treatment approach is that the medicine, MDMA, is not in itself the therapy but is rather a powerful tool for both clinician and participant. MDMA can induce a heightened state of empathic rapport and facilitate the therapeutic process (Grob & Poland, 1997). The benefits of increased rapport combined with a willingness to explore past trauma in an atmosphere of hope, reassurance, and encouragement enable the subject to develop alternative cognitive structures and change the meaning of his/her suffering. These effects in combination with the decreased fear response induced by MDMA are hypothesized to enhance the rate of recovery from PTSD. Many psychotherapies for PTSD involve the induction and extinction of abnormal autonomic responses through revisiting traumatic experiences in psychotherapy with an appropriate level of emotional engagement (Foa et al., 2009). To be effective, exposure must be accompanied by a degree of emotional engagement or "fear activation" while avoiding dissociation or overwhelming emotion (Foa et al., 2007). This has been referred to as working within the "optimal arousal zone" or "window of tolerance" (Wilbarger and Wilbarger, 1997; Siegel, 1999; Ogden et al. 2006). Frequently treatment is ineffective because patients are unable to tolerate feelings associated with revisiting the trauma, or because emotional numbing during exposure to traumatic memories precludes a level of engagement necessary for extinction (Jaycox and Foa, 1999). MDMA appears to temporarily reduce fear and increase interpersonal trust, without clouding the sensorium or inhibiting access to emotions. PTSD patients are prone to extremes of emotional numbing or overwhelming anxiety, and often have a narrow window between thresholds of under and over-arousal (Ogden and Pain, 2006). MDMA may catalyze therapeutic exposure by widening this window and allowing patients to stay emotionally engaged without being overwhelmed by anxiety while revisiting traumatic experiences.

The successful use of MDMA in therapy depends on "the sensitivity and talent of the therapist who employs (it)" (Grinspoon & Doblin, 2001, p. 693). The therapist carefully works with the participant to establish a sense of safety, trust, and openness, and to emphasize the necessity of trusting the wisdom of the participant's innate capacity to heal the wounds of trauma. As Greer and Tolbert (1998) note, "The relationship should be oriented toward a general healing for the client, who should feel safe enough in the therapists' presence to open fully to new and challenging experiences" (p. 372). This requires that the therapists carefully set the parameters of treatment and prepare the participant for the process before each MDMA-assisted session. The post-session integrative aspect of the therapy aims to concretize the lessons gained in a non-ordinary state of consciousness and so improve the participant's level of functioning in everyday life. These strategies are introduced at the beginning of therapy and emphasized throughout the process.

Note: Throughout the Manual quotes from study participants are in italics.

2.0 CONDITIONS FOR THE USE OF MDMA – ASSISTED PSYCHOTHERAPY

This section of the manual addresses the conditions necessary for MDMA-assisted psychotherapy. MDMA can have profound emotional and physical effects. Its use requires thorough assessment and preparation of the participant. The participant must commit to: comply with dietary and drug restrictions, attend all preparatory therapy and follow-up sessions, and complete the evaluation instruments.

The therapists commit to: providing adequate preparation time during non-drug sessions; giving careful attention to the set and setting during MDMA sessions (Metzner, et al, 1988; 2001); and ensuring adequate follow-up therapy. The therapists remain with the participant during MDMA-assisted sessions until the acute emotional and physical effects of the MDMA have worn off, as determined by examining physiological signs, degree of self-reported distress (Subjective Units of Distress, SUDS, must be at or below baseline) and by clinical judgment concerning stability. The therapists and participant must all agree that the participant is in a safe and stable condition at the end of the therapy session. The participant commits to an overnight stay in the treatment facility, accompanied by an attendant, and he or she must also agree to find a friend, relative or partner who will provide transport home from the psychotherapy session following the MDMA session. The participant also commits to daily telephone contact with the therapists for a week after each MDMA session. The therapists commit to being available for phone contact 24 hours a day between sessions.

2.1 Prerequisites and Contraindications

The first prerequisite for undergoing MDMA-assisted psychotherapy for PTSD is that the participant must meet the DSM – IV criteria for current PTSD. In early pilot studies, a CAPS score of 50 or above is used as an indicator of PTSD of at least moderate severity. The participant must have experienced at least one unsuccessful attempt at treatment with medications (including an SSRI or SNRI) and/or psychotherapy. In early and pilot research studies, only individuals who continue to meet the diagnostic criteria for PTSD after receiving an SSRI for three months or more and after receiving at least 12 sessions of psychotherapy for six months or more were enrolled in the study. The participant must also have a medical history and physical examination to rule out any medical condition that would contraindicate this form of therapy. These conditions may include major cardiovascular, cerebrovascular, or other medical disorders judged by the examining physician or the principal investigator (PI) to be significant (see below for other medical exclusionary criteria).

People suffering from PTSD experience a high co-morbidity rate of other anxiety and mood disorders (Brady, et al, 1994; Faustman & White, 1989). Within the mood disorder spectrum, those who meet the criteria for Bipolar Affective Disorder Type 1 must be excluded from this therapeutic approach (see exclusion criteria); however those meeting the criteria for other mood and anxiety disorders are eligible to participate.

The next prerequisite is that the participant refrain from taking any psychiatric medications from the outset of therapy until two months following the final MDMA session. If a participant is currently taking psychiatric medication, then agreement to suspend medication must be approved by the participant's

prescribing physician, and this discontinuation must be monitored appropriately. Generally the participant should be medication-free for at least 5 times a particular drug's half life. Careful clinical judgment must be used to exclude any participant who cannot safely discontinue medication.

The third prerequisite is that for one week preceding each MDMA session the participant refrain from taking the following:

a.) Herbal supplements
b.) Nonprescription medications (with the exception of non-steroidal anti-inflammatory drugs or acetaminophen), unless with prior approval of the treating therapist.
c.) Prescription medications (except for birth control pills, thyroid hormones, other hormone replacement, or other medications approved by the physician supervising the MDMA-assisted therapy). If the participant is taking any prescription medications to be discontinued before the session, their personal physician must give permission.

It is also necessary that the participant refrain from taking anything by mouth except alcohol-free liquids after 12 A.M. the evening before an MDMA-assisted session. The participant must also agree to refrain from using any psychoactive drug other than caffeine or nicotine for 24 hours following the session. These restrictions are carefully reviewed with the participant during and after presentation and signing of the Informed Consent.

There are several categories of prospective participants for whom this therapy is contraindicated, including:

a.) Pregnant or nursing women and women who are of child-bearing potential and not practicing an effective means of birth control.
b.) Participants with a history of primary psychotic disorder or bipolar affective disorder type 1.
c.) Participants with an eating disorder with active purging.
d.) Participants with substance abuse or dependency within the past three months.
e.) Participants who present a suicide risk or who are at risk for hospitalization.
f.) Participants who appear to be at risk for victimization or self-harm. Participants who have engaged in self-harm within 6 months or have made suicide attempts within 6 months of this study.
g.) Participants who do not meet the appropriate medical criteria.

In all early or pilot research studies, individuals with dissociative identity disorder and borderline personality disorder are to be excluded from treatment. However, in later research studies, individuals with these disorders may be eligible for treatment, if they can remain stable when unmedicated and if careful clinical judgment is exercised and additional follow-up support is available.

The above information is gathered during the initial evaluation and introductory sessions. The therapist must carefully follow these guidelines and document compliance with therapy-related guidelines and restrictions. Establishing this context for treatment provides the participant with a sense of safety and comfort and also ensures adequate preparation of the set and setting for therapy. It is an important opportunity for the therapists to facilitate development of a therapeutic alliance, identify the participant's concerns, respond to questions and prepare the participant for MDMA-assisted treatment sessions.

2.1 Assessment Protocol – Baseline Measures

2.1.1 Assessment Battery (Two Weeks Before Treatment)

Diagnosis is made by means of structured interviews to enhance diagnostic reliability and interview validity. An assessment battery to establish baseline measures of PTSD symptomatology, mood state and global functioning is performed approximately two weeks before the onset of treatment and consists of the following diagnostic instruments:

1. Structured Clinical Interview for the DSM-IV: SCID-IV (First et al, 1994). The SCID is a semi-structured interview that permits accurate diagnosis of life-time and current psychiatric disorders using DSM-IV criteria.

2. Clinician-Administered PTSD Scale: CAPS (Blake et al, 1990). The CAPS is a structured interview designed specifically for the assessment of PTSD. It assesses the seventeen symptoms of PTSD along with eight associated features. Forms 1 and 2 will be given to measure current and lifetime PTSD diagnosis (CAPS-1); CAPS-2 allows for the assessment of PTSD symptom status over time.

3. Other measures may be added according to the specific protocol. For example: The Impact of Events Scale: IES (Horowitz et al, 1979). The IES is a 15-item self-report scale designed to measure the extent to which a given stressful life event produces subjective distress, The Symptom Checklist 90: This is a standardized instrument used to measure subjective feeling states, The NEO Personality Inventory: (Piedmont, 1998). This model of personality structure provides insight as to the internal psychological forces that have resulted in Axis I psychopathology, The Beck Depression Inventory (BDI-II), The Global Assessment of Functioning (GAF) etc..

2.1.2 Additional Assessments (During and Post-Treatment)

Several additional assessment measures may be used during and post-treatment, as outlined below:

4. Working Alliance Inventory: WAI (Hovrath and Greenburg, 1989). The WAI is a 36-item self-report scale designed to assess the quality of the working alliance existing between participant and therapist. This measure will be administered once during the second introductory session and again during the follow-up therapy session occurring after each MDMA session.

5. Subjective Units of Distress: SUDS. This is a standardized subjective rating scale by which a subject can quickly rate comfort level throughout the session. It will be used to assess subjective distress during the course of each MDMA-assisted session

6. The Repeatable Battery for the Assessment of Neuropsychological Status: RBANS (Randolph, 1997). This assessment measures change in a participant's neuropsychological status over time. The

domains assessed include: Immediate Memory, Visuospatial/Constructional, Language, Attention, and Delayed Memory.

7. The Paced Auditory Serial Addition Task: PASAT (Roman et al 1991). This assessment is a sensitive measure of information-processing speed and efficiency, concentration skills, and immediate memory.

8. Rey-Osterrieth Complex Figure: (Mitrushina et al, 1999). This measures visuoperceptual skills, spatial organizational skills, and memory.

In the first MDMA/PTSD study measures 6, 7 and 8 were administered at baseline and again after both MDMA-assisted sessions to measure neurocognitive function in specific domains selected to assess memory and attention, two areas found to be affected by regular Ecstasy use (Fox et al, 2001; Gouzoulis-Mayfrank et al, 2000; Morgan, 1999; Rodgers, 2000).

3.0: PREPARATION FOR EXPERIMENTAL THERAPY SESSIONS

3.1 Therapist Foundation

In addition to standard training in the psychotherapeutic treatment of PTSD, the therapists should understand the qualities of MDMA that enhance and intensify the therapeutic experience, including the "apparent facility in inducing heightened states of empathic rapport" (Grob et al, 1996, p. 103). Therapists are likely to substantially benefit from personal experience with non-ordinary states of consciousness. Ideally this includes personal experience with MDMA in a therapeutic setting. If this is not possible, a series of Holotropic Breathwork™ sessions (a non-drug method that activates a similar therapeutic process) would also be beneficial (Grof, 2000).

This personal experience is important because it:

- Increases the therapist's level of comfort with intense emotional experience and its expression.
- Provides first-hand validation of and trust in the intelligence of the therapeutic process as it arises from an individual's psyche.
- Familiarizes the therapist with the terrain and flavor of non-ordinary states of consciousness. This can be invaluable to the therapist's effort to understand and empathize with the participant's experience. It may especially help therapists to identify features of the experience that might be most helpful, and to be comfortable supporting people during times when the process is difficult and unsettling.
- Provides the therapist with an intrapersonal working knowledge of the integration process related to this therapeutic approach.
- Enhances the credibility of the therapist – the participant's sense of security and treatment alliance deepens with understanding that the therapist has had a similar kind of experience.

The therapists should develop an orientation toward following and supporting whatever course the participant's own emotional process takes, rather than trying to impose upon it some predetermined course or outcome. The therapists are charged with maintaining a high level of empathic presence throughout the therapy session. This empathic presence helps the participant stay with his/her inner process when it is important to do so and also enhances the therapists' ability to appropriately respond to the participant's non-verbal behavior, have a dialogue with the participant when necessary, and offer physical touch when indicated.

It is important for the therapists to be prepared for the fact that, during experimental sessions, participants may have transpersonal experiences (Grof 2000). These may include unusual sensations in the body, perinatal and spiritual experiences as well as other experiences that appear to transcend conventional Western concepts of consciousness and its relationship to the physical body. Depending on the therapists' own background and belief system the content of these experiences may present a challenge to their understanding. The therapists are not required to understand or even have an opinion about the ontological status of these experiences, but it is essential that they accept them as real and important aspects of the participant's experience and convey respect for and openness toward the participant's view of them, without dismissing or pathologizing any experience based on its unusual content.

Another area in which therapists may have diverse points of view and approaches has to do with multiplicity of the psyche and dissociation. Dissociation is a common or even universal feature of PTSD and, although people with Dissociative Identity Disorder have been excluded from early studies of MDMA-assisted therapy, many participants have exhibited lesser degrees of dissociation during their MDMA or non-drug psychotherapy sessions. It is important that therapists are familiar and comfortable with working with these situations. In the DSM-IV multiplicity is discussed only as part of pathological dissociation, however in MDMA-assisted psychotherapy it is important that therapists understand that multiplicity is also a normal phenomenon in individuals without dissociation. This fact and therapeutic methods for working with have been described in detail by Roberto Assigioli [Psychosynthesis], Richard Schwartz [Internal Family Systems Therapy (IFS)] and others. (references here). While training in one of these methods is not a requirement for therapists, familiarity with them, particularly IFS can be very valuable, because participants may talk about their inner experience in terms of awareness of different parts of their psyche. It is essential that such experiences not be pathologized by the therapists.

3.2 Stage One: Establishing a Therapeutic Alliance, Gathering Information, Participant Orientation

The preparation phase of therapy involves three stages: establishing a therapeutic alliance; creating a safe psychological and physical space; and participant preparation. While the content and process of each of these stages is woven in each interaction with the participant, the foundation is laid during the three ninety-minute introductory sessions with the therapists. The term "experimental session" is used in this manual to refer to either MDMA-assisted sessions with full, medium or low dose MDMA or inactive placebo sessions, as determined by the particular research protocol being followed.

3.2.1 Establishing a Therapeutic Alliance

The first stage of the preparation phase provides adequate time in non-drug therapy sessions to establish a safe and positive therapeutic alliance, which is an absolute prerequisite for treatment (Johnson, 1996, Johnson et al., 2008). The participant must feel assured that his/her well-being will be attended to with utmost care in order to gain the most benefit from the MDMA session. The therapists introduce themselves and explain how they became interested in this work and describe as their experience in treating PTSD. This reinforces the therapists' experience and commitment to support the participant throughout the process. Greer and Tolbert (1998) note that self-disclosure on the part of the therapist creates a context for collaboration, intimacy, and trust. It also can give the participant a sense of shared identification with the therapists, which can increase personal comfort as the participant enters a state of heightened vulnerability.

Participant: *"With all the PTSD that's got to be out there … I was so afraid to admit how I feel. I felt like I was the only one."*

Therapist: "You are not in that position any more."

Participant: *"No one really listened to how I was feeling. They just wanted to give me another prescription."*

Therapist: "Anything else that comes up for you, thoughts … feelings?"

Participant: *"I've been feeling nervous, anxious, not sleeping well. I know a part of it is being free of the antidepressant. I am agitated, short-tempered."* (Sniffing)

Therapist: "Let's practice the abdominal breathing. This is one method to help you be with your feelings .Part of the approach we're going to use in the sessions is to support you in staying present with whatever feelings come up. It's a paradox that breathing into feelings rather than moving away from them can lead to healing, moving through them, instead of away."

Participant: (Inhalation/ Exhalation)

Therapist: "In some ways the process begins before we actually begin. It's begins ahead of time, as you set the intention to do it. And as you get closer, these feelings are natural. It is not easy. In some ways your psyche is already making use of what you decided to do."

Participant: *"It helps to understand. I am willing to try anything. Hell, I was in therapy every week for a whole year and never really addressed my symptoms."*

3.2.2 Gathering Information

The therapists ask open-ended questions, provide some feedback to the participant about the results of his/her psychological testing and medical evaluation, and encourage the participant to share what he/she believes is personally significant information.

Therapist: "We don't have all the results from your tests, but we spoke with the doctor and all the results so far tell us that you meet the criteria for this treatment. Let's start with any thoughts or questions that may have come up for you."

Participant: *"The session with Dr. Wagner was good. I can see where it is starting to open up a can of worms. The process is already starting with me. Part of me is very excited, and part is very skeptical, like 'uh oh, is this really what I need to be focusing on.' There was a question on the PTSD scale where Dr. Wagner asked if I had dreams. I said 'no,' then it dawned on me. I don't have dreams about my father actually doing whatever he did, but I have dreams about my mother. She never really worried about what he was doing or how he was abusing us or how he was abusing her. She would worry whether the fallout from Chernobyl got into my Mars candy bar and I got nuclear poisoning. She worries about things that are completely out of control. And she goes on and on in our conversations and we are "close." But I realize that I do dream about her. Just the other night I had a dream about how we were talking on the phone. And in this particular dream the light was white and she went into her normal, 'I'm worried about this, I'm worried about where you are living', without actually helping, cuz she wants to help, but my*

father won't let her help even though she makes all the money. And, um, the phone just came unplugged from the wall and I thought it was really interesting that … and then my first instinct was to plug it back in and call her back. And so I started thinking about that because it was right after the testing."

Therapist: "MMMmmm"

Participant: *"And I said (to Dr. Wagner), 'No, I don't have dreams about this and then how I continuously have dreams about her. He's not in the dreams, but she's in the dreams. And how she's not this kind, compassionate mother like she used to be. How she's changed. It's really interesting. I've tried to resolve my anger towards her. And I think it is harder now that I have a child. To think, 'I don't care who you are or how much I love you or how dependent I am on you, I'm going to take my child away from you. You know I wouldn't even let my child in the room with people who even think like that, except that I do let him go with my father knowing … so it's kind of a … so it's interesting that the process is already starting to work even though I haven't had any therapy."* (Laughs)

Therapist: "Well that is typical."

Therapist: "Yes, the screening does tend to stir things up for a lot of people. And also as you were saying, the intention to do this work also sets your psyche in motion about it, from the time that you decide that you are going to do it. I think it is an important question that you bring up … 'Is this the time that I can be focusing on this or do I need to focus on day to day life?' What's your feeling about that now?

Participant: *"Well, I vacillate, but I figure that this is an opportunity for my day-to-day life to get better … or not. At least it's an opportunity that doesn't come across your path every day. I am a school counselor by profession; I'm in no state to actually be a school counselor. So I consciously or subconsciously cannot go and pursue jobs because I know there are things I need to work on my self. So I think this is the time to do it … even if it is hard."*

The therapists guide these interviews to gather information about the participant's present symptoms, event(s) that caused the PTSD, previous treatment and outcome, other psychiatric history, and medical, social and family history.

Therapist: "We'd like to talk in more detail about the sessions and we'd also like to hear more detail about your history and the trauma in particular. We can do that in any order you want. Do you feel like talking more about your self and your trauma now or would you like to hear about the sessions?"

The therapists also discuss with the participant his/her previous experiences with MDMA, psychedelic drug use, or other non-ordinary states of consciousness. During this interaction the therapists must collect enough information for a sound understanding of the participant. This interaction is also an opportunity for the therapists to address any concerns the participant may have about his/her treatment.

3.2.3 Participant Orientation

In this stage, the therapists orient the participant to the therapeutic process. The therapists talk about the scope of the MDMA session. They discuss the participant's expectations, motivations, and the ability of the participant's innate capacity to heal the wounds of the trauma. The

therapists may liken the effect of the MDMA to an opportunity to step inside a safe container in which it will be easier to remain present with his/her intrapsychic material. The participant should be encouraged to cultivate an attitude of trust in the wisdom and timing of the inner healing process that is catalyzed by this approach.

The therapists encourage an attitude of openness toward the MDMA-facilitated experience in whatever way it unfolds. The therapists explain that often the deepest, most effective healing experiences take a course that is quite different from the one predicted by the participant's rational mind. Participants are encouraged to welcome difficult emotions rather than to suppress them, in order to better resolve deep-seated patterns of fear, powerlessness, guilt, and shame.

The therapists prepare the participant for the likelihood that revisiting their trauma and experiencing their PTSD symptoms is likely to be part of the therapeutic process at some point. They encourage them to be as open as possible to fully experiencing, expressing and understanding the PTSD symptoms and the other impacts the trauma has had on their life. The therapists explicitly agree to provide support, safety, and guidance for the participant in working with whatever emotions and memories arise.

Therapist: "We want to emphasize our commitment to you and to be available for you. It is a privilege to support you as you do this work."

Therapists make it clear that participation in the study remains voluntary throughout the study, and that if their safety and well being always takes precedence over the scientific objectives of the study.

Therapist: "If you decide you need to be back on an antidepressant or for any other reason you may not want to continue in the study we ask you to let us know at any time. You are always free to change your mind. What's most important is your well being."

Participant: *"I think after experiencing 4 of 5 life stressors, like losing my job, typically I would say I need to go on an antidepressant. But because of the study, I am excited because I am also faced with working through this without being on anything. I think that I am cognitively aware enough to know that if I really feel like I'm slipping I would be able to let you know or ask for it."*

It is essential that the therapists use clinical judgment and personal awareness to ascertain when to take action to facilitate the participant's process vs when to silently witness the participant's experience(explained in more detail in Stage Three). The participant is encouraged to feel free to request support from the therapists during times of intense emotion or painful memories. Such support can take the form of being touched or held, receiving reassurance, or simply talking about what they are experiencing.

Therapist: "We want to reaffirm our commitment to be present for you. We will make this a safe place for you to have whatever experience comes up. If difficult things come up try to stay with them and fully experience them and use your breath to move into them. And ask us for anything you need. We'll weave alternating periods of going inside, using eye shades, listening to music if you want to and then talking to us when you feel like it."

Therapist: “Sometimes if we’ve been talking for a while we may suggest you bring your attention inside or you may just get the sense that you need to do this.”

The attendant is a registered nurse (RN). The RNs are trained by the therapist to appropriately attend to the participant overnight. These nurses are selected for their ability to act as reliable and compassionate attendants, and to recognize when to call the therapists in the event that the participant is experiencing physical or emotional distress the night after an experimental session. These individuals must be able to be present with other people’s emotions without becoming emotionally reactive themselves.

Attendants see to the participant’s need for food or liquids, and offer companionship by sitting or taking a walk with them, according to the participant’s desires. They are instructed to listen compassionately if the participant wants to talk, but not to interpret the participant’s experiences or otherwise act as therapists. The emphasis is on listening and being quietly present rather than talking. Accordingly, the attendant avoids initiating long conversations with the participant or being intrusive in any way on the participant’s experience, other than to inquire about their comfort or their physical or emotional needs.

3.3 Creating a Safe Psychological and Physical Space

Establishing a safe and therapeutic physical setting and mind set for the participant requires that the therapists take an active role in creating an environment that is conducive to the full range of the MDMA therapeutic experience, by allowing and encouraging the participant to fully attend to his/her internal experience.

The physical setting should be:

- Private, with freedom from interruption.
- Quiet, with minimal external stimuli.
- Comfortable, with a futon or similar furniture for the subject to either recline or sit up with support from pillows. There should be blankets and good ambient temperature control.
- Aesthetically pleasing – fresh flowers and artwork are a nice addition. Images with powerful negative or disturbing connotations should be avoided

To whatever degree possible the setting should be similar to a comfortably furnished living room rather than a medical facility, however the participant should be aware of all safety measures and equipment in place to respond to the unlikely possibility of a medical complication. There should be rooms with sleeping arrangements to accommodate the participant, an attendant, and a selected significant other. A kitchen and eating space should also be available, and good quality food that suits the participant’s tastes and is easily digested should be on hand. Art supplies can be a useful addition that provide the opportunity for nonverbal expression that may facilitate the continuing unfolding and integration of the experience at the end of the day.

The participant is provided with eye shades, headphones and a pre-selected program of music. Music for the drug session is selected qualities that are likely to elicit emotional responses or to facilitate a sense of passage or transformation. Music is chosen to support emotional experience while minimizing suggestion, therefore music containing lyrics is generally avoided (Grof, 2000). The participant has the option to request periods of silence and the therapists have the option to forgo sections of the musical program. Headphones, and usually eyeshades are removed during conversation with the therapists. Participants may also elect to forgo eyeshades and/or headphones at any other time they choose to.

To foster a therapeutic mindset and contribute to a collaborative therapeutic alliance, the therapists and participant discuss the parameters of each session and make several specific agreements during the preparation sessions, including:

1. The participant, accompanied by a trained attendant, agrees to remain overnight in the clinic or office. The participant is permitted to have his/her significant other spend the night unless the clinicians judge it to be contraindicated.

2. The participant agrees to have a prearranged ride home the following morning.

3. At least one of the therapists is present in the room at all times during the entire MDMA session. Except for occasional brief periods in which one therapist at a time may leave the room, both therapists will be in the room throughout the sessioin.

4. The participant and therapists discuss the possibility of physical contact with the participant in the form of nurturing touch or focused bodywork. The therapists assure the participant that at no time will they engage in any form of sexual contact. The participant is invited to ask for nurturing touch, (holding of a hand or being held). The participant is also instructed to use the word “stop” as a specific command if the therapists are doing anything the participant wants them to discontinue. The therapists agree to always respond to this command unless there is a situation in which touch is necessary for the participant’s safety (eg: keeping them from falling or from self harm). The therapists should also ask the participant how close to them they want the therapists to sit, and, during the experimental sessions, the therapists should remain attentive to any possible changes in the participants comfort level with their degree of proximity.

5. The participant agrees to refrain from self-harm, harm to others, and harm to property. If, in the judgment of the therapists, the participant is engaged in any dangerous behavior, the participant agrees that he or she will comply with the therapists request to stop. The participant understands that failure to respond to the request may require an appropriate level of intervention.

During the preparation sessions and again at the beginning of each experimental sessioin the participant and therapists address any fears or other concerns the participant may have. The therapists collaborate with the participant to develop strategies that will increase the participant’s feeling of safety.

Therapist: “What is on your mind since our last session? Any questions or thoughts?”

Participant: *"I've been through a gamut of emotions, nervous, anxious and not sleeping well. I just don't feel rested, dragging myself out of bed. I'm real tired."*

Therapist: "Do you have an idea about what the anxiety is about?"

Participant: *"I think it is about the upcoming study. I really can't think of anything else. It's the unexpected. I am not good at surprises. I want to know what's coming from one day to the next."*

Therapist: (Long silence.)

Participant: (Crying) *"It scares me."*

Therapist: "Can you say more about what scares you?"

Participant: *"I am afraid I'll be a different person. What if I get rid of all of this and Tom won't love me anymore? What if I'm not the person he fell in love with? He reassured me that this was silly. But I have been like this for so long. Who am I? What if I am not really a person? What if? What if? I can come up with a thousand rationales for why I am like this."*

Therapist: "That's an understandable concern, and we're glad you're letting us know about it. Even change for the better can be scary because it's unknown. Often when people heal there can be a period when it's challenging to get used to the changes and discover how to integrate them into life and relationships. In reality what we expect based on our own experience in our own healing work, as well as working with many other people is that actually as you heal you'll be more deeply yourself; you'll be reconnected with yourself in a deeper way. And it's true that there may be periods when it's hard to trust that."

Therapist: "One thing you said earlier was that you wanted to run off and hide. Do you think there's a way part of you has done that?"

Participant: *"I think there was a lot of me that disappeared."*

Therapist: "So the MDMA may help you not have to run away, help you face things you've felt you had to move away from.

The participant is made aware that he/she will be in a heightened state of vulnerability and will likely experience a range of emotions, thoughts, and physical sensations. The therapists discuss the process of helping the participant gain relief from difficult, intense emotions or distressing thoughts and remind the participant that he/she is in a safe environment and under the care of experienced clinicians. The participants are taught diaphragmatic breathing techniques to aid in the relaxation and self-soothing process. They are also encouraged to use their awareness of the breath as a technique for staying present with experiences, especially difficult experiences from which they might otherwise attempt to distance themselves.

3.4 Use of the Breath

The therapists explain two different ways they will ask participants to use their breath:

1) Diaphragmatic breathing will be used to aid relaxation ("stress inoculation") near the beginning of the session if anxiety comes up during the onset of the MDMA effect. It is explained that some people feel anxious during this time and others do not. If they do it will be transient, and it can be helpful to use the breath to release tension from the body and, as much as possible relax into the experience.

2) Later in the session if anxiety or any other intense emotion comes up, rather than trying to relax, it is often most helpful to use the breath to "breathe into" the experience and stay as present with it as possible in order to fully experience, process it and move through it.

Another important aspect of ensuring safety and support involves inquiring about his/her social support network. Before any MDMA-assisted treatment session, the therapists and participant should consider ways in which the members of his/her support system can help the participant during the time between therapy sessions. The therapists should explain the potential value of sharing knowledge about the treatment sessions with selected members of the participant's social support system, as well as the potential pitfalls of doing so and the importance of using discretion about whom to tell about their deep personal experiences. There are several factors to consider regarding discussing the experience with others:

- It can be valuable to share the experience with someone who is supportive and willing to listen, especially if they've been briefed ahead of time about the concept that the healing process may at times involve an increase in painful emotions and they understand that this does not represent a worsening of the underlying problem.
- Some people may not understand that "non-ordinary states" may be beneficial in a therapeutic setting, and may have judgments about the use of drugs like MDMA because of its illegal use as "Ecstasy". Participants should be advised to consider this possibility before discussing their experience during a period when they may be emotionally vulnerable following an experimental session.
- Following experimental sessions, participants may feel particularly open and eager to talk about their experience in the session and about their trauma. Although this may be an important part of their healing process, they should be cautioned to use careful judgment about with whom they want to share this sensitive information.

The participant may choose to invite a significant other (friend, family member, or partner) to spend time with them at the close of at least one MDMA session. This can be a valuable experience that enhances the supportive relationship. It should be cleared in advance with the therapists based on the same clinical judgment they would use in considering the therapeutic value of an overnight stay by a significant other.

Maintaining physical safety includes providing access to treatment for possible reactions to the medicine during or immediately after each treatment session. Most reactions can be dealt with through supportive care, but some, such as hypertensive reaction, could need additional intervention. Although there have not been any serious reactions requiring medical intervention during any MDMA research sessions, MDMA-assisted psychotherapy should be done in a setting where Advanced Cardiac Life Support (ACLS) is rapidly available in the unlikely event of an acute cardiovascular complication. The clinic or office should have means of readily assessing blood pressure and heart rate during the MDMA session. When providing beverages, the therapists should ensure that participants do not consume more than 3 L over the course of the MDMA session, and they may wish to provide electrolyte-containing beverages (such as

Gatorade) instead of water as a means of reducing risk of hyponatremia. Therapists should make contingency plans for responding to other unlikely events.

4.0 EXPERIMENTAL PSYCHOTHERAPY SESSIONS

4.1 *The First MDMA-assisted or Placebo Session*

The overall goal of an MDMA-assisted session is to reduce the symptoms of PTSD and improve overall functioning and quality of life. This is accomplished by allowing each participant's experience to unfold spontaneously without a specific agenda about its content or trajectory. The therapists' responsibility is primarily to follow and facilitate rather than direct the experience, and to the support and occasionally guide the participant if he or she encounters emotional or somatic blocks or has undue difficulty processing trauma-related memories or any other painful memories, thoughts, and feelings. The therapists are also there to help explore and validate new perspectives about life experiences, and to join with participants in appreciating joyful or affirming experiences and enjoying moments of beauty, heart opening and humor.

4.1.1 Initiating Therapy

At the beginning of the MDMA session, the therapists review the approach to therapy and the range of experiences that may occur during the session, and to inquire about any concerns or questions the participant might have. This encourages the participant to disclose his/her feelings and provides an opportunity for the therapists to reassure the participant, to remind him or her of the value of a non-directive approach and to reinforce receptivity towards the healing potential of the therapeutic experience.

Participant: *"I have this thing about the unknown. It just doesn't sit well with me. I don't do well with it. When I know what to expect it's OK. Not knowing and having unanswered questions, I just don't do well with. Like the idea of possibly having flashbacks … and I don't know, worst case scenario."*

Therapist: 'It's really natural to be anxious about that. One of the challenges of this approach is being willing to go into it and work with whatever comes up. Your reactions are common. I think it is helpful to remember nothing is going to come up that is not already there. Whatever comes up is something you are walking around with already but maybe not fully conscious of. It's scary. The paradox is, although it could stir up memories or even flashbacks, temporarily, it allows you to move through them in a way so that you are actually more apt to be free of them and less likely to have them be a problem for you in the long run. It's possible you could have more symptoms temporarily, like we talked about.

Participant: *"Yeah right. Is this one of those things where you won't remember what happened? Like being under sedation?"*

Therapist: "You'll remember this. One of the qualities of MDMA is that it makes it easier to face memories and not be overwhelmed, and actually work through them and the painful emotions in

a way that is healing rather than re-traumatizing. In everyday life flashbacks and memories can come up spontaneously and overwhelm you. We are trying to change this by inviting whatever comes up to come up in a safe setting, with the medicine helping you approach it without being overwhelmed. The idea is to approach your memories with less fear and less defensiveness.

Participant: (Sigh) *"If that can happen …"*

Therapist: "We're here to help you stay with what you're experiencing and encourage you not to judge whether it's the right thing or the wrong thing, but experience it as fully as possible."

Participant: *"Uh huh."*

Therapist: "Ask for support in whatever way you need, if you want us to hold your hand or hold you or if you want to talk to us. It's really good to ask for support if you feel you can. I know a lot of your tendency can be to tough your way through …"

Participant: *"My normal approach is to suck it up."*

Therapist: "Today is an invitation and encouragement to let go of as much of that as possible. This is a whole day for you to have all the support you need, all the support you are able to accept, and allow yourself to feel and work with whatever comes up rather than pushing it away or sucking it up."

As the therapists give the medicine to the participant they explain that MDMA is known to increase feelings of intimacy or closeness to others and to reduce fear when confronting emotionally threatening material (Adamson 1985; Cami et al. 2000; Downing 1985; Greer and Tolbert 1998; 1986; Grinspoon and Bakalar 1986; Grob et al. 1996; Harris et al. 2002; Tancer et al. 2001; Vollenweider et al. 1998). They remind the participant that in the context of psychotherapy, a combination of drug effects serves to facilitate the therapeutic process by allowing the participant to revisit the trauma without feeling overwhelmed by the terror or shame that may have overwhelmed him/her in the past. These effects include enhanced positive mood, changed thoughts about meaning, increased access to distressing thoughts and memories, reduced anxiety and increased feelings of empathy or closeness to others, and decreased self-blame and judgment. This combination of drug effects should support the participant in overcoming the emotional numbing of PTSD and allow him/her to more fully open to experiencing the full range of emotions (grief, fear, rage and also joy, happiness, love, comfort) without the subjective feeling of being overwhelmed. The participant is guided towards a relaxed state and encouraged to focus his/her attention on abdominal breathing.

Onset of subjective and physiological effects begins 30 to 60 minutes after oral administration. During this period the participant is in a comfortable position and may find it helpful to focus on his/her breathing. Within approximately 15 minutes of ingesting the MDMA, the participant is encouraged to recline on the futon, use eye shades and headphones if they are comfortable doing so, and relax into the music selected for the session. The therapist softly reminds the participant to be open to whatever unfolds and trust his/her innate healing capacity. From this point on, the MDMA-psychotherapy session consists of periods of inner focus during which the participant attends to his/her intrapsychic experience without talking, alternating with periods of interaction

with the therapists. The ratio of inner focus to interaction is typically approximately 50:50, but varies considerably from session to session. During the periods of inner focus the therapists maintain a clear empathic presence to support the process.

Therapist: "You mentioned that you're worried that this stuff with your dad may come up. We want to remind you that we're here to support you in working with whatever comes up, and we believe that whatever does come up is coming up for healing."

Participant: *"OK. I feel good about that."*

Therapist: "We don't want to direct this nearly as much as we want to follow and support the way it unfolds for you. So we trust that your own inner healing mechanism will bring up whatever needs to come up. As we talked about before, we would like to have an agreement that at some point if nothing about the trauma has come up spontaneously we'll bring that up in some way so that we can work with it. But we will let your own unfolding of the process take the lead."

In some cases the participant may become anxious at the onset of the MDMA.

Participant: *"I feel really weird. My arms and legs feel heavy and tingly."*

Therapist: "I want to remind you that you're in a safe place, and we're paying close attention to how your body is reacting. Use your breath. What you're experiencing is a normal reaction to the MDMA effect starting. By using your breath like we practiced you can stay with the energy in your body."

Participant: (Begins breathing. Music is soft and melodic.)

Therapist: (After a long silence) "It's very common to have a lot of energy. One thing is to breathe into it and experience it, maybe savor it and also if your body wants to move, just let your body express itself."

Participant: *"I need direction. I'm just going every which way. I need something to focus on. I need something to think about … too many thoughts."*

Therapist: "Try to see what direction the medication gives you. Instead of trying to control your thoughts, trust the medicine will unravel these knots in some way and take on direction. I know there is an abundance of energy in your body, so you do not have to make your body relax, just let your thoughts float by."

4.1.2 ***Period of peak effects***

Peak effects typically occur 70 to 90 minutes after drug administration (Harris et al, 2002; Tancer & Johanson 2003; Liechti & Vollenweider, 2001), and persist for 1 to 1.5 hours. The therapists check in with the participant after 60 minutes if the participant has not talked since the administration of the medication. This check-in reminds the participant of the therapists'

presence and provides the therapists with a sense of the participant's inner state. Based on this information, the therapists either encourage the participant to return to an inner focus or to share more about their inner experience.

To check in with the participant at 60 minutes one of the therapists may put a hand gently on the participant's shoulder (if the participant has previously given permission to be touched in this way) and ask softly:

Therapist: "It's been an hour and we're just checking in to see how you're doing."

Participant: *"I don't remember so much about my childhood. It's hard for me to imagine that I can heal this stuff if I don't remember what it is. I just want to dig it out."*

Therapist: "So what I encourage you to do right now, as much as possible, is to stay with all of that, including the feelings of frustration and concerns about your not being able to remember. Let yourself just go into feeling all of it and let go of worrying about whether you can remember or not remember. As much as you can, let go of worrying about how you are going to heal. Breathe into the process and trust your own healing intelligence with the help of the medicine."

As the session progresses, the participant is likely to experience a positive mood and a sense of trust in both self and others. During some sessions this occurs relatively early in the session and seems to provide a platform from which the participant is then able to approach the emergence of traumatic memories and painful emotions with a greater sense of strength and safety that comes with an empathic shift in consciousness. This expansion in consciousness aids the participant in developing a new sense of mastery over the trauma and accompanying painful emotions. During other sessions participants are confronted by traumatic memories relatively early in the session before they have affirming experiences. In this case, affirming experiences are likely to come later in that session or in subsequent sessions, and contribute to a sense of resolution and healing and a shift in perspective about the world.

An example of affirming experience early in the session:

In her first MDMA- assisted session this subject started with a Subjective Units of Distress (SUDS) rating at 7/7. She reported being very anxious about the unknown, including fear that flashbacks would be triggered. Forty-five minutes after MDMA administration she said,

"My legs are a little heavy and my chest is a little hot, not a bad thing, I'm not nervous anymore. I feel warm and fuzzy I'm not stressed at all."
At 1 hour point her SUDS was 0.
"Colors are bright, I feel warm inside, there's lots of energy…. My thoughts are coming fast; I need some direction. Love, I'm seeing blocks to it"
The therapists suggested she focus her attention back inside. After a few minutes she said,
" I just heard, 'You're the greatest!"…. I see the link between the derealzation and the rape"
She talked briefly about the rape and became aware of anger, self blame and feeling alone, then said,

"There has been despiration under the numbness. I feel protected now, I finally feel loved and protected. (tears) It's good to have someone who cares."
She went on to talk some more about the rape in this session with realizations about how experiences in childhood had made her vulnerable, but much of the session was appreciating being able to really feel,for the first time, how much love and safety there was in her marriage. In the follow-up sessions she said, *"now I have a map of the battlefield. I think next time I'll be able to go deeper processing the trauma,"* which she did.

An example of experience of being confronted by traumatic memories relatively early in the session:

One subject, in her first MDMA session started crying an hour after MDMA administration, described fear, sadness and blurry vision and body sensations that she'd had when she was stabbed. She went on to spontaneously re-experience the trauma in detail as if watching a movie with time slowed down and said, *"It feels more real now than when it happened."* At times she was able to describe it to us, at other times she was having full blown flashbacks saying, *"Please don't let me die, I have things I have to wrap up, get down, get down,"* as she held her hands up as if to protect herself. This continued for more than an hour with the therapists listening empathically and periodically making contact to remind her of their presence.

It is common for participants to spontaneously make connections between their feelings about specific traumatic events and earlier childhood experiences. Often they arrive at insights about how earlier experiences may have left them more vulnerable to being traumatized later, or may have affected their response to subsequent trauma.

Therapist: "You were beginning to sense the fear."

Participant: *"It changed from fear to 'I'm really mad at myself for allowing it to happen.'"*

Therapist: "Is that easier to feel than the fear?'

Participant: *"I guess so."*

Therapist: "Because you were experiencing that and the fear began to come up and I invited you to go inside and feel the fear. How long before it switched to the anger?"

Participant: *"Not long at all."*

Therapist: "Do you think your mind does that to distract you from the feeling of fear."

Participant: *"That's possible. After the initial, 'What the hell is going on,' my mind clicked into 'This is not happening. This is just too absurd to be happening' … all the way back to when I was little … I never felt protected, really. There's never been any support. I wasn't free to be me … just what the situation called for. I had to do it then too, be what the situation called for."*

(Long silence.)

"I feel like a lot of this baggage I've been carrying around I put onto myself – either disappointment in myself or self blame. Don't get me wrong, I don't think I deserved it or asked for it or did something to bring that on. I don't feel that way at all. It's like your baseline and you've got your self-doubt, desperation on top of that and before you know it you've got a 7-layer burrito. I can feel every one of them. I don't know how to express it or articulate it but I can feel every one of them. It's not the "Yuck" that I used to describe. They're stacked one on top of the other. I guess I have just done it for so long that when the rape happened it was the straw that broke the camel's back. I just left. My mind said that's enough, no more."

The MDMA-assisted psychotherapy helps the participant face traumatic memories and associated thoughts and emotions. With more self-acceptance and less self-criticism, the participant gains self-confidence and a sense of self-efficacy and control over unfolding memories, thoughts or feelings. A sense of inner calm, rather than extreme arousal, on confronting trauma-related material is expected to help the participant examine memories and thoughts more closely and objectively, while at the same time allowing powerful emotions to surface. The sense of safety may work in concert with facilitated recall to allow deeper exploration of trauma-related events and their effects on relationships and other aspects of the participant's life. As mentioned in the introduction, this is in keeping with observations from other methods of therapy that, to be effective, trauma processing must be accompanied by a degree of emotional engagement or "fear activation" while avoiding dissociation or overwhelming emotion (Foa 2009). This has been referred to as working within the "optimal arousal zone" or "window of tolerance" (Wilbarger 1997, Siegel 1999, Ogden 2006).

Participant: *"Fear is the only emotion I've ever really known that well ... afraid of this, afraid of that. That's all I remember feeling for as far as I can remember. Heart stopping, gut-wrenching fear."*

Therapist: "Hmmm" (Long silence/soft piano music)

Participant: *"I've kept all this inside for so long. It feels so heavy, these emotions ... it's like I was trained this way ever since I can remember. Children were to be seen and not heard. From that point on I sought to make myself as insignificant as possible. Then after the rape happened, I was headline news. I knew everyone at the hospital. I was ashamed, like I had a scarlet letter."*

Therapist: "I think it's important for you to experience these feelings of fear and shame. You've been holding on to these emotions for so long, and also the belief that you have to be a certain way. It is a really powerful thing to feel, just the realization of it."

Participant: *"And it all ties into how I handled my adult relationships, 'cuz I was always afraid to be myself because nobody would like me as myself. Then Tom comes along and I don't have to be a certain way. Now I have someone I can lean on and somebody that is there for me and doesn't judge me. It's a great feeling."*

As the participant experiences a greater sense of closeness to others, with more trust and intimacy, she/he may also feel empathy and forgiveness for the self and others. Ideally this progression leads the participant to feel worthy despite the shame or distress caused by the traumatic event or events.

"I felt that interconnection between me and Tom. I haven't felt it for a long time and that's what makes me feel so much better, knowing that it is still there. It's been a big stressor for me not to have felt that anymore."

Such insights may also help the participant develop greater trust with the therapists and make it easier to talk about his/her inner experience. The participant may also be more likely to comply with any suggestions intended to improve the therapeutic experience or to help the participant stay engaged with a particular element of the experience, such as a difficult memory, feeling or insight.

"It sucks to just live. Y'all are really a godsend. It is so nice to have someone who understands. For so long it's been take this pill, take that pill. The night that I was raped, the first thing that popped into my mind was 'they are not going to believe me because of the T-shirt I was wearing'. I really thought nobody would believe me. And here you are. Just throughout the years, everyone said take this and take that. Nobody's really bothered to dig down to the symptoms and help me figure out what's causing this."

As the therapists listen and talk with the participant, they are also assessing whether such verbal interaction is indicated or whether it may be an attempt to defend against difficult or painful emotional material. Although the overall therapeutic approach should be largely non-directive, nevertheless sometimes guidance or redirection may be valuable. If the participant seems to be intellectualizing, then the inner experience is probably not resolved and needs more time to unfold. This is sometimes referred to as the participant "getting ahead of the internal emotional experience." In this situation, it is necessary for the therapists to intervene and guide the participant back to his/her internal experience. In this case guidance should be offered as a possible choice without implying that it is expected or is the only correct course to follow, eg:

- "Would you like to tell us more about that?"
- "Would you be willing to experiment with not distracting yourself that way for a few minutes just to see what you might discover?"
- "Maybe this would be a good time to put the eye shades and headphones on and go back inside to let the medicine help you with this?"
- "I just noticed that your voice changed. Is there something going on that you notice?"

Bringing attention to the body and/or the breath may be useful ways of directing attention back toward inner experience.

Therapist: "It may be helpful to really get into a comfortable position and allow your body to sink into the mattress."

Participant: *"I feel so crooked. Are you going to be able to walk me through any of the traumatic experiences to kind of help me focus?"*

Therapist: "Absolutely. If it feels like it's the time to do that now, we can help you do that, but it might be better at this point to go inside and relax into the way the experience will unfold as much as you can. Sometimes talking can get in the way of the experience. We can talk more later." (This response was based on the therapist's sense that the participant was trying to force the experience and was looking for outer direction at the expense of inner awareness.)

Participant: *"I feel really restless."*

Therapist: "Just attempt to go with the flow with that energy for a little while."

Therapist: "I think you should lie down, sink into the mattress and let your body get comfortable with that movement if you need to. Try and let your breath take you through the confusion and let the medicine work as you breathe and take you through it."

Participant: *"If you don't mind, could you remind me to breathe into it? Just give me a little sign to breathe."*

Therapist: "How about if I just touch your shoulder to remind you? Remember the words, 'Don't get ahead of the medicine. Let the medicine take you where you need to go."

If the subject "resists" a suggestion, it is usually better to accept and follow whatever direction the person takes, rather than to further challenge or interpret the resistance at that point. There may be exceptions to this if someone appears to be repeatedly avoiding something. In that situation, if the therapist decides to directly address the resistance it should be done gently, as a collaborative exploration, and with respect for the fact that the underlying intent of a defense is self-protection. (As in other therapies, processing the resistance itself rather than trying to push past it should be the approach.) With a gentle, minimally directive approach, given time the person is apt to come back to the issue spontaneously later in the session or in subsequent MDMA or integration sessions. At this point they may have valuable insights about the resistance as well as the underlying issue. This is an area where there is room for flexibility and the therapists' intuition and judgment. Insights arrived at spontaneously are likely be of greater benefit, and it is also true that sometimes direction from the therapist may help create a valuable opportunity for healing. It is important to have a good balance in this area, weighted more toward self-direction than direction from the therapists.

The therapists must recognize and attend to both the participant's underlying psychological processes and the experience produced by the medicine. This involves simultaneously supporting the participant in processing the negative effects of the trauma and in experiencing the softening effects of MDMA. The therapists' presence and the effects of the medicine can provide a sense of safety as the participant's barriers to perception open to allow increased access to memories, thoughts and emotions.

Participant: *"Sometimes I am so detached from my family. Sometimes I don't even feel like I'm Aileen's mom. There's just not that … I don't know."*

Therapist: "Your derealization takes all of your attention."

Participant: *"My perception is off."*

Therapist: "This is a safe time to notice your own experience more. Try to focus on your experience rather than have it outer-directed or having to just make it through. It appears to be unfolding today that there are these layers connected not only with the rape, but the experiences before. First, the top layer is the depersonalization when that veil came down, then there is self-judgment and under there is fear and anger. It is finally safe to revisit that."

Participant: (Breathing softly.)

Increased sensitivity to interpersonal relationships and intimacy issues may allow participants to consider ways in which their symptoms have altered or impaired their relationships with others. With this perspective, participants are better able to view their interpersonal relationships realistically, without judging themselves or others too harshly.

Participant: *"Did you tell Tom that I love him?"*

Therapist: "No. Sorry I missed that but I can call him back. Is that something you are experiencing deeply now?"

Participant: *"Yes, on a deep level, a deep feeling for all the love and understanding what I am going through and not knowing how to help. He's my soul mate. I don't know what I'd do without him. That deep love I feel right now. I haven't felt that for so long."*

An increased focus on interpersonal relationships may benefit participants who have distanced themselves from others as a way of coping with the trauma or PTSD symptoms. Feelings of interpersonal trust may also help participants who have experienced a lack of support from significant others after traumatic events. The therapists and participant may explicitly seek to explore these areas during part of the MDMA session.

During the MDMA session, the participant may experience strong negative emotional reactions, including a feeling of loss of control. When the therapists see that the participant's distress is interfering with his/her ability to focus on the inner experience, they intervene, encouraging the participant to stay with deeper levels of emotion, and to trust that it is safe to face the experience. They encourage the participant to surrender control and fully experience and express their feelings, including any fear of losing control. The therapists' guidance may take the form of:

- introducing previously practiced breathing exercises, (e.g., "use your breath to stay with the experience, breathe into it")
- verbal statements assuring the participant that he/she is in a safe place and what is coming up now is part of the healing process
- encouraging the participant to talk about or otherwise express his/her emotions (eg. tears, screaming, other sounds)
- holding the participant's hand; or providing other nurturing touch

In this way, the therapists help the participant stay with powerful emotional experiences of fear, anxiety, shame, guilt, etc., rather than trying to suppress or avoid them. The therapists remind

participants that this as a natural progression of the therapeutic process; opening to and moving through inner territory which they may have previously been afraid to fully face.

An example of helping the participant with a difficult experience:

Participant: (deep breaths) *"Fear."*

Therapist: "Fear. Where do you feel it in your body?"

Participant: *"In my chest. It's hard to breathe, kind of a suffocating kind of fear."*

Therapist: "Any images or content associated with it?"

Participant: *"No, just deep seated fear. Just that wrong feeling. It's just wrong. I don't know how to explain it. It's like that 'take the wind out of your sails … that overwhelming suffocating fear, terror, just out of control helpless fear."* (Crying)

Therapist: "I would understand this as something you've been carrying around and it is now coming up to be expressed and for healing."

Participant: *"It's weird. My body, I know I'm safe, but my mind just doesn't want to know it. It's a weird combination of my mind is telling my body one thing and my body is going 'NO' but my mind is just that, just that … it's like someone is throwing a wet blanket on me. It's just that suffocating; you know you can't catch your breath … just fear."*

Therapist: "Remember your breathing. We are right here with you. "

Often the invitation to focus inward and/or to bring awareness to the body and use the breath is enough to allow the participant to stay with a difficult experience and eventually move through it to new insights and a sense of clearing, opening and relaxing of the body. If not, the therapists may offer some level of focused bodywork as an added catalyst to the process (see below and Appendix B).

Often participants have vivid images that may depict some aspect of their healing process. For example:

"I felt deeply connected to painful feelings of the traumas as I saw them go by in spheres, but it didn't cause anxiety. I felt deep sadness in my heart, [crying] *but also deep happiness that I was healing it and letting it go."*

"It's like, every time I go inside I see flowers and I pick one, and that's the thing to work on next. And there are things that are hard to take, but each time I move through them it feels so much better."

"It's like there have been ropes tied around me and now they're loosening."

"I see huge white doors with beautiful white glass, so huge and heavy, but a master has engineered them so you can open them with one hand. It's only without the fear that the doors are so light. How interesting! If I go up to them with all the fears it makes me weak. I'm taking those fears out of different parts of my body, looking at them and saying 'it's ok but I'm leaving you here.' The fear served me well at one time, but not now for going through these doors."

"I'm a huge pile of fertilizer composting and turning into beautiful rich soil. It's a perfect time to have rain. I'm a converter, I'm the earth, I am. Leaves, rain, even acid rain hit me, and I have a powerful ecosystem, all can be absorbed. What we're doing here is turning compost."

4.1.3 *Later Part of the Session*

As the effects of the MDMA subside, the therapists may communicate with the participant more extensively about what she or he experienced during the session. The therapists ask if the participant would like to give more detailed feedback on his/her emotional and psychosomatic status (Grof, 2001). However, there should be no pressure to do so at this point, and much of this discussion may be left for follow-up sessions.

Therapist: "There is no pressure to talk now, but we might want to give you the opportunity to share more detail if that feels right. Sometimes people have the sense that it is best to hold the experience in silence until the next day and others find it useful to talk about it at this point."

The therapists encourage the participant to reflect on and accept the experience, and to consider any new insights. If the participant indicates physical pain, tension, anxiety, or other signs of distress, the therapists may use focused bodywork at this point (Appendix B).

To prepare for focused bodywork the participant is reminded to use the word "stop" if there is ever any touch he or she does not want. He or she should be told that this command will always be obeyed by the therapists unless such touch is necessary to protect the subject from physical harm. This will avoid confusion between communications that are meant to be directed to the therapists and expressions that are part of the participant's inner experience.

When the participant's emotional distress is impeding a participants experience to they point where they are not able to process and move through spontaneously, the following steps may be helpful. In most cases, these steps should be taken sequentially, proceeding to the next step only if necessary:

1) Ask, "What are you aware of in your body?" This helps the participant become conscious of the link between distressing emotions and any somatic manifestations. Making this link and making the suggestion to "Breathe into that area and allow your experience to unfold" may be the only intervention that is needed.
2) Encourage the participant to "Use your breath to help you stay as present as you can with this experience. Go inside to allow your inner healing intelligence to work with this." If the participant is still under the influence of the MDMA add, "The medicine will help that to happen."

3) If the participant is quite agitated (anxious affect, moving on the mat, opening eyes) it may be helpful to hold his or her hand, or to put a hand gently on the participant's arm, chest or back, or on an area where he or she is experiencing pain, tension or other physical symptoms. This can be reassuring and help refocus attention on inner experience but should only be done with the participant's permission.
4) Ask, "Is there any content (specific images, memories or thoughts) coming up with these feelings?" If so, the therapists may wish to speak to the participant about it. The opportunity to put the experience into words may in itself be therapeutic, especially in this safe setting. This also may be an opening for the therapists to help the participant explore connections between current symptoms and past traumatic experiences, and to begin to put these experiences into perspective in his/her current life.
5) After this period of talking, and periodically throughout the session, encourage the participant to "go back inside," to focus on his/her own inner experience.
6) If the participant continues to express or exhibit emotional distress or somatic tension or pain, bodywork of a more focused nature may be indicated (Appendix B).

If severe anxiety persists despite the above measures, a benzodiazepine may be used as a "rescue medication." This is rarely, if ever, necessary. However, if a particularly severe panic reaction does occur during or after the first MDMA session, the therapists will decide whether or not the participant should undergo a second MDMA session. This decision should only be made after assessing the participant during the follow-up session the next day, and should subsequently be thoroughly explained and discussed with the participant. In many cases, if the person is willing, it is beneficial to proceed to another MDMA session as an opportunity to process and resolve underlying causes of the anxiety, rather than reinforcing the idea that it must be avoided.

As the MDMA session draws to a close, the participant may invite a significant other into the consultation room to assist with re-entry and join the participant in his/her integration process. This should be discussed and planned for in advance, and the therapists should meet with the participant and significant other so they can assess the quality of the relationship and the significant other's ability to be appropriately supportive without being directive or intrusive. If there is reason to believe that a visit at this time would interfere with rather than support the integration process, they should advise against contact with the significant other until the next day.

If a significant other is invited to visit, when he or she arrives the participant and therapists explain the participant's present condition to the visitor and encourage the significant other to share any concerns or questions he/she may have. The therapists may explain some of the after-effects of the MDMA experience, and together the group may discuss what might be expected over the course of time as the healing process unfolds.

The participant remains overnight in the treatment setting, accompanied by a trained attendant, and the participant may be given the option for his/her significant other to stay as well. Both the participant and the attendant are given a means to contact the therapists. The therapists are available by phone and they can also return to the clinic if requested by the participant or the attendant.

The therapists examine physiological measures (blood pressure, pulse, and temperature) and self-reported distress and mental state to make a clinical judgment concerning the participant's stability and the waning of drug effects. If the participant is experiencing residual emotional distress, the therapists use clinical judgment to asses the intensity of distress and to gauge what interventions should be employed. In most cases, the proper intervention will be to allow the participant to express his/her feelings, and to help him/her understand the importance of these feelings in the overall healing process. The therapists will only depart from the clinic when they have concluded that the participant is emotionally and medically stable and that most MDMA effects have subsided.

The participant should be informed that, though the acute effects of the MDMA have worn off, the effects of the MDMA session inevitably continue to unfold over the hours and days following the session. Often they are encouraged to write about their experience and/or do artwork with materials provided as ways of continuing to explore and express their unfolding experience. They are also encouraged to pay attention to and write down any dreams they remember in the days following the session. The participant is also assured that the therapists will continue to provide support and help in working through and resolving any difficulties. Before leaving, the therapists may review and assist the participant in practicing relaxation and self-soothing techniques that were taught in the introductory sessions. If the participant's distress is not sufficiently decreased by the above measures, the therapists should consider focused bodywork as described in Appendix B. A "rescue medication" may be administered if extreme anxiety persists and all other interventions have failed to reduce anxiety to a tolerable level.

If all means of reducing the participant's distress have failed and the participant remains severely anxious, agitated or in danger of self harm or suicide, or is otherwise psychologically unstable at the end of a two-hour stabilization period, the therapists may decide between one of two options: (1) the therapists may then meet with the participant daily until the period of destabilization has passed; or (2) the participant may be hospitalized until she or he is in a stable condition. All participants will be aware of these possibilities when consenting to undergo MDMA-assisted psychotherapy. The therapists would use these unlikely options under extreme conditions, and all other options will be tried before hospitalization.

The participant will also be encouraged to pay close attention to his/her dreams and work with expressive art materials.

In early and pilot studies, the therapists will contact the participant for a week after each MDMA session to assess the psychological well-being during this time period.

The participant spends the rest of the evening and night in a comfortable private room in the clinic or offices of the therapists. The attendant is on duty during this time and has a separate room in which to rest. The attendant can function as an impartial and empathic listener, if necessary, but primarily serves as a supportive caretaker and monitors the mental and physical state of the subject. The attendant contacts the therapists if at any time the participant seems to be experiencing undue distress.

The participant may spend time indoors or outdoors, so long as the attendant is nearby. However, the participant is encouraged rest, reflect on and integrate the recent experience a quiet

atmosphere. The participant may also spend time with the selected friend, family member, partner or spouse as mentioned earlier.

A follow-up session occurs on the morning following each MDMA session, as explained in Section 5.2.

4.2 *Subsequent Experimental Sessions*

Unless there is a medical or psychological complication in the first session, all participants are eligible for one or more additional MDMA sessions, according to the protocol. They should be asked to discuss their thoughts and feelings about whether or not they choose to undergo an additional session. The therapists should also give their opinions about it. The participant's decision about whether to continue is respected unless the therapists have an overriding reason for excluding the participant on grounds of safety.

Typically, for participants who are offered more than one MDMA-assisted session, the sessions occur 3-5 weeks apart. All the principals and procedures that apply to the first MDMA-assisted session also apply to subsequent sessions, although explanations and reminders at the beginning of the session can be briefer in subsequent sessions. In addition, when preparing for subsequent sessions, the therapists should inquire about and explore any intentions the participant might have for the second session based on their experiences in the previous sessions. Based on these intentions the therapists and participants may make agreements that the therapists will remind the participant of an issue they want to explore, will help them notice when they are avoiding certain subjects, will use or refrain from bodywork etc. Having recognized and discussed these intentions, subjects should also be encouraged to "hold the intentions lightly", meaning not to be heavy handed in trying to direct or control their experience. Therapists and participant should strive to strike a balance between making use of what they have learned from the previous experience and taking the opportunity to build on it, versus maintaining a large degree of "beginners mind" and remaining open to the natural unfolding of the next experience guided by the participant's inner healing intelligence.

Participant: *"I felt so good after the first session and my whole outlook had changed. I guess for the most part it still has."*

Therapist: "The last time you said you wanted to more specifically address talking about the trauma. Do you still feel that way?"

Participant: *"Oh yeah. I think that's what's got me so nervous."*

Therapist: "So as far as the way we approach bringing up the trauma … Do you have any thoughts about how you want that to happen?"

Participant: *"All I can really tell you is that I'm not the 'beat around the bush' type of person."*

Therapist: (Laughs)

Participant: *"Bluntness is usually the best thing. I can't think of a really good way to approach it. I mean, um, I don't know, whatever you think."*

Therapist: "I hear you about not beating around the bush. I like that about you. I think it's useful to strike a balance between giving the experience a chance to come up the way it is naturally going to come up for you, if it does, and us gently guiding you in that direction in accordance with your intention, if we need to. So probably, like the last time, we'll wait for a while and if you haven't checked in with us after an hour, we'll check in with you."

Participant: *"Sure"*

The second MDMA session can facilitate a deeper emotional experience, due to several factors: an already established therapeutic alliance, familiarity with the structure and nature of the MDMA session, experience with the effects of MDMA, and an increased openness to further exploration. The psychic material that has revealed itself during the first MDMA session and the therapeutic work occurring in the follow-up non-drug sessions may help the participant trust the process more deeply this next time. Given this stronger sense of trust and familiarity, the participant is likely to move even further beyond his/her defenses.

4.3 Role of the Therapist During MDMA-Assisted Therapy Sessions

A primary role of the therapist in MDMA-assisted therapy is to create and maintain a safe therapeutic alliance with the participant. The therapists' own self-awareness is a crucial requirement. They must be fully present during the participant's processing of trauma and at the same time, maintain healthy, appropriate boundaries. In so doing, the therapists encourage the participant to stay present with his/her inner experience and facilitate the participant's willingness to explore new and unexpected perceptions which may arise during the healing process.

Thus the strength of the therapeutic experience relies heavily on the therapists' ability, their level of comfort with intense emotions, and their skill in remaining empathically present and open to a range of emotional experiences the participant is likely to undergo. The therapists maintain an awareness of the participant's intentions for the session while allowing for additional psychic material to emerge. They also consider the psychological factors influencing the participant, including the participant's expectations of the therapists (Widmer, 1998).

To maintain the delicate balance between focusing on the inner experience and providing a safe space for exploring this experience, the therapists must respect the natural healing mechanisms of the participant's own psyche and body. This involves skillfully interweaving interaction with the participant and periods of silent witnessing.

Participant: *"When my brother left there was just no contact for me. I really felt abandoned. He was a rock for me. I could feel safe. He was a really good brother, and then he went to California, and he was gone."*

Therapist: "Do you think it would be a good time to go inside and work with those feelings?"

Participant: *"Yeah."*

Therapist: (After a long silence). "How is it going in there?"

Participant: *"It is really crazy. And not at all what I was expecting. ... I don't know if I can even verbalize it. Some of it is really dark and some of it is not. It is kind of anxiety-provoking. It's like stuff I had no idea was in me. I am OK being there. It's not realistic at all. I am not really trying to connect it with anything. It is kind of like I want to get out of my skin. I kept wanting to stop and then wanting to stay. I'll stop if it gets too weird."*

Therapist: "It's ok not to put it into words at this point."

Participant: *"OK."*

During the MDMA treatment session, the therapists act both as guides and supportive figures. As guides, the therapists facilitate the healing process and encourage the participant to focus on his/her innate capacity to heal the wounds of trauma. This role may require therapists to redirect behavior, as when participants are requested to discontinue talking if the communication seems to represent either defensive avoidance or a distraction from the opportunity to experience and benefit from the unique effects of the medicine. These MDMA effects can lead to important insights and healing that arise through a non-linear process. This process is enhanced by allowing the medicine to bring forth experiences instead of intervening -- a posture of acceptance rather than analysis. In this vein, the therapists often need to follow, rather than guide, the participant as he/she explores new and unexpected perceptions and realizations.

At times, participants may describe experiences of exhilaration, joy, resolution or self-affirmation. The therapists encourage the participant to accept and perhaps further explore these experiences. These experiences may serve to soften or reduce the intensity of distressing memories, thoughts or feelings and may provide a life-affirming perspective for the participant.

Participant: *"This is such a fun way to spend the day. I am really having a lot of fun. I was thinking that I hope you guys are having as much fun as I am."* (Laughs)

Therapist: "We're enjoying it too. Thank you."

Participant: *"This is what I love about this work. It is, like so beautiful on one level. I feel like every one should have the experience of what the collective unconscious is and about how full we are. It is just really lovely. Some of it is painful and creepy too, but a lot of it for me is just so, I am going 'Wow I can't believe I have this in my head. I can't believe it is in me.' It is really a neat experience. It is very reassuring because even when it gets dark and kind of uncomfortable, I am like, I feel very clear that it is just part of what I am made of and it is OK."*

As supportive figures, the therapists provide comfort and reassurance to the participant when he or she is facing upsetting, potentially overwhelming thoughts, memories or feelings. With a combination of empathic listening, questions and observations the therapists facilitate two complimentary aspects processing these challenging experiences: 1) facing and even amplifying the experience in order to allow the spontaneous unfolding of the healing process without trying

to direct it and 2) clarifying, understanding and gaining new perspectives about past experience and painful emotions. Therapists must attend to balancing their responsibilities as facilitators and as noninvasive observers. This may prove challenging at times, particularly when the therapists must decide when it is desirable for the participant to explore and confront his/her inner experience without any interaction with the therapists, and when interaction is appropriate to facilitate a particular avenue of experience.

The role of the therapists is clarified and strengthened by agreements concerning appropriate behavior during and after the treatment session. Any sexual behavior between therapists and participant is absolutely prohibited, and this agreement assures participants that their heightened vulnerability will not be exploited, while simultaneously fostering a safe environment for offering physical comfort during the treatment session. Everyone also agrees that the participant will remain within the confines of the treatment area until completion of the sessions. It is the responsibility of the therapist to assess the participant's emotional stability and the degree to which the medicinal effects have subsided before permitting the participant to leave.

Therapist: "One kind of thought and feeling that sometimes comes up for people is 'I gotta get out of here'. If that does happen for you it's important to acknowledge and work with that feeling by talking to us about it and working with it as part of your inner process, but not to act it out on the physical plane. Can we have an agreement that you will stay until after we meet the morning after the session."

Participant: *"I can see myself having that feeling. I've had it a couple of times already, like the first day I was here in the waiting room, but yes, I can agree to that."*

The therapists offer verbal reassurance when needed and nurturing touch if requested, and provide techniques to help the participant relax and gain a sense of security in the face of trauma memories and related feelings. They may remind participant of their presence and encourage the participant to use breathing exercises or request focused bodywork if needed. The therapists also maintain a safe setting by immediately discontinuing any action, including verbal or physical contact, when the participant says "Stop." Support is also offered by reminding the participant of the strengths and the tools that he or she inherently possesses, such as self-soothing skills that can be used in the face of intense emotional experience, and the ability to survive and arrive at new insights about painful experiences.

Commonly, the therapists are called upon to help the participant examine and negotiate ambivalent feelings or self judgment regarding the appropriateness of emotions or thoughts he or she is experiencing during the MDMA session. For example, finally being able to express anger at an abuser may engender guilt, or the participant may experience cognitive dissonance between newfound feelings of self-forgiveness and self-acceptance and habitual thoughts of self-blame and self-loathing related to the traumatic experience(s). Here the therapists must determine whether or not to intervene. In either case, the therapists seek to maximize the benefits of the inner experience catalyzed by MDMA, while at the same time ensuring that participant is safe and is not re-traumatized by the potential internal conflict. Often this involves simply allowing the experience to unfold without interruption or interference. At other times interaction, support and guidance may be very helpful. Maintaining this balance requires a focus on the verbal and

nonverbal communications of the participant, and an understanding of any potential difficulties the participant might be facing related to the specifics of the participant's psychological history and the nature of his/her healing process. For example, if someone is known to have a tendency to isolate, then the therapists would have a lower threshold for checking in with them and asking about their experience. On the other hand, if someone has a tendency to defend against painful feelings by talking and intellectualizing, the therapists would be quicker to encourage them to put the eyeshades and headphones back on and focus attention "back inside." Maintaining a skillful balance also requires a thorough understanding of the nature of MDMA effects and the non-linear manner in which they can lead to healing effects.

The principal therapist is responsible for disqualifying any participant who has had a sufficiently adverse physiological or emotional response to MDMA during the first session to indicate that he/she would be at risk during a second MDMA session.

5.0 : FOLLOW-UP AND INTEGRATION SESSIONS

The following section describes three aspects of the integrative follow-up sessions: (1) the post-session on the morning following experimental sessions; (2) the structure, nature, and focus of the follow-up sessions; and (3) the therapists' role during these integrative follow-up therapy sessions. It is difficult to predict how much difficulty a given participant will have with the integration process, so it is important to be alert to possible problems as well as open to the possibility of an easy integration that requires minimal intervention beyond empathic listening and sharing in appreciating the participants healing and growth. The therapists should therefore remain flexible in their response to each participant's particular needs.

5.1 Follow-up and Integration Sessions

The initial ninety minute follow-up treatment session is scheduled for the day after the first experimental session and is designed to initiate the integration process. It provides an opportunity to discuss the participant's experience during the experimental session and to process any thoughts or feelings that have come up since the session, including difficult reactions such as anxiety or self-judgment. Participants should be invited, but not required, to talk more about some of the details of their experience during the experimental session, to direct attention toward any insights or emotional shifts that may have resulted and to consider how these changes may be integrated into daily life. Detailed discussion of this kind is often useful during the initial follow-up. On the other hand, at this point, sometimes people have a sense that they would rather allow their inner experience to continue unfolding without attempting to put it into words. If this is the case, the therapists should validate that choice, but should ask for enough information for them to be aware of the participant's emotional state and any difficult feelings or thought patterns that should be addressed before the participant leaves the office.

Therapists remind participants that their experience will continue to unfold in the ensuing hours, days and even weeks. Therapists should re-emphasize their commitment to support the participant during this continued unfolding, and review the procedure by which they can be contacted at any time should the participant or his/her designated support network need to talk with them about any difficulties or concerns.

Subjects should be encouraged not to engage in strenuous, stressful or over-stimulating activity for the remainder of the day, and to rest and relax as much as possible, which may include such activities as a hot bath and a gentle walk in nature.

Plans should be made for daily contact with the therapists by telephone for a week following each experimental session, and two to four additional sessions should be scheduled as indicated by the protocol

Follow-up sessions will continue the integration process and address any challenges that arise. They also prepare the participant for the subsequent MDMA session or the completion of the protocol as appropriate. The therapists engage in an active dialogue and elicit detailed disclosure as a means to accomplish the following:

1.) Assessing how the participant tolerated the MDMA session and discussing the content of the MDMA session and the participants emotional, intellectual and physical response to it. Processing includes discussing the effects on PTSD symptoms and creating ways to integrate new perceptions and insights gained from the MDMA session.

2.) Ensuring that the participant understands that the experience catalyzed by the MDMA-session will likely unfold and resolve over days or even weeks following the treatment session.

3.) Processing any emotional distress or cognitive dilemmas that may arise.

4.) Introducing focused bodywork into the therapy in the event that the participant is experiencing emotional distress that he/she is not able to move through spontaneously or with talk therapy.

5.) Validating any affirming experiences and insights that occurred during the experimental session and helping participants learn to re-connect with and continue to gain from these experiences.

6.) Determining any possible contraindications for the second MDMA-assisted treatment session.

7.) Discussing and reinforcing activities such as journaling or other creative expression, meditation, yoga or other activities that, on a regular basis in daily life, will provide time for the quality of attention that is conducive to ongoing healing and self-awareness.

The therapists remind the participant that they have two options for dealing with upsetting thoughts, memories or feelings lingering after the MDMA session. One is to set aside time to experience them as fully as possible; feeling free to call the therapists for support if necessary. An important basis of this approach is the perspective that waves of difficult experience may recur for some time as a part of the healing process. A second option is to perform relaxation and centering techniques, such as diaphragmatic breathing. This option may be chosen if a given situation does not allow for the first approach. These exercises may be especially important immediately after each MDMA session, as the anxiolytic effects of MDMA decline while some upsetting memories, thoughts or feelings brought forth during the session remain. Information on the utility of focused bodywork and breathing exercises can be reinforced in integration sessions in preparation for the next MDMA session.

Content from the MDMA session will cue the therapists to the likelihood of the participant requiring (or requesting) focused bodywork to assist in working with physical tension or pain. This work catalyzes the healing process by releasing any emotions that may be contributing to somatic complaints and otherwise keeping energy blocked within the body. Focused bodywork is only done with participant permission and is immediately discontinued if the participant requests "Stop." Although focused bodywork may be an important part of the follow-up and integration

sessions for some participants, it should not be used prematurely in an attempt to resolve challenging emotions or their somatic manifestations if they are spontaneously being adequately experienced, emotionally processed and expressed. The focused bodywork is most appropriate in situations in which emotional or somatic symptoms are not resolving because their full experience and expression appears to be blocked. (See Appendix B for more information on focused bodywork.)

Example of focused bodywork in an Integration Session:

Therapist: “How are you today?”

Participant: *“Much better today than yesterday. But you know, this morning, it was the same feeling I had yesterday morning. When my eyes popped open, when the alarm went off, the dread hit me right in the gut. You know, that, ‘I don’t want to get out of bed. I don’t want to do this day.’ Just like I had a bad case of the “don’t want to’s.” I just didn’t feel like I had the strength to get up and face another day. I mean it was just, the minute my eyes popped open, it was dread, knot in my stomach, the anxiety. I mean it was just like automatic. Last night. I slept really well, about 9 hours of sleep. I didn’t have any bad dreams. It was like flipping on a switch, my eyes popped open and here it came. Just felt, it makes me feel sick in my stomach, that kind of fear. You know, that you feel nauseated, just like you want to throw-up. That’s been pretty much the theme today. I haven’t had any other emotional outbursts. I didn’t cry at all today, haven’t felt angry, just that dread, that lump in my gut.”*

Therapist: “So it is like yesterday but on a lower level.”

Participant: *“Much lower. I think a lot of it is my mind set, too. I felt so much better after leaving here last night, realizing if it does happen again, I will live through it. It’s probably going to happen again, but I feel more prepared. It didn’t become overwhelming at all today.”*

Therapist: “MMMmmm.”

Participant: *“Dread and fear were there for so long. You get so used to it you don’t know what it is anymore, especially after having the anxiety disappear. It feels like a whole new wound. It wasn’t the same. It just felt dreadful.”*

Therapist: “Would you be willing to explore that or work with that a little bit today? See what you may discover. Do you feel like you’d like to do some bodywork with that lump in your stomach?”

Participant: *“Yeah. It is time to try some of that, too.”*

Therapist: “It might be a good way to work with it since you know where it is in your body.”

Participant: *“I can envision this croquet ball made out of metal. That’s what is in my mind and that’s how it feels, like a metal croquet ball just sitting right there and it is cold.”*

Therapist: “And that is what you talked about in your sessions, a cold metal feeling in your stomach.”

At this point if the participant agrees, they move to either the futon or a mat on the floor with the participant lying down and the therapists sitting on either side.

Therapist: “So maybe just use your breath and breathe into that feeling in your stomach. I encourage you to remain present with whatever comes up and if your body wants to express it in any way, stand, move, or if you want some resistance from us.”

As the focused bodywork was done, the participant breathed into it and experienced a deep sobbing.

Participant: *“Thank you. I feel a lot lighter. I wonder what that was. I want to know what that was. Just this tightness, this ball, I don’t know what it was. I mean it was like fear and anger and everything in one … started going up and went back down and now it is gone. So is that funny feeling in my stomach and now it is gone.”*

Therapist: This may be what you already processed in your sessions and this is what is left in your body, those emotions.”

Participant: *“This is cool. It is cool for it to be gone.”*

The therapists must exercise judgment about when focused bodywork is indicated to help facilitate the therapeutic process and when it is preferable to allow the process to proceed at its own pace.

For the purposes of this manual we will use the term “focused bodywork” to refer to touch (usually in the form of giving resistance for the subject to push against), which aims to intensify and thereby release tensions or pains in the body that arise during therapy. “Touch” is used as a broader term, including both “focused bodywork” and nurturing touch such as hand holding or hugging. The subject of touch in psychotherapy is complex and is discussed in more detail in Appendix B.

The ultimate goals of MDMA-assisted psychotherapy are to eliminate symptoms and attain an improved level of functioning. This is accomplished as the participant weaves all aspects of therapy into a new relationship with self, others, and with his/her traumatic history. This phase of treatment brings these elements together, in a cohesive, harmonious way. Paradoxically, in some sense, integration begins during introductory therapy sessions, when the participant and therapists discuss the scope of healing potential with this therapeutic approach. Integration involves the ability to access and apply to daily life the lessons, insights, changes in perception, awareness of bodily sensations, and anything else that has been revealed during MDMA sessions.

The therapists and participant use several strategies to bring lessons gleaned from the non-ordinary state of consciousness over the bridge to the ordinary state of consciousness. This is done during the integrative follow-up sessions as the participant works with the therapists to understand and accept the changes he/she has undergone. It involves integrating the meaning of the memories, thoughts, feelings, and insights experienced during the MDMA assisted sessions and determining how this new meaning will be manifested in daily living.

The therapists encourage the participant to record and examine material from the MDMA sessions. They will suggest ways to facilitate this, such as: listening to music from the sessions, listening to the voice-recordings from the MDMA sessions, practicing breathing techniques, or drawing, singing, dance, exercise, painting, or other forms of creative expression. The use of creative endeavors for recalling and retaining memories, thoughts, feelings or insights from MDMA-sessions may provide the participant with a new set of coping skills with which to restructure anxiogenic cognitions and trauma-related environmental cues and triggers. The therapists support these activities that allow the restructuring to emerge from the participant's own thought process, emotional processing and continuing self-exploration.

Each integrative follow-up session should begin with an invitation for the participant to talk about whatever is on his/her mind. This is to ensure that the participant's experience rather than the therapists' agenda will direct the session. After allowing sufficient time for this open-ended discussion and exploration, the therapists should consider directing the session into other potentially useful areas. The therapists may use a variation of the following comments, always in the spirit of offering something for the participant to consider, and with respect for the fact that it may or may not apply to any given individual:

- "Sometimes one of the challenges of this kind of therapy is that the MDMA experience may cause significant changes in a person's point of view or belief systems. It can sometimes be hard to reconcile these changes in thinking with old beliefs or with the attitudes of other people in your life or with the society in general. Is this something you've noticed?

  "Since I've realized how shut down I had been I don't ever want to go back to being that way, so I'm having a hard time in business situations or with my father knowing when not to say everything I'm feeling."

- "Since the MDMA experience is quite unique it can be hard to explain to other people, and it can be painful if such an important experience is misunderstood or judged by other people in your life. It may be important to exercise judgment about how and when you talk about your experience."

- "Often people have very valuable insights and corrective emotional experiences with the help of MDMA that aid in decreasing fear and judgmental thinking. Sometimes the next day the judging mind can get active again and start doubting the truth of these experiences, or sometimes people can have emotional reactions the next day that are different from those they had during the MDMA session. This can sometimes be confusing or upsetting. It's really helpful to acknowledge and talk about it if you're having any experiences like this."

  "*After all these years of not talking about it, today I was thinking, 'was it really safe to reveal that I felt physical pleasure along with horror when I was abused'?"*

"Now that the medicine has worn off I sometimes feel guilty for saying the things I did about my parents not being emotionally available. I know it wasn't about blame, but there's still that judging voice that says we don't talk about any of this."

- "It is very common for the MDMA experience to continue to unfold for days after the session. Often it unfolds in an easy, reassuring way, but sometimes it can be more difficult. Sometimes working with traumatic experiences in any therapy, including MDMA assisted therapy, can stir things up so that symptoms may temporarily get worse. This may come in waves of emotion or memories. When this happens it is part of the healing process and we're here to help you work with anything that comes up for you after the MDMA sessions. It's important to let us, ("and your other therapist" if they have one) know about it if you have any difficulties like this.

"*The anger feels like a volcano, I'm afraid of being a one man wrecking crew, I feel such sadness, loneliness, nausea."*

- "Sometimes people have powerful insights and a sense of comfort and peace that they've rarely or never experienced before. It's natural to want to hold on to this, and sometimes people tell us that when some of the old painful experiences return it feels like a failure or that it means they didn't really have any healing. It is helpful to anticipate that painful feelings are bound to come sometimes and some of the old patterns of thinking, feeling and reacting are bound to reconstitute themselves, even after you've seen past them so clearly. That's a natural part of the process, and what happened in the MDMA experience is likely to help you recognize and step out of these patterns sooner even when you do get caught. People often tell us that being able to think back to the experience can change your relationship to these painful emotions."

"I have respect for my emotions now (rather than fear of them) What's most comforting is knowing now I can handle difficult feelings without being overwhelmed. I realize feeling the fear and anger not nearly as big a deal as I thought it would be."

"Being able to feel again is indescribable, like a blind person being able to see again. I used to have a barrier between me and everyone else."

"Without the study I don't think I could have ever dug down deep, I was so afraid of the fear. In the sessions there was just no fear; that builds your confidence. When I tried in therapy before it would send me into a tail spin."

"It has felt like growing up, I feel wiser, more emotionally mature."

- "It may be helpful to write about your MDMA experience and your thoughts and feelings since then. It's best to write this for yourself without the thought of doing it for anyone else, but if you want to bring it in to share with us that could be useful as well. It may also be helpful for you to listen to the audio tape of the session in connection with this assignment."

- "It can be helpful to write down your dreams and bring them in to discuss with us. For some people MDMA makes dreams more vivid and meaningful."

- "There are some books we can recommend that address some of the experiences you've been talking about."

- "Drawing, painting, collage, working with clay can all be helpful, nonverbal, ways of expressing and further exploring your experience."

- "If a lot of feelings or images are coming up for you after the MDMA session it's good to allow them to unfold and explore them when you have time and energy to do so, but it can also be important to set them aside when you have other obligations or when you need a break. It may be helpful to write a sentence or two about what you are setting aside and acknowledge that you will attend to it later, either in the therapy or when you have the time and energy. Hot baths, walks in nature, physical exercise, working in the garden, cleaning the house, nourishing food, playing with a pet are all activities that can help to ground you in the present."

- "If there are tensions left over in the body, yoga or a massage can be helpful."

- This is not a "no pain, no gain" situation. Sometimes moving through waves of painful feelings and memories is part of the unfolding process, but connecting with easy, affirming, pleasurable experiences are part of the healing too and are at least as important as willingness to be with the painful ones.

  "I feel a whole deeper level of consciousness, calmer, peacefulness, I don't remember ever having this, my mind has never been at peace like this"

  "I feel like I'm walking in a place I've needed to go for so long and just didn't know how to get there. I feel like I know myself better than I ever have before. Now I know I'm a normal person. I've been through some bad stuff, but…those are things that happened to me, not who I am…This is me, the medicine helps, but this is in me."

- Sometimes during MDMA sessions there are very rapid shifts and people feel that something difficult has really resolved. Its good to be open to that possibility, but often it's more that people feel they've gotten past some big obstacles and made important steps along their path of healing and growth so they're in a better position to keep working with it and continuing to heal and grow.

  "I got a glimpse of more of what I'm capable of growing into…I'm motivated to keep practicing openness until it gets more developed …"

  "Now I have a map of the battlefield."

> *"I had never before felt what I felt today in terms of loving connection. I'm not sure I can reach it again without MDMA but I'm not without hope that it's possible. Maybe it's like having an aerial map so now I know there's a trail."*
>
> *"Last night I had a clear sense that I got where I needed to get. What was missing has been found. What I needed I've gotten. I don't feel like I need to do it again. I think there are still other issues in my life that I can work on with less intense methods."*

During the integrative follow-up therapy sessions, the participant continues the process of accessing and interpreting the other levels consciousness experienced during the MDMA sessions. This expansion in consciousness may lead to a personal paradigm shift. The shift in self and other-related cognition and emotion is then applied to subsequent experiences that trigger unwanted and habitual patterns of thought or emotion. For instance, a lack of trust in the safety of the environment or the trustworthiness of others can be countered by accessing the sense of safety and closeness to others first experienced during the MDMA-assisted session. With the therapists' help, the participant develops a bridge between ordinary consciousness and his/her experiences in non-ordinary states of consciousness, so that these states are experienced more as a continuum than as separate realms. For example, the participant is able to readily access two of the most noted therapeutic aspects of the MDMA experience, "inhibiting the subjective fear response to an emotional threat" (Greer & Tolbert, 1998, p. 371) and increasing the range of positive emotions toward self and others (Adamson, 1985; Cami et al, 2000; Grinspoon & Bakalar, 1986) at times when he/she may be confronted with cues of the traumatic event(s). This allows the participant to maintain a sense of calm security in the face of these anxiogenic stimuli. The ability to expand consciousness in this way helps the participant restore a sense of intrapersonal safety and gain mastery over the debilitating symptoms of PTSD.

Participant: (Crying)

Therapist: "Can you tell us, what's going on?"

Participant: *"I'm just not holding it together very well. I've been like this all day long.* (Crying, sniffling) *It took everything I had to get out of bed this morning."*

Therapist: "What feelings are you having?"

Participant: *"Right now I am just pissed.* (Crying) *I'm very angry.* (Sniffling*) I was scared that I was just going to lose it. You know, I just couldn't hold myself together. As busy as I tried to stay at work, you know, I didn't even want to go to work this morning."*

Therapist: "Were you angry when you woke up this morning?"

Participant: *"No, I wasn't angry. I was more hopeless this morning."*

Therapist: "You know, Tamra, I know this is really hard, especially hard to do this and go to work at your job. As hard as it is, I think this is really valuable what is coming up for you. You said you saw the

feelings one time, the second time you had the feeling, and now the feelings are still coming. The fact that they are still coming this strongly is much more than just a superficial kind of moving through them. You are really moving through them in a deep way.

Participant: *"I know. It's so bad. I don't want my life to be like this and I'm just pissed off that I have to go through all of this.* (Sobbing) *I'm afraid it is never going to go away. I'm gonna be stuck like this forever."*

Therapist: "You know, we've seen this so many times in Breathwork and in this work with MDMA, that we know when this kind of thing happens, especially when you're feeling it all in your body, it's not a sign that you are getting worse or you're going to be this way forever. It's a sign that you're really dealing with this stuff that you've been carrying around all this time."

Participant: *"It's so overwhelming, though. I'm afraid I'm just going to crack up. You know I'm afraid I'm just going to lose it. I'm afraid I can't handle it."*

Therapist: "I can understand that. Did the Lorazepam help?"

Participant: *"I stopped shaking, but that's as far as it went. I actually took one, then I waited about an hour and a half and I took another one."*

Therapist: "MMMmmm"

Participant: (Big breath.)

Therapist: "So maybe, this is so different from the way you've been used to keeping it together. As you talked about… 'OK that's done, it's behind me and it's time to move on'. And that's served you in some ways, but the cost of that has been to be cut off from your feelings, being anxious and experiencing derealization. So now your psyche is not letting you do that any more."

Participant: *"But the derealization has been so bad. It's just been off the charts last night and this morning. I was just sitting there and Tom got up to make coffee and I was just, I didn't think I was going to make it. It was past surreal. It was past anything that's ever been."*

Therapist: "Often what happens is both things intensify. You start to have the feelings you've been having this defense against, and they intensify, and so the defense intensifies."

Participant: *"That makes sense.* (Calmer now). *I hadn't thought about that. All I could think of is I know it is going to get worse before it gets better. But am I going to be able to live through the worst part?"*

Therapist: "Remember the last time, your first day back at work was hard for you."

Participant: *"Yeah."*

Therapist: "And it has been different this weekend than the last time, but your first day back at work you had some anxiety. It was hard, it wasn't like today. That's been my experience with MDMA, a few days after and it hits me like that, with anxiety and even panic attacks, it's scary but it always goes away."

Participant: (Big breath, sigh) *"I told Tom this morning, 'What's gonna happen if I get so incapacitated that I can't work?'"*

Therapist: "So far you have been able to work and hold it together when you needed to. You've been doing great. It was just a few days, couple of days this weekend, and remember you just had a very powerful session. You know, it can really help to have the perspective that these intense feelings are part of the healing process, but that still doesn't mean you can just finess it and not really feel them. When you're processing fear you really do feel the fear. "

Participant: *"It's so strong. It's not like the sadness in my chest. It isn't localized, something I can put my finger on. I think that worries me too. I think it should be a certain way and it's not. You know I just flat out think I'm losing it. I'm going crazy."*

Therapist: "It's really hard to just surrender to trusting that your process is unfolding the way it needs to. When you're in the middle of it, it's really hard to have that perspective. I think the more you can set aside your judgment about whether it is going the right way or the wrong way, and just follow it and let us support you in it you'll see that it's leading you in the direction of healing."

Participant: *"I'm sure it is too. It's just so dang scary. It's so overwhelming."*

Therapist: "One thing that can happen is that during the session you may feel like you are having those feelings, but you may not really have the emotions until after. It's very common for it to present like this – having these emotions now – that kind of lag behind the session is common."

The therapists recognize that the information revealed during the MDMA and integrative follow-up sessions serves as a starting point for enhancing the participant's emotional and behavioral repertoire in response to trauma triggers and PTSD symptoms. In the days between the MDMA sessions and integrative follow-up sessions, the participant is encouraged to be mindful of any changes in his/her perceptions thoughts, feelings, interactions, and other experiences. When confronting emotionally threatening material he/she is encouraged to return to or reactivate the feelings of intimacy and closeness to others and the reduced fear originally experienced during the MDMA treatment sessions. Teaching the participant to do this between MDMA sessions involves cueing him/her to recall the accepting attitude experienced during the MDMA session and to ask him/herself, "How can I best use my new knowledge in this situation?" The therapists will validate the participant's use of this technique.
The newly constructed meanings that the participant has arrived at through MDMA sessions and integration of this material afterwards can serve as a template for coping with a variety of PTSD symptoms, including those related to anxiety and those related to interpersonal relationships. The participant should feel less fearful, with a greater sense of self-control or insight when confronted with trauma-related triggers or memories.

Participant: *"Basically more than the trust I have in other people, it hits the trust I have in myself, the ability to know my inner strengths -- and I know they are there. It's just when it shakes you to the core you can't help but second guess and question. It's feels like it's bombarding me from different directions and you don't know which way to go or what to do."*

Therapist: "In a way it is shaking to the core. In a way that is what you asked for."

Participant: (Laughs). *"That's what I got, it wasn't in the brochure."*

Therapist: "We didn't have those terms exactly, but I think shaking you to the core is going to involve releasing the old ways of having to keep that false sense of control."

Participant: (Sighs) *"Does the derealization ever go away?"*

Therapist: "Yes"

Participant: *"I'm trying to train my brain to enjoy it. I have all these tools; I just need to remember to use them."*

Strengthened interpersonal trust helps the participant to further develop his or her social network. Greater insight into the whole range of thoughts and feelings about the trauma gives the participant confidence in confronting his or her emotions and reduces the likelihood of emotional numbing. Maintaining and nurturing the participant's social network may also be made easier when an individual has gained a sense of mastery over feelings of terror or shame and when he or she is better acquainted with these feelings. Relying on the new perspectives gained from the MDMA session, the participant can confront anxiety-producing situations with more confidence and may be more comfortable with asking for assistance from his/her supportive network.

"I have respect for my emotions now (rather than fear of them) What's most comforting is knowing now I can handle difficult feelings without being overwhelmed. I realize feeling the fear and angeris not nearly as big a deal as I thought it would be."

"Being able to feel again is indescribable, like a blind person being able to see again. I used to have a barrier between me and everyone else."

5.3 Therapists Role During Follow-Up and Integration Sessions

During follow-up and integration sessions, the therapists are present to answer any questions the participant may have about his or her experiences and offer support and encouragement as the participant processes the intrapsychic realities and new perceptions gained through the MDMA session. The therapists take a supportive and validating stance toward the participant's experience. They also facilitate the participant's understanding of the trauma from insights and perspectives gained from the opening of new channels of emotion and thought, and the clearing of other reactions and thoughts that may have outlived their usefulness. The therapists may offer insights or interpretations of the participant's experience, but this should be minimized. Participants should be encouraged to exercise their own judgment about what comments they may or may not find useful and to primarily apply their own experience and understanding.

The therapists work to maintain the participant's focus on his/her therapeutic goals, work through the memories of the traumatic event(s), and help the participant come to new conclusions about the meaning of these events. The therapists clearly position themselves throughout the therapy in the roles of empathic listener, trustworthy guide, facilitator of deep emotional expression and catharsis, and assistant to participant's bodily wisdom in self-healing.

As empathic listeners, the therapists attend to the participant's account of his/her inner experience and create space for the participant's own meanings or for his/her ambivalent thoughts and feelings about the experience. The therapists offer the appropriate assistance needed for the participant to cope with any apparent ambiguity, while fostering the awareness that it is the participant who is responsible for his/her own healing.

The process of MDMA-assisted psychotherapy for the treatment of PTSD continues well after the MDMA sessions are complete. The challenge at this stage is to help the participant develop a wider behavioral and emotional repertoire with which to respond to anxiogenic stimuli. To reach this goal the therapists and participant embark on integration of the treatment process. To function effectively in everyday life, the participant must be able to integrate the valuable insights from the treatment process.

REFERENCES

Adamson S (1985) Through the gateway of the heart: Accounts of experiences with MDMA and other empathogenic substances. Four Trees Publications, San Francisco, CA.

Assigioli, R. (1971) Psychosynthesis. Viking Penguin, New York

Blake DD, Owens MD, & Keane TM (1990). Increasing group attendance on a psychiatric unit: an alternating treatments design comparison. J Behav Ther Exp Psychiatry, 21: 15-20

Brady K, Killeen T, Saladin M, Dansky B, & Becker S (1994). Comorbid substance abuse and posttraumatic stress disorder: characteristics of women in treatment. American Journal of Addiction, 3, 160-164

Cami J, Farre M, Mas M, Roset PN, Poudevida S, Mas A, San L, de la Torre R (2000) Human pharmacology of 3,4-methylenedioxymethamphetamine ("ecstasy"): psychomotor performance and subjective effects. J Clin Psychopharmacol 20: 455-466

Davis M, Walker DL, Lee Y (1997) Amygdala and bed nucleus of the stria terminalis: differential roles in fear and anxiety measured with the acoustic startle reflex. Philos Trans R Soc Lond B Biol Sci 352: 1675-1687

d'Otalora, M. MDMA and LSD Therapy in the Treatment of Post Traumatic Stress Disorder in a Case of Sexual Abuse http://www.maps.org/research/mdma/moaccount.html

Downing J (1986) The psychological and physiological effects of MDMA on normal volunteers. J Psychoactive Drugs 18: 335-340

Dunn BG and Greene E (2002) Voices, A History of Body Psychotherapy. USA Body Psychotherapy Journal, 1: 53-117

Faustman, WO & White, PA (1989). Diagnostic and psychopharmacological treatment characteristics of 536 inpatients with posttraumatic stress disorder. J Nerv Ment Dis, 177(3), 154-159

First MB, Spitzer R, Gibbon M, & Williams J (1994). Structured clinical interview for Axis I DSM-IV disorders. Patient Edition (SCID-I/P, vs 2.0)

Foa, F.B., Keane, T.M., & Friedman, M.J. (2000). Introduction. In Foa, F.B. et al (Eds), Effective Treatments for PTSD (pp.1-17). New York: Guilford Press.

Foa FB, Rothbaum BO, Furr JM. (2003) Augmenting Exposure Therapy with other CBT Procedures. Psychiatric Annals, 33(1) 47-53.

Foa EB, Hembree EA, Rothbaum BO. (2007): *Prolonged exposure therapy for PTSD: emotional processing of traumatic experiences: therapist guide.* New York: Oxford University Press.

Foa EB Keane TM, Friedman MJ, Cohen JA. (2009) Effective treatments for PTSD, practice guidelines from the international society for traumatic stress studies, 2nd ed. Guilford Press, New York, NY

Fox HC, Toplis AS, Turner JJD, Parrott AC (2001) Auditory verbal learning in drug-free polydrug users. Human Psychopharmacol Clin Exp, 16: 613-618

Fox, HC, Parrott, AC and Turner, JJD (2001) Ecstasy use; Cognitive deficits related to dosage rather than to self-reported problematic use of the drug. J of Psychopharmacology, 15: 273-281

Gamma A, Buck A, Berthold T, Liechti ME, Vollenweider FX (2000) 3,4-Methylenedioxymethamphetamine (MDMA) modulates cortical and limbic brain activity

as measured by [H(2)(15)O]-PET in healthy humans. Neuropsychopharmacology 23: 388-395

Gasser P (1994) Psycholytic Therapy with MDMA and LSD in Switzerland. MAPS Newsletter 5: 3-7

Gouzoulis-Mayfrank, E, Daumann J, Tuchtenhagen F, Pelz S, Becker S, Kunert HJ, Fimm B, Sass H (2000) Impaired cognitive performance in drug free users of recreational ecstasy (MDMA). J Neurol Neurosurg Psychiatry 68: 719-725

Greenspan M (1995) Out of bounds. Common Boundary, July/August; 51-58

Greer G, Tolbert RA (1986) Subjective reports of the effects of MDMA in a clinical setting. J Psychoactive Drugs 18: 319-327

Greer GR, Tolbert R (1998) A method of conducting therapeutic sessions with MDMA. J Psychoactive Drugs 30: 371-379

Grinspoon L, Bakalar JB (1986) Can drugs be used to enhance the psychotherapeutic process? Am J Psychother 40: 393-404

Grinspoon L, Doblin R (2001) Psychedelics as catalysts in insight-oriented psychotherapy. Social Research, 68; 677-695

Grob CS and Poland RE (1997). MDMA. In Lowinson JH, Ruiz P, Millman RB , Langrod JG (Eds.) Substance Abuse: A comprehensive textbook, 3rd Ed (pp. 269-275). Willians and Wilkins, Baltimore MD,

Grob CS, Poland RE, Chang L, Ernst T (1996) Psychobiologic effects of 3,4-methylenedioxymethamphetamine in humans: methodological considerations and preliminary observations. Behav Brain Res 73: 103-107

Grof S (2001; 1980) LSD Psychotherapy. Multidisciplinary Association for Psychedelic Studies, Sarasota FL.

Grof S (2000) The Psychology of the Future. SUNY Press, Albany, NY.

Harris DS, Baggott M, Mendelson J, Mendelson JE, Jones RT (2002). Subjective and hormonal effects of 3,4-methylenedioxymethamphetamine (MDMA) in humans. Psychopharmacology (Berl). 162: 396-405

Horvath AO and Greenberg LS (1989). Development and validation of the Working Alliance Inventory. Journal of Counseling Psychology, 36 (2), 223-233

Horowitz M, Wilner N, & Alvarez W (1979). Impact of Event Scale: a measure of subjective stress. Psychosom Med, 41, 209-218

Jaycox, LH, Zoellner L, Foa EB, (2002) Cognitive-Behavior Therapy for PTSD in Rape Survivors. Journal of Clinical Psychology, 58(8) 891 - 906.

Jaycox LF, Foa EB (1999) Obstacles in Implementing Exposure Therapy for PTSD: Case Discussions and Practical Solutions. Clinical Psychology and Psychotherapy 3:176–184

Johnson SM (1996) Emotion focused couple therapy with trauma survivors; Strengthening attachment bonds. Guilford Press: New York NY.

Johnson MW, Richards WA, Griffiths RR (2008) Human hallucinogen research: guidelines for safety. J Psychopharmacol, 22(6): 603–620

Krupnick JL. (2002) Brief Psychodynamic Treatment of PTSD. Journal of Clinical Psychology, 58(8) 919-932.

Lester SJ, Baggott M, Welm S, Schiller NB, Jones RT, Foster E, Mendelson J (2000) Cardiovascular effects of 3,4-methylenedioxymethamphetamine. A double- blind, placebo-controlled trial. Ann Intern Med 133: 969-973

Liechti ME, Gamma A, Vollenweider FX (2001a) Gender differences in the subjective effects of MDMA. Psychopharmacology, 154: 161-168

Mas M, Farre M, de la Torre R, Roset PN, Ortuno J, Segura J, Cami J (1999) Cardiovascular and neuroendocrine effects and pharmacokinetics of 3, 4-methylenedioxymethamphetamine in humans. J Pharmacol Exp Ther 290: 136-145

Metzner R, Adamson S (2001) Using MDMA in Healing, Psychotherapy and Spiritual Practice. In Holland J (Ed). Ecstasy: The complete guide. (pp. 182-207). Inner Traditions: Rochester VT. Originally published in ReVision 10(4) (1988) The nature of the MDMA experience and its role in healing, psychotherapy and spiritual practice.

Milakovich J (1998) Differences between therapists who touch and those who do not. In Smith EW, Chance NR, Imes S (Eds).Touch in Psychotherapy. (pp. 74-91) The Guilford Press: New York, NY.

Mitrushina, Maura N; Boone, Kyle Brauer; D'Elia, Louis F.(1999). Handbook of normative data for neuropsychological assessment. Oxford University Press, New York, NY.

Montgomery S & Bech P (2000) ECNP consensus meeting, March 5-6, 1999, Nice. Post traumatic stress disorder: guidelines for investigating efficacy of pharmacological intervention. ECNP and ECST. European Neuropsychopharmacology. 10: 297-303

Morgan MJ (1999) Memory deficits associated with recreational use of "ecstasy" (MDMA). Psychopharmacology (Berl) 141: 30-36

Naranjo C (2001) Experiences with the interpersonal psychedelics. In Holland J. (Ed) Ecstasy: The Complete Guide. (pp. 208-221) Inner Traditions; Rochester VT.

Ogden P, Minton K, Pain C (2006) Trauma and the body. W.W. Norton & Company, New York, NYPiedmont, Ralph L. (1998). The revised NEO Personality Inventory: Clinical and research applications. Plenum Press, NewYork, NY.

Rasmusson AM, Charney DS (1997) Animal models of relevance to PTSD. Ann N Y Acad Sci 821: 332-351

Rodgers, J. (2000). Cognitive performance amongst recreational users of "ecstasy." Psychopharmacology, 151, 19-24

Randolph, C. (1998). Repeatable Battery for the Assessment of Neuropsychological Status manual. The Psychological Corporation, San Antonio, TX.

Roman, Deborah D; Edwall, Glenace E; Buchanan, Rebecca J; Patton, Jim H. (1991). Extended norms for the paced auditory serial addition task. Clinical Neuropsychologist, 5: 33-40

Schwartz,R. (1995) Internal Family Systems Therapy. Guilford Press: New York

Siegel D. (1999) The Developing Mind. Guilford Press: New York

Styk J (2001) MDMA Therapy in Switzerland. From site: http://www.inch.com/~jholland/newuploads/styk.htm
Published on-line: Date unknown, prob. between Aug-Nov 2001

Tancer ME, and Johnson C-E (2001). The subjective effects of MDMA and mCPP in moderate MDMA users. Drug Alcohol Depend, 65: 97-101

Urasano J et al, American Journal of Psychiatry Supplement, v 161, n. 11, November 2004

Vollenweider, FX, Gucker, P., Schönbächler, R, Kamber, E, Vollenweider- Scherpenhuyzen, MFI, Schubiger, G, & Hell, D (2000). Effects of MDMA on 5-HT uptake sites using PET and [11C]-McN5652 in humans. Data presented at 2000 conference of the German Society for Psychiatry, Psychotherapy and Neuromedicine [Deutsche Gesellschaft für psychiatrie, Psychotherapie und Nervenheilkunde]

Vollenweider FX, Gamma A, Liechti M, Huber T (1998) Psychological and cardiovascular effects and short-term sequelae of MDMA ("ecstasy") in MDMA-naive healthy volunteers. Neuropsychopharmacology 19: 241-251

White KE (2002) A study of ethical and clinical implications for the appropriate use of touch in psychotherapy. USA Body Psychotherapy Journal, 1; 16-41

Widmer, S (1998) Listening into the heart of things: The awakening of love: On MDMA and LSD: The undesired psychotherapy. Gerolfingen, Switzerland: Basic Editions.

Wilbarger, P. & Wilbarger, J. (1997), Sensory defensiveness and related social/emotional and neurological problems. Van Nuys, CA: Wilbarger. (May be obtained from Avanti EducationProgram, 14547 Titus St.,. Suite 109, Van Nuys, CA, 9l402)

Wolfson PE (1986) Meetings at the edge with Adam: A man for all seasons? Journal of Psychoactive Drugs 18: 329-333

APPENDIX A: COMPARISON OF THERAPEUTIC APPROACHES FOR TREATING PTSD

In November 2004 the American Psychiatric Association (APA) published Practice Guidelines for the treatment of PTSD (1). The three psychotherapeutic interventions recommended for established PTSD are:

- Cognitive and behavior therapies
- Eye movement desensitization and reprocessing (EMDR)
- Psychodynamic psychotherapy

Although the APA endorses the above therapies in their Practice Guidelines, it is noteworthy that they also imply the need for research into more effective treatment techniques, with their statement that “there is a paucity of high-quality evidence-based studies of interventions for patients with treatment-resistant PTSD….” (1).

The APA practice guidelines state that the goals of PTSD treatment “include reducing the severity of … symptoms…(by) improving adaptive functioning and restoring a psychological sense of safety and trust, limiting the generalization of the danger experienced as a result of the traumatic situation(s) and protecting against relapse.” It goes on to say that “…factors that may need to be addressed in patients who are not responding to treatment include problems in the therapeutic alliance; the presence of psychosocial or environmental difficulties; the effect of earlier life experiences such as childhood abuse or previous trauma exposures…” (1)

Despite significant differences between these types of therapy, including MDMA-assisted therapy, they all share some important theoretical underpinnings. Moreover, some of the therapeutic experiences that occur with any of these approaches are very similar. This is not surprising, since each approach, in its particular way, is stimulating universal, innate healing mechanisms. For instance, the nondirective approach of MDMA-assisted therapy often leads to the spontaneous occurrence of many of the kinds of experiences that are more directly elicited and thought to be therapeutically important in these other approaches. As noted previously in this treatment manual, the therapists’ role is first to prepare participants for this likelihood by encouraging a non-controlling and open attitude toward experiences that arise and then to support the unfolding and the subsequent integration of these experiences. MDMA can act as an important catalyst to this process.

Table 1 briefly compares the major therapeutic approaches for treating PTSD, including the therapeutic elements discussed in the APA guidelines, in Dr. Edna Foa’s excellent manual of cognitive-behavioral therapy for PTSD (2), and in the protocol outlined in this treatment manual.

References

1. Urasano J et al, American Journal of Psychiatry Supplement, v 161, n. 11, November 2004

2. Foa E and RothbaumB, Treating the Trauma of Rape, Cognitive-Behavioral Therapy for PTSD, The Guilford Press, New York, NY, 1998