MDMA-Assisted Psychotherapy for the Treatment of Posttraumatic Stress Disorder

A Revised Teaching Manual Draft (Revised 11/24/08)

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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, <u>http://www.maps.org/research/mdma/moaccount.html</u>; 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 MDMAassisted therapy for PTSD.

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 the 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 are hypothesized to enhance the rate of recovery from PTSD.

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.

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 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.

2.1 Prerequisites and Contraindications

The first prerequisite for conducting MDMA-assisted psychotherapy with 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. The participant must have experienced at least one unsuccessful attempt at treatment with medications and/or psychotherapy, including a trial treatment with a selective serotonin re-uptake inhibitor (SSRI). 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 will be enrolled in the study. With respect to the current study, the type of previous psychotherapy must be established as effective, based on a controlled clinical trial. This includes cognitive-behavioral therapy (including exposure therapy), stress inoculation training, including anxiety management, and insight-oriented psychotherapy (Foa et al. 2003; Jaycox et al. 2002; Krupnik 2002; Resick and Schenk 1992). 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 and in writing 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, hormone replacement, NSAIDS, or other medications approved by the physician supervising the MDMA-assisted therapy). If the participant is taking any other 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 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 who weigh less than 50 kg or more than 105 kg.
- e.) Participants with substance abuse or dependency within the past three months.
- f.) Participants who present a suicide risk or who are at risk for hospitalization.
- g.) 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.
- h.) 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.

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 semistructured 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. 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.
- 4. Symptom Checklist 90: This is a standardized instrument used to measure subjective feeling states.
- 5. 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.

2.1.2 Additional Assessments (During and Post-Treatment)

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

- 6. Working Alliance Inventory: WAI (Hovrath and Greenburg, 1989). The WAI is a 36-item selfreport 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.
- 7. 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
- 8. 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.

- 9. 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.
- 10. Rey-Osterrieth Complex Figure: (Mitrushina et al, 1999). This measures visuoperceptual skills, spatial organizational skills, and memory.

In the current study, measures 8, 9 and 10 will be administered as baseline and again after both MDMAassisted 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 PHASE I: PREPARATION FOR MDMA-ASSISTED THERAPY SESSIONS

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 two ninety-minute introductory sessions with the therapists.

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

3.1.1 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). 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 and let them inform you of what is going on inside of you."

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."

3.1.2 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.

3.1.3 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 deepseated patterns of fear, powerlessness, guilt, and shame.

The therapists also remind the participant to be open to experiencing, understanding, and achieving relief from his/her PTSD symptoms and the underlying trauma as part of the therapeutic process. The therapists emphasize their commitment to help the participant with realizing, feeling, and expressing the emotional material that may arise during the session. They 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."

Therapist: "If you decide you need to be on an antidepressant you can do that. 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 absolutely essential that the therapists use clinical judgment and personal awareness to ascertain when to facilitate the participant's process vs when to silently witness the participant's experience, as explained in more detail in Stage Three. The participant is encouraged 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.

3.2 Creating a Safe Psychological and Physical Space

Establishing a safe setting 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. A safe physical and psychological space allows and encourages the participant to attend to his/her internal stimuli. The setting as a whole is designed to minimize the impact of external stimuli and to support the participant's attention to his/her intrapsychic process. The therapists create a favorable setting in two basic ways: by establishing a contract with the participant, as outlined below, and by attending to several physical details of the setting. For instance, the participant should be able to recline comfortably in a setting devoid of any unfavorable distractions (free of all objects that could have powerful negative or disturbing connotations). While the research setting should be as supportive as possible, the participant should be aware of all safety measures in place to respond to the unlikely possibility of a medical complication. The participant is provided with eye shades and a pre-selected program of music. Music for the drug session is selected on the basis of its ability to elicit emotional responses or to facilitate a sense of passage or transformation. Music is chosen to support emotional experience while minimizing suggestion, with music containing lyrics generally avoided (Grof, 2000). The participant has the option to request periods of silence and the

therapist has the option to forgo sections of the musical program. Participants may also elect to forgo eyeshades.

To create the safest possible psychological space, the therapist and participant discuss the parameters of each session and make several specific agreements, 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 contraindicated by the clinicians.
- 2. The participant agrees to have a prearranged ride home the following morning.
- 3. At least one of the therapists is present at all times during the entire MDMA session.
- 4. The participant and therapist discuss the possibility of physical contact with the participant in the form of focused bodywork and nurturing touch is discussed. 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 except when such action is necessary for the participant's safety.
- 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 complies with the therapists request to stop according to the terms of this agreement. The participant understands that failure to respond to the request may require an appropriate level of intervention.

To enhance further the safety of the psychological space, the participant and therapists address any fears the participant may have, no matter how trivial or catastrophic. 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 is a real issue; however, in reality you'll be more deeply yourself. You'll be reconnected with yourself in a deeper way."

Therapist: "One thing you said earlier was that you wanted to run off and hide. Maybe you lost part of yourself, a part of you disappeared."

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

Therapist: "So this might be an answer without having to run away. You may find that you become more deeply yourself. You are willing to do this and face it."

The participant is 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 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.

Another important aspect of developing a psychologically and physically safe space involves a joint exploration of the members of the social support system surrounding the participant. Before any MDMA-assisted treatment session, the therapists and participant may consider ways in which the members of his/her social support network 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. 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 a safe physical space 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, may need additional intervention. 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 or pulse during the MDMA session. When providing beverages, the therapists should ensure that participants do not consume over 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. In this early pilot study, the therapists are

prepared to treat a number of unlikely adverse events, and they will have an emergency medicine physician and nurse present for five hours after drug administration.

3.3 Therapist Foundation

In addition to standard training in the psychotherapeutic treatment of PTSD, therapists 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 BreathworkTM 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, especially features that might be most helpful or 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 encourage the participant to share his/her internal process at the start of the MDMA session. 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.

The therapists realize the medicine's qualities to enhance and intensify the therapeutic experience. The therapists respect the medicine's "apparent facility in inducing heightened states of empathic rapport" (Grob et al, 1996, p. 103) and operate within the previously discussed ethical guidelines and established parameters of treatment. The therapists remain mindful of their own mental set vis a vis this therapy, especially their own beliefs related to the use of MDMA as an adjunct to therapy.

4.0 PHASE II: MDMA-ASSISTED PSYCHOTHERAPY SESSIONS

This section discusses the three steps in the Phase II: MDMA sessions: initiating therapy, first MDMA-assisted therapy session, and second MDMA-assisted therapy 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 gaining new perspectives about life experiences and clearing emotional and somatic blocks resulting from past trauma as the participant confronts trauma-related memories, thoughts, and feelings within a designated "safe space" provided by the therapeutic set and setting and the effects of the MDMA.

The MDMA-assisted treatment sessions are discussed below in four sections. As the therapists prepare the participant for ingesting the medication, they review common manifestations of the MDMA experience (Section 4.1). The next step involves working with the acute and sub-acute effects of the medication (Section 4.2). The role of the therapists throughout the treatment session is discussed separately in Section 4.3.

4.1 Initiating Therapy

At the beginning of the MDMA session, the therapists review a range of experiences that can occur during the session, and inquire about any concerns the participant might have. This encourages the participant to disclose his/her feelings about the process and provides the therapists with the opportunity to reassure and support the participant's 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 not conscious of. It's scary. The paradox is although it could stir 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. All that we talked about. 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: "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 orient toward the deleterious effects of the trauma sans the terror 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 selfblame and judgment. This combination of drug effects should support the participant in overcoming the emotional numbing of PTSD and open him/her to more fully experiencing the full range of emotions (grief, fear, rage) 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. The decrease in emotional numbing may also create a context in which the participant is able to experience a fuller range of emotions including joy, happiness, love, and comfort.

4.2 MDMA-Assisted Therapy Sessions

4.2.1 First MDMA-Assisted Therapy Session

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. The participant is encouraged to recline on the futon, use eye shades, and relax into the music selected for the session. The therapist softly reminds the participant to be open to whatever unfolds and trust his/hers innate healing capacity.

Therapist: "You mentioned that you're worried that this stuff with your dad may come up and it is fine for this type of material to arise."

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."

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 reminds the participant of the therapists' presence and provides the therapists with a cue as to the participant's inner status. After this brief interaction, the therapists encourage the participant either to return to an inner focus or share the 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. 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."

Most of the MDMA-treatment session consists of the participant attending to his/her intrapsychic experience and the therapists maintaining a clear empathic presence to support the process of the MDMA-treatment session. As the session progresses, the participant is likely to experience a positive mood and a sense of trust for both self and others. This allows for the emergence of traumatic memories and painful emotions supported by 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.

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: "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.)

Participant: "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 7layer 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 the traumatic memories and associated thoughts and emotions. With more self-acceptance and less self-criticism, the participant gains self-confidence, 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 the powerful emotions to surface. The sense of safety and facilitated recall may work in concert to facilitate deeper or more intense exploration of the trauma-related events and/or their effects on relationships and other aspects of the participant's life.

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.

Participant: "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."

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 instructions intended to improve the therapeutic experience or to help the participant experience fully a particular element of the experience, such as a difficult memory, insight or feeling.

Participant: "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. 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.

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. 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."

The therapists must recognize and work with both the participant's underlying psychological processes and the experience produced by the medicine. This involves simultaneously supporting the participant in experiencing the negative effects of the trauma and experiencing the softening

effects of MDMA. The therapists' presence and the effects of the medicine provide a feeling 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-pride and under there is fear and anger. It is finally safe to revisit that."

Participant: (Breathing softly.)

The therapists continually create a safe space for the participant as he or she experiences increased access to memories or thoughts. The medicine may also produce in some participants a feeling of loss of control. The therapists work with the participant to embrace these feelings and move through them as the participant is encouraged to surrender control and open to inner emotions which may previously have been too fearful to encounter.

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 more 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."

The 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. This may take the form of introducing the 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, orienting the participant to the "here and now"; encouraging the participant to talk about his/her emotions; holding the participant's hand; or providing other nurturing touch. In this way, the therapists help the participant to stay with and move through his/her emotional experience, (i.e., the participant stays with the fear, anxiety, shame, guilt, etc.), and acknowledge this as a natural progression of the therapeutic process. At this point in the session, the therapists and participant may engage in some level of focused bodywork (Appendix B).

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 is 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."

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 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 newly experienced 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:

- 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 participants 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 (while still avoiding excessive verbalization).
- 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 drug 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.

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 recovery process. The participant and therapists explain the participant's present condition to the visitor, and the therapists 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 significant other (with the participant's permission) are given a means to contact the therapists. The therapists are available to speak with the participant during this time and they can also rapidly return to the clinic if requested by the participant or the attendant.

The therapists examine physiological measures (blood pressure, pulse, and temperature) and selfreported distress and mental state to make a clinical judgment concerning the participant's stability and the strength of drug effects. When the drug effects are no longer apparent and the participant is judged to be emotionally and medically stable, the therapists may leave the clinic.

Any place where MDMA-assisted therapy is performed should be equipped with rooms that can house the participant, an attendant, and a selected significant other. A kitchen and eating space should also be available, and good quality food should be on hand. Art supplies can be especially useful at this point, and the participant can be encouraged to continue his/her process symbolically with the art materials.

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.

4.2.2 Second MDMA-Assisted Therapy Session

The participant and therapists integrate the progress and experience from the previous session to explore intentions for the second MDMA session. Additional intentions may evolve as the medicine continues to open the participant's awareness to what is necessary to decrease their symptoms of PTSD. The participant is reminded to follow his or her inner experience throughout the session. As previously described, the therapists guide and support the participant throughout this process. The second MDMA-assisted therapy session is conducted in a manner identical to the first session, and typically occurs about three to four weeks later.

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 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 (Phase II)

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 undergoes. 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, 1997).

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 all of 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 stay. I'll stop if it gets too weird."

Therapist: "It isn't necessary to feel as though you have to verbalize it right 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 may need to follow the participant as he/she explores new and unexpected perceptions.

At other times, participants may describe experiences of exhilaration, joy, resolution or selfaffirmation. The therapists, as guides, provide room for these expressions and encourage the participant to accept and perhaps further explore these experiences. The therapists may inquire as to how the participant experiences these feelings as part of his/her healing process. 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 are. 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 and assist him/her in facing overwhelming and upsetting thoughts, memories or feelings. The therapists encourage the participant to reach new perceptions or insights by empathic listening, questions or observations that may help amplify the experience, verbal and physical comfort on request, and techniques to help the participant relax and gain a sense of security in the face of trauma related feelings.

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.

The therapists provide verbal and physical comfort upon request. 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 space through the immediate discontinuation of any action, including verbal or physical contact, when the participant says "Stop." Support is also offered by reminding the participant of his or her own strengths and the tools that he or she possesses, such as new insights or self-soothing skills that can be used in the face of intense emotional experience.

In conducting MDMA-assisted treatment sessions, 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 and when interaction with the therapists is appropriate to facilitate a particular avenue of experience.

The therapists may also help the participant examine and negotiate ambivalent feelings toward the appropriateness of emotions or thoughts he or she is experiencing during the MDMA session. For example, 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 potential benefits of the MDMA-facilitated inner experience while at the same time ensuring that participant is safe and is not re-traumatized by the internal conflict. 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 as a part of his/her healing process.

Toward the end of the session as the participant is emerging from the effects of the MDMA, the therapists assess the participant's emotional stability, alertness to ascertain whether the participant continues to experience altered perception. This assessment is made by using the methods described above for the first MDMA session. The therapists allow the MDMA session to end only when they conclude that the participant is stable and alert. If the participant is experiencing residual emotional distress, the therapists use clinical judgment to asses the apparent 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 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. The participant is also assured that the therapists will continue to provide support and help in working through and resolving any difficulties. At this point in time and before leaving, the therapists may wish to 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. As mentioned above, 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 this 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 are only likely to use these options under extreme conditions, and all other options will be tried before hospitalization.

As described above, 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. All participants eligible for a second MDMA session should discuss their thoughts and feelings about undergoing the second session. The consequences of continuing MDMA-assisted therapy and the consequences of discontinuation will be frankly discussed. The participant's decision about what he or she would prefer is respected unless the therapists have an overriding reason for excluding the participant on grounds of safety.

At the end of the MDMA session or upon departing on the night of the session, the therapists may provide the participant with specific suggestions to write about his/her thoughts, feelings, and experiences of the day, and to bring this writing to the follow-up session. 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.

5.0 PHASE III: FOLLOW-UP AND INTEGRATION SESSIONS

The following section describes three aspects of the integrative follow-up sessions: (1) the postsession; (2) the structure, nature, and focus of the follow-up sessions; and (3) the therapists' role during these integrative follow-up therapy sessions.

5.1 Post MDMA-Session

The post MDMA-session is established for the participant the day following his/her medicinal experience. Therapists emphasize their commitment to support the participant's process. Therapists 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. The protocol for other emergencies is also reviewed at this time.

In the post MDMA-session the therapists provide a ninety minute integrative therapeutic session. Several aspects of this session help the participant feel supported and safe after an MDMA session, including:

- 1.) Knowing that he/she has access to the therapists at any time may reduce any anxiogenic thoughts the participant may have about his/her experience.
- 2.) Knowing that he/she is scheduled for psychotherapy less than 24 hours after the MDMA session for an opportunity to debrief and understand the intensity of his/her experience.
- 3.) Knowing that the therapists may have had an opportunity to work with or speak with members of the participant's support system.
- 4.) Knowing that the therapists may have had the opportunity to dialogue with participant's primary therapist if he or she is in therapy.
- 5.) Knowing that the weekly follow-up sessions are an opportunity to connect with the therapists and process any experience they may have of a heightened state of vulnerability.

In addition, participants receive daily contact with the therapists by telephone for a week after each MDMA session.

5.2 Follow-up and Integration Sessions

The initial ninety minute follow-up treatment session is scheduled for the day after the MDMA session and is designed to initiate the integration process. The therapists and participant begin the process of understanding the lessons and experiences of the previous day. The therapists schedule two to four additional sessions, generally one week apart, before the second MDMA session. These sessions are designed to assist the participant with integrating the events of the MDMA session through exploring the participant's psychological, emotional, and physical response. Follow-up sessions scheduled after the first MDMA session will also prepare the participant for the second MDMA session. The therapists engage in an active dialogue and elicit detailed disclosure as a means to accomplish the following:

1.) Examining the events of the MDMA-assisted treatment session and exploring what is occurring for the participant on a psychological, emotional, and physical level.

- 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.) 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.
- 4.) Assessing how the participant tolerated the MDMA session and processing some of the content of the MDMA session. Processing includes discussing the effects on PTSD symptoms and creating ways to integrate new perceptions and insights gained from the MDMA session.
- 5.) Determining any possible contraindications for the second MDMA-assisted treatment session.

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 the relaxation and centering techniques, such as diaphragmatic breathing. This option may be chosen if the 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 this session 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 the physical areas in which there might be tension and pain. This work catalyzes the healing process by releasing any emotions that may be contributing to somatic complaints and otherwise keeping emotional energy blocked within the body. Focused bodywork is only done under the condition of 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 emotional 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 her 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 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 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."

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 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 whatever else has been revealed during MDMA sessions.

The therapists and participant use several strategies to bring the 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 MDMA-session related memories, thoughts, feelings or insights 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 thinking and 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 make sure 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 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."
- "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.
- "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. It may also be helpful 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."

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 helps the participant restore a sense of intrapersonal safety and gain mastery over the debilitating symptoms of PTSD.

Participant: (Crying)

Therapist: "Oh my, 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: "Where 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 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 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, that 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. 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 keep it together. As you talked about... 'OK that's done, it's behind me and it's time to move on' and 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, the anxiety and it scares the death out of me – the panic attacks and it usually 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. You've been doing great. It was just a few days, couple of days this weekend, and you had a very powerful session."

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 that you are going to present like this – having these emotions – 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 the PTSD symptoms. As the days between the MDMA sessions and integrative follow-up sessions unfold, the participant is instructed 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.

MDMA-assisted psychotherapy utilizes the effects of MDMA administered within a therapeutic setting to help people gain insights into their symptoms and adopt new, more effective means of coping with these symptoms. 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 ad 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 give the participant confidence in confronting his or her emotions and reduce 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.

5.3 Therapists Role During Follow-Up and Integration Sessions (Phase III)

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.

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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.

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Therapeutic Element	Cognitive Behavioral Therapy	EMDR	Psychodynamic Psychotherapy	MDMA-Assisted Psychotherapy
Prolonged exposure (either in vivo exposure or trauma reliving in therapy)	For in vivo exposure, develop a hierarchy list of situations, and assign specific homework involving exposure to these situations. For imaginal exposure, ask the patient to describe the trauma in detail in the present tense. This is done repeatedly over a number of visits.	A target image related to the trauma is used as a starting point, with a non-directive approach to what follows. Patient is encouraged to "let whatever happens happen." Discussions with the therapist are intermittent.	The traumatic events are discussed, but the specific approach of prolonged exposure is not included. (In practice psychodynamic psychotherapy and cognitive behavioral therapy are often combined.)	Non-directive approach to the way trauma comes up and is processed, with encouragement to stay present rather than distracting from difficult memories and emotions. Discussions with the therapists are intermittent. (Note that a contract is made before the session that if the trauma does not come up spontaneously the therapist will bring it up, but thus far trauma has always come up spontaneously; in effect, prolonged exposure happens spontaneously.
Cognitive restructuring	 Identify "negative thoughts and beliefs/cognitive distortions. Challenge them using Socratic method. Modify them by arriving at rational response. 	Cognitive restructuring often occurs spontaneously and may be catalyzed by therapist's adding "cognitive interweave," if needed.	Focus on the "meaning of the trauma for the individual in terms of prior psychological conflicts and developmental experience and relationships" (1)	Cognitive restructuring often occurs spontaneously, with minimal therapist intervention in this regard. Elements of both cognitive-behavioral and psychodynamic approaches may be used in follow-up integration sessions, but always in response to the way the experience is continuing to develop for the subject rather than according to a predetermined structure.
Anxiety management training (AMT), including stress inoculation training (SIT)	Relaxation skills are often taught at outset of treatment, such as breathing exercises, deep muscle relaxation, imagery.	EMDR protocol includes establishing an effective relaxation method at outset often guided visualization.	Not a specific element of psychodynamic therapy, but clinically is often combined.	Subjects are taught relaxation, often using diaphragmatic breathing.

Table 1. Comparison of Therapeutic Approaches for PTSD (Continued)
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Therapeutic Element	Cognitive Behavioral Therapy	EMDR	Psychodynamic Psychotherapy	MDMA-Assisted Psychotherapy
Increased awareness of positive experiences, including present safety	May be part of cognitive restructuring, or may occur spontaneously after prolonged exposure.	Often occurs spontaneously, most often toward end of session.	May occur as a result of examining present and past relationships and experiences. Typically happens later in therapy.	Usually occurs spontaneously, often early in the first MDMA session. May provide a sense of safety and well-being that provide a platform for deeper processing of painful experiences later in the session or in a subsequent session.
Clearing of tension in body and other somatic symptoms	Therapist directs attention to the body.	Therapist directs attention to the body.	Not generally considered as part of psychodynamic psychotherapy.	Mentioned in preparatory sessions and treated as an important therapeutic component that may be inadequately addressed in usual talking therapies. MDMA-assisted psychotherapy tends to bring this somatic component to awareness and allows for its release, often spontaneously and sometimes by: the therapist directing attention to body symptoms (as is done in Dr. Foa's examples of imaginal exposure p.167), or by using the kind of focused body work described in Appendix B.
Transference and countertransference issues	Not a focus, but therapists should be aware of them.	Not a focus, but therapists should be aware of them.	Interpretation of transference may be important part of the intervention.	Not a focus, but therapists should be aware of them and the fact that they can be heightened in non-ordinary states such as that induced by MDMA. Should be addressed openly and honestly and inquired about if there seems to be a significant unspoken dynamic. Therapists are self disclosing and collaborative. Transference is addressed early rather than letting it build, as can happen in psychodynamic therapy.

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Table 1. Comparison of Therapeutic Approaches for PTSD (Continued)
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Therapeutic Element	Cognitive Behavioral Therapy	EMDR	Psychodynamic Psychotherapy	MDMA-Assisted Psychotherapy
Difficulties with therapeutic alliance – a possible obstacle to successful treatment	Time and attention are given to developing alliance, with some limitations in time- limited therapeutic protocols (Dr. Foa recommends 9 sessions with the possibility of 3 more and mentions that, "there is a point of diminishing returns" with patients who have not responded to that course of treatment.)	Time and attention are given to developing alliance.	Time and attention are given to developing alliance.	Time and attention to are given to developing alliance. Both the set and setting of the treatment model and the effects of MDMA promote a sense of trust and therefore development of a therapeutic alliance in a relatively short time.
"The effect of earlier life experiences such as childhood abuse or previous trauma exposures" (1) as complicating factors that may cause treatment resistance	May be addressed in cognitive restructuring.	May come up spontaneously in EMDR sessions.	Discussing this may be a focus of psychodynamic psychotherapy.	Early experience of abuse or lack of support often comes up spontaneously in MDMA sessions, typically with insight about connections between this early experience and PTSD. This insight and the concomitant emotional connection and processing often occur with little or no intervention from the therapists.

APPENDIX B: FOCUSED BODYWORK

For the purposes of this manual we use the term "focused bodywork" to refer to touch, (usually in the form of giving resistance for the subject to push against) which is aimed at intensifying and thereby releasing tensions or pains in the body that arise during therapy. "Touch" will be 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, in some circles, controversial. Many therapists believe that any physical contact with a client is contraindicated. On the other hand, numerous practitioners of various methods of "body centered psychotherapy" consider the appropriate use of touch to be an essential part of the therapeutic process. (references) In MDMA-assisted psychotherapy mindful use of touch can be an important catalyst to healing during both the MDMA sessions and the follow-up therapy. Touch must always be used with a high level of attention and care, with proper preparation and communication, and with great respect for the subject's needs and vulnerabilities. Any touch that has sexual connotations or is driven by the therapist's, rather than the client's, needs has no place in therapy, and can be counter-therapeutic or even abusive. By the same token, withholding nurturing or therapeutic touch when it is indicated can be counter-therapeutic and, especially in therapy involving non-ordinary states of consciousness, may even be perceived by the client as abuse by neglect. (reference)

Some of the pitfalls related to touch are:

- Touch could be motivated by the therapist's own sexual desires or needs for physical contact.
- The participant may misinterpret touch as being sexual or exploitative when it is not.
- Touch may distract the participant from his or her inner experience. While touch has the potential to help a client move through and resolve difficult emotional experience, there is the danger that either the client or the therapist may unconsciously use touch it as a means of avoiding or moving attention away from an experience that is uncomfortable.
- The act of intervening with focused bodywork may give the participant the unspoken message that something from outside him/her is required for healing. An important principal of MDMA-assisted psychotherapy is that the healing experience is guided by an intelligence from within the clients own psyche and body. The therapist must be careful to take his or her cues about touch from the experience of the participant and to help the participant avoid the misconception that the therapist is the source, rather than the facilitator, of his or her therapeutic experience.
- The therapist may use touch to satisfy his or her own need to do something in the role of therapist. Not only can this lead to an unwelcome distraction from the client's experience, it runs counter to an important principle; healing often comes as a result of bringing conscious attention to difficult feelings or memories, and staying present in this challenging experience without doing

anything to change or escape it. At the same time, the participant can learn to recognize and understand in a deep and enduring way when the feelings and associated thought patterns they are experiencing are the result of old experience, and do not apply to their present situation in life. Part of preparing someone for MDMA-assisted psychotherapy is teaching them the value of this approach.

• Focused bodywork can be used prematurely in an attempt to resolve challenging emotions or their somatic manifestations before they have been adequately experienced, emotionally processed and expressed. It is important to convey to clients that the experiences catalyzed by MDMA-assisted therapy will likely continue to unfold and resolve over days or even weeks following the MDMA sessions. Therapists must exercise judgment about when focused bodywork is indicated to help move the therapeutic process forward, and when it is preferable to allow the process to proceed at its own pace.

Principles of Focused Bodywork and Nurturing Touch

In most cases, little or no focused bodywork will be required in the MDMA sessions themselves. Focused bodywork is more likely to be indicated in the integrative follow-up sessions as a means of working with unresolved emotional and somatic difficulties.

Despite the fact that MDMA-assisted psychotherapy is likely to involve less focused bodywork than LSD psychotherapy, the principles underlying this approach are those developed by Stanislov Grof, MD in his research with LSD psychotherapy. He points out that:

At the time when the effect of the drug is decreasing it is important to engage in verbal exchange with the subject, to get detailed feedback on his or her emotional and psychosomatic condition. If at this time he or she is experiencing discomfort, such as depression, anxiety, blocked aggression, feelings of guilt, circular thinking, headaches, nausea, muscular pains, intestinal cramps, or difficulties in breathing, this is the time to suggest active intervention. The possibility of this happening should have been discussed during the preparation period. The first step is to find out exactly what type of experience is involved....It is also important to encourage the subject to scan his or her body for signs of physical pain, tension or other forms of distress indicating energy blockage. There is, in general, no emotional distress or disturbing and incomplete psychological gestalt that does not show specific somatic manifestations. These concomitant psychosomatic symptoms then become the entry points for...intervention. (Grof, 2001, p. 144)

In preparation for the session the participant should be asked to use the work "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 the touch is necessary to protect the participant from physical harm. This will avoid confusion between communications that are meant to be directed to the therapists and statements that are part of the participant's inner experience.

Therapists may take specific measures if the participant is experiencing emotional distress that is impeding their experience. 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 at that point.
- 2) Encourage the person 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 it is during the MDMA session add, "The medicine will help that to happen."
- 3) If the participant is quite anxious (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 subject'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. This should only be done with the participant's permission.
- 4) If this does not lead to resolution of the distress, ask, "Is there content (specific images, memories or thoughts) that's coming up with these feelings?" If so it may be helpful to talk about it. The opportunity to put the experience into words may in itself be therapeutic, especially in this safe setting and with the tendency of the MDMA to decrease judgment and fear and to increase trust. This also may be an opportunity to help the participant explore connections between symptoms and past traumatic experiences, and to put these experiences into perspective in his/her current lives.
- 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 unresolved emotional distress or somatic tension or pain continues, again ask, "What do you notice happening in your body?" (Pain or tension caused directly by the MDMA will be treated somewhat differently and will be discussed below). If there is tension or pain in the body, ask, "Would you like to work with it?" If so, start with gentle massage in the identified area. This alone may bring resolution or may allow the experience to unfold further (e.g., further awareness and expression of feelings, connections to other experiences or patterns of thought and behavior, spiritual awareness).
- 7) If, during the massage, the participant's body responds spontaneously by pushing against the therapist's hand, the therapist should give resistance for the participant to push against and should encourage him/her to allow the body to move in whatever way it is inclined to. Encouragement should also be given to allow expression of any words or sounds that may accompany the experience.

8) If the massage itself does not either resolve the symptoms or lead to spontaneous pushing against the therapists' resistance, then the therapists should apply resistance to the affected area (which may be either a very specific point or a broad area) and invite the subject to, "take a few breaths into this area. Then when you're ready push against me with all your power, hold it as long as you can, and express yourself in whatever way you can – with sounds, words or body movements." This process should be repeated (moving the location as needed, following the participant's instructions about where the tension is) until the participant has a sense or release and relief or until he/she decides to stop, or in the therapists' judgment needs to rest.

The above steps should be offered to participants as possible ways of working with their symptoms *if they so choose*. Participants should never be pressured to do focused bodywork or to be touched in any way. Participants should be encouraged to ask for whatever they feel they need, even if it is quite different from what they or the therapists would have predicted.