

**MDMA-Assisted Psychotherapy for the Treatment of Posttraumatic Stress Disorder.**

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## **MDMA-Assisted Psychotherapy for the treatment of Posttraumatic Stress Disorder**

### ***Introduction:***

MDMA produces an experience that has been described in terms of “inhibiting the subjective fear response to an emotional threat” (Greer & Tolbert, 1998, p. 371) and increasing the range of positive emotions toward self and others (Adamson, 1985; Cami et al, 2000; Grinspoon and Bakalar, 1986). Though promising, reports of the benefits of MDMA-assisted psychotherapy remain anecdotal (Adamson, 1985; d’Otalora, <http://www.maps.org/research/mdma/moaccount.html>; Gasser 1994; Greer and Tolbert 1998; Metzner and Adamson, 1988, 2001; Naranjo, 2001; Styk, 2001; Wolfson 1986) or based on an uncontrolled study (Greer and Tolbert 1986). As a result, 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 people with treatment-resistant posttraumatic stress disorder (PTSD). This manual will provide researchers with a method of MDMA-assisted psychotherapy to be used in conducting these trials.

PTSD is clearly a public health problem that causes a great deal of suffering and accounts for a significant portion of health care costs. PTSD is a complex biopsychosocial condition which is characterized by a combination of three types of symptoms: fear and hyperarousal, intrusive reexperiencing of traumatic experiences, and numbing and withdrawal. A combined treatment of MDMA and psychotherapy may be ideal for the treatment of PTSD because, “the MDMA experience usually involves an almost total attenuation of the usual fear or anxiety reactions, it is ideal in one sense, for exploring traumatic memories or phobic reactions” (Metzner, et al 1988, p.14). Hence, the goal of MDMA-assisted psychotherapy for the treatment of PTSD is to enable a person to restructure his/her intrapsychic realities and develop a wider behavioral and emotional repertoire with which to respond to anxiogenic stimuli. The search for a wider array of more effective treatments is of utmost importance.

PTSD is also a disorder for which there is, 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 approach to these problems is to develop drugs and/or psychotherapeutic treatments that will 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 fact, the biological and the psychotherapeutic approaches overlap and re-enforce each other. Knowledge about the connections between the neurobiologic effects and the therapeutic effects of MDMA is far from complete, but it has been observed that MDMA acutely decreases activity in the left amygdala (Gamma, et al 2000). This action is compatible with its reported reduction in fear or defensiveness, and is in contrast to the stimulation of the amygdala observed in animal models of conditioned fear, a state similar to PTSD (Charney 1997, Davis 1999). A possible result

of MDMA-assisted psychotherapy is the interruption of the stress-induced neurochemical abnormalities produced by the condition. This manual will provide the researcher with a method of MDMA-assisted psychotherapy to be used in conducting a scientific study to investigate the possible risks and benefits of this treatment.

The purpose of this manual is 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 subjects as "subjects" rather than "patients", however, when describing the investigators' roles as therapists, we have chosen to refer to them as "therapists", leaving implicit the fact that they are investigators in a research study.

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

### ***Goals of this Manual***

The 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 will assist in the process of standardizing and validating this treatment in the context of controlled clinical trials and will provide therapists with appropriate strategies for preparing the subject for MDMA-assisted sessions, conducting the MDMA sessions, and facilitating follow-up sessions designed to expand and integrate the therapeutic process.

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The foundation of this treatment is the theoretical assumption that the medicine, MDMA, is not in itself the therapy. Rather, MDMA is considered a powerful ally for both clinician and subject. The adjunctive position of MDMA in the therapeutic process is based partly on its ability to induce a heightened state of empathic rapport along with its ability to facilitate the therapeutic process (Grob & Poland, 1997). The treatment paradigm rests on hypotheses concerning the benefits of increased rapport combined with the effects of a heightened therapeutic process. These effects are hypothesized to enhance the rate of recovery from PTSD.

The successful use of MDMA in therapy is dependent on “the sensitivity and talent of the therapist who employs (it)” (Grinspoon & Doblin, 2001, p. 693). With this understanding, the therapist carefully works with the subject to establish a sense of safety, security, trust, and openness, and to delineate the intended goals of the therapy prior to the MDMA-assisted session[s]. As Greer and Tolbert (1998) noted, “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 therapist carefully sets the parameters of treatment and prepares the subject for the process prior to and during each MDMA-assisted session. The post-session integrative aspect of the therapy is aimed at bringing the lessons gained in a non-ordinary state of consciousness across the bridge to the ordinary state of mind where these lessons can translate into advances in an individual’s level of functioning. These strategies are introduced at the beginning of therapy and emphasized throughout the process.

Additionally, this manual will outline the inclusion and exclusion criteria, the assessment protocol and other specifics of our current research study of MDMA-assisted therapy for PTSD.

### ***Conditions for the use of MDMA – assisted Psychotherapy with PTSD***

This section of the manual will address the conditions for the use of MDMA-assisted psychotherapy. MDMA can have profound emotional and physical effects. Its use requires thorough assessment and preparation. The subject must be committed to compliance with dietary and drug restrictions, preparatory therapy and follow-up sessions, and completing evaluation instruments.

The therapists must be committed to providing adequate preparation time during non-drug sessions and to giving careful attention to the set and setting during the MDMA sessions (Metzner, et al, 1988; 2001), and to providing adequate follow-up therapy. The therapists must remain with the subject during MDMA-assisted sessions until the acute emotional and physical effects of the MDMA have worn off. The therapists and subject must all agree that the subject is in a safe and stable condition at the end the therapy session. The subject must agree 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 subject must also agree to daily telephone contact with the therapists for a week after each MDMA session.

The first prerequisite for conducting MDMA-assisted psychotherapy with PTSD is that the subject 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 subject 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. In early and pilot research studies, only individuals without any improvement in their condition 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, previous psychotherapy must be one for which there exists a controlled clinical trial indicating efficacy. 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 subject must also have a medical history and physical examination to rule out any medical condition that would require exclusion from this form of therapy.

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

The next prerequisite for inclusion is that the subject must be willing to refrain from taking any psychiatric medications from the outset of therapy until two months following the final MDMA session. If the subject is currently taking psychiatric medication, then agreement to suspend medication must be approved and in writing by the subject's prescribing physician and this discontinuation must be monitored appropriately. In general, it is recommended that the subject be medication free for at least 5 times a particular drug's half life. Careful clinical judgment must be used to exclude any individual who could not safely discontinue medication.

The third prerequisite is that for one week preceding each MDMA session the subject adheres to the following:

- a.) Refrain from taking any herbal supplement.
- b.) Refrain from taking any nonprescription medications (with the exception of non-steroidal anti-inflammatory drugs or acetaminophen unless with prior approval of the treating therapist).
- c.) With the permission of their physician they will not take any prescription medications (with the exception of birth control pills, thyroid hormones, hormone replacement, NSAIDS, or other medications approved by the physician supervising the MDMA-assisted therapy).

It is also necessary for the subject to refrain from taking anything by mouth except clear alcohol-free liquids after 12A.M. the evening before an MDMA-assisted session. Activity for the 24 hours following the session involves an agreement to refrain from the use of any psychoactive drug. These restrictions are carefully reviewed with the subject during and after presentation and signing of the Informed Consent.

There are several categories of prospective subjects for whom this therapy is contraindicated. These include:

- a.) Pregnant or nursing women and women who are of child-bearing potential and not practicing an effective means of birth control.
- b.) People with a history of primary psychotic disorder or bipolar affective disorder type 1.
- c.) People with an eating disorder with active purging.
- d.) People who weigh less than 50 kg or more than 105 kg.
- e.) People with substance abuse or dependency within the past three months.
- f.) People who present a suicide risk or who are at risk for hospitalization.
- g.) People who do not meet the appropriate medical criteria.
- h.) People who appear to be at risk for victimization or self-harm. People who have engaged in self-harm within 6 months or have made suicide attempts within 6 months of this study.

In all early or pilot research studies, individuals with dissociative identity disorder and borderline personality disorder will 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, so long as careful clinical judgment is exercised.

This information is given and obtained during the initial evaluation and introductory sessions. The therapist is required to stringently follow these guidelines and to document compliance with them. Knowing that this context for his/her treatment is reliably in place provides the subject with a sense of safety and comfort. It also establishes a foundation for adequate preparation of the set and setting for therapy. It is an opportunity for the therapists to facilitate development of a therapeutic alliance, identify the subject's concerns, respond to questions and prepare the subject for the nature of the MDMA-assisted treatment sessions.

### ***Assessment Protocol – Baseline Measures***

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

1. Structured Clinical Interview for the DSM-IV: SCID-IV (First et al, 1994). The SCID is a semi-structured interview that permits accurate diagnosis of life-time and current psychiatric disorders using DSM-IV criteria.
2. Clinician-Administered PTSD Scale: CAPS (Blake et al, 1990). The CAPS is a structured interview designed specifically for the assessment of PTSD. It assesses the seventeen symptoms of PTSD along with eight associated features. Forms 1 and 2 will be given to measure current and lifetime PTSD diagnosis (CAPS-1) and 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.

The perceived strength of the therapeutic alliance and the rapport between subject and therapist will be assessed with the measure below. This measure will be administered once during the second introductory session and again during the follow-up therapy session occurring after each MDMA session.

6. Working Alliance Inventory: WAI (Hovrath and Greenburg, 1989). The WAI is a 36-item self-report scale designed to assess the quality of the working alliance existing between subject and therapist.

The measure listed below will be used to assess subjective distress during the course of each MDMA-assisted session:

7. Subjective Units of Distress: SUDS. This is a standardized subjective rating scale by which an individual can quickly rate comfort level throughout the session.

The following measures will be administered at baseline and again after both MDMA-assisted sessions to measure neurocognitive function in specific domains selected to assess memory and attention, two areas found to be affected by regular Ecstasy use (Fox et al, 2001; Gouzoulis-Mayfrank et al, 2000; Morgan, 1999; Rodgers, 2000).

8. The Repeatable Battery for the Assessment of Neuropsychological Status: RBANS (Randolph, 1997). This assessment measures change in an individual'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 visuo-perceptual skills, spatial organizational skills, and memory.

### ***Preparation Phase for MDMA-assisted Therapy Sessions***

The Preparation phase of therapy involves three stages. Stage One: Establishing a Therapeutic Alliance; Stage Two: Creating a Safe Psychological and Physical Space; and Stage Three: Therapists' Preparation. While the content and process of each of these stages is woven in each interaction with the subject, the foundation is laid during the two ninety minute introductory sessions with the therapists.

#### **Stage One: Establishing a Therapeutic Alliance, Gathering Information, Subject Orientation**

##### **Establishing a Therapeutic Alliance**

The first stage of the Preparation phase provides adequate time in non-drug therapy sessions for establishing a safe and positive therapeutic alliance. The therapeutic alliance is a prerequisite for treatment (Johnson, 1996). The development of trust and understanding between therapists and subject is essential. A safe and positive therapeutic alliance is one in which the subject feels assured that his/her well-being will be attended to with utmost care. The therapists introduce themselves and share how they became interested in this work as well as their experience in healing PTSD. This may help to assure the subject of the therapists' experience and commitment

to support the subject throughout the process. Greer and Tolbert (1998) note that self-disclosure on the part of the therapist created a context for collaboration, intimacy, and trust. Additionally, appropriate self-disclosure from the therapists gives the subject a sense of shared identification with the therapists. This identification may also have the benefit of increasing personal comfort as the subject enters a state of heightened vulnerability.

### **Gathering Information**

The therapist-subject interaction includes sharing mutually relevant information. Here the therapists ask open-ended questions, provide some feedback to the subject about the results of his/her psychological testing and medical evaluation, and encourages the individual to share what he/she believes is personally significant information. The therapists guide these interviews to gather information about the subject's present symptoms, event(s) that caused the PTSD, previous treatment and outcome, other psychiatric history, and medical, social and family history. The therapists also inquire about and discuss with the subject his/her previous experiences with MDMA, psychedelic drug use, or other non-ordinary states of consciousness. During this interaction the therapists should ensure that they have gathered sufficient information and established a sound understanding of the subject. This interaction is an opportunity for the therapists to inquire about and address any concerns the subject may have about his/her treatment.

### **Subject Orientation**

In this stage of therapy, the therapists orient the subject to the therapeutic process. The therapists begin a dialogue with the subject about the scope of the MDMA session. They discuss the subject's expectations, motivations, purpose, and intentions for the therapy sessions. 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 subject should be encouraged to cultivate an attitude of trust in the wisdom and timing of their own healing process as is catalyzed by this approach.

The subject is advised to include experiencing, understanding, and achieving relief from his/her PTSD symptoms and the underlying trauma as part of the therapeutic goal. Here the therapists want to clarify the subject's expectations and intentions and 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 what one's rational mind might have predicted. Subjects are encouraged to welcome difficult emotions rather than to suppress them, in order to better resolve deep-seated patterns of fear and powerlessness.

The therapists emphasize their commitment to help the subject cope with and recover from all the emotional material that may arise during the drug session. This commitment from the therapist is explicitly discussed. They agree to provide support, safety, and guidance for the subject in working with whatever emotions and memories arise within the session. It is sine qua non for the therapists to use clinical judgment and personal awareness regarding when it is best to facilitate the subject's process and when it is best to silently witness the subject's experience. (This will be discussed at greater length in stage three of this phase of treatment). The subject is encouraged to feel free to ask for support from the therapists during times of intense emotion or painful memories. They may

ask to be touched or held, ask for reassurance, or simply to talk about what they are experiencing. The scope of creating a safe psychological and physical space is discussed in the following section.

During the second introductory non-drug therapy session the subject will be introduced to the attendant who will accompany him or her during their overnight stay at the clinic. This will help subjects feel more comfortable and familiar with the attendant. The attendant will be a registered nurse (RN), and will always be of the same sex as the subject he or she will be staying with. The RNs will be trained by the therapists in how to appropriately fulfill this role. These nurses will be selected for their ability to act as reliable and compassionate attendants, and to recognize when to call the therapists in the event that the subject is experiencing physical or emotional distress during the night following an experimental session. A necessary quality for these individuals will be the ability to tolerate being in the presence of other people's emotions without becoming emotionally reactive themselves. Attendants will be taught to be attentive to the subject's needs for food or liquids, and to offer companionship by sitting with them or taking a walk according to the subject's desires. They will be instructed to listen compassionately if the subject wants to talk, but not to attempt to interpret the subject's experiences or otherwise act as therapists. The emphasis will be on listening rather than talking and on being quietly present. The attendant will be taught to avoid initiating long conversations with the subject or being intrusive in any way on the subject's experience, other than to inquire about their physical or emotional needs and their comfort.

### **Creating a Safe Psychological and Physical Space**

Establishing a safe setting for the subject requires that the therapists take an active role in creating an environment that is conducive to the full range of the MDMA therapeutic experience. They must provide a setting in which the subject is able to recline comfortably. In order to minimize any unfavorable distractions the setting should be free of all objects that would be likely to have powerful negative or disturbing connotations. The research setting will be made as supportive as possible, yet the subject can be aware of all safety measures in place to respond to the unlikely possibility of a medical complication. The subject 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 (Groff, 2000).

The creation of a safe physical and psychological space is meant to allow and encourage the subject 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 subject's attention to his/her intrapsychic process. The subject has the option to request periods of silence and the therapist has the option to forgo sections of the musical program. Subjects may also elect to forgo eyeshades.

To maximize the creation of a safe psychological space, the therapist and subject discuss the parameters of each session. Several specific agreements are made. These agreements include the following:

- 1) The subject, accompanied by a trained attendant, agrees to remain overnight in the clinic or office. The subject may ask to have his/her significant other spend the night. However this must be cleared in advance by the therapists. In this situation, the therapists should meet with the subject and significant other in

advance and exercise clinical judgment about whether or not it would be therapeutic for the significant other to spend the night with the subject following the session.

- 2) The subject 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 experience.
- 4) The subject's psychological safety also includes establishing the parameters with respect to experiencing and expressing sexual feelings. The role of the therapists' possible physical contact with the subject in the form of bodywork and nurturing touch will be discussed. The therapists assure the subject that at no time will they engage in any form of sexual contact with the subject. The subject is invited to ask for nurturing touch, (holding of a hand or being held). The subject is also instructed to use the word "stop" as a specific command if the therapists are doing anything that the subject wants them to discontinue. The therapists agree to always respond to this command; the only exception being when the therapists are doing something to the subject that is necessary for the subject's safety.
- 5) The subject agrees to refrain from self-harm, harm to others, and harm to property. If, in the judgment of the therapists, the subject is engaged in any dangerous behavior, the subject complies with the therapists' request to stop according to the terms of this agreement. The subject understands that failure to respond to the request may require an appropriate level of intervention.

To further prepare and provide the subject with a safe psychological space, the subject and therapists address any fears the subject may have, including catastrophic fears. The therapists listen with an empathic ear and collaborate with the subject on strategies that will increase the subject's feeling of safety. The subject 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 subject gain relief from difficult, intense emotions or distressing thoughts and assure the subject that he/she is in a safe environment and under the care of experienced clinicians. Subjects are taught diaphragmatic breathing techniques to aid in the relaxation and self-soothing process. They are also taught to use awareness of the breath as a technique for being able to attend to experiences, especially difficult experiences from which they might otherwise attempt to distance themselves.

Another important aspect of assuring a psychological and physical safety involves an assessment of the social support system surrounding the subject. Prior to any MDMA-assisted treatment session, the therapist and subject may consider ways in which the members of his/her social support network can be of help to the subject 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 subject's social support system. The subject may choose to invite a significant other (friend, family member or partner) to spend time with them and the therapists at the close of at least one MDMA session. Depending on the nature of the relationship with the significant other, this may be a valuable experience that enhances the supportive relationship. It should be cleared in advance by the therapists based on the same kind of clinical judgment they would use in considering the therapeutic value of an overnight stay by a significant other.

Maintaining safety includes access to treatment for possible reactions to the medicine during or immediately after each treatment session. Most such 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 where the MDMA session will occur should have means of readily assessing blood pressure and pulse during the MDMA session. When providing beverages throughout the MDMA session, the therapists should ensure that subjects do not consume over 3 L over the course of the MDMA session, and they should 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.

### **Stage Three: Therapists' Preparation**

In addition to standard training in the psychotherapeutic treatment of PTSD, therapists would substantially benefit from personal experience with non-ordinary states of consciousness. Preferably, this would include personal experience with MDMA in a therapeutic setting. If this is not possible for legal or medical reasons, a series of sessions using Holotropic Breathwork (a non-drug method for working with non-ordinary states) would also be beneficial. This personal experience is important for several reasons:

- 1) It will increase the therapist's level of comfort with intense emotional experience and its expression.
- 2) It will provide first hand validation of and trust in the intelligence of the therapeutic process as it arises from an individual's psyche.
- 3) It affords the therapist familiarity 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 subject's experience.
- 4) Therapists familiar with non-ordinary states of consciousness should also be familiar with features of the experience that the subject might find most helpful or particularly unsettling. Additionally, the therapist has an intrapersonal working knowledge of the integration process related to this type of therapeutic genre.
- 5) The subject's sense of security and treatment alliance will be enhanced if the subject is aware the therapist has had a similar kind of experience.

At the start of therapy, the therapists encourage the subject to share his/her purpose and intention for the therapy experience. During the session the therapist is aware of this intention and may under some circumstances redirect the subject's attention to it. However, the therapist should be guided by and should follow and support the particular course that the subject'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 supports the subject in staying with his/her inner process when it is important to do so. Furthermore, this empathic presence allows for the therapists to appropriately respond to the subject's non-verbal behavior, have a dialogue with the subject when necessary, and offer physical touch when indicated.

The therapists enlist the medicine's qualities to enhance 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 understand the importance of their own mental set vis a vis this therapy and have a clear understanding of their own beliefs related to the use of MDMA as an adjunct to therapy. The following section will discuss the three steps in Phase II: MDMA sessions.

### ***Phase II: MDMA Sessions***

The overarching goal of an MDMA-assisted session in this population is to reduce the symptoms of PTSD and to improve overall functioning and quality of life. This is accomplished through gaining new perspectives on the subject's life experiences, and clearing emotional and somatic blocks resulting from past trauma. This is accomplished through confronting 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 three steps. As the therapists prepare the subject for ingesting the medication, they take time to talk with the subject and familiarize him/her with the MDMA-experience. The next step involves working with the acute and sub-acute effects of the medication and the final step addresses the therapists' role throughout the treatment session.

#### **Step 1: Initiating therapy**

The MDMA treatment session begins with the therapists and subject reviewing the subject's goals for the session, the range of experiences that can occur during the session, and any concerns the subject might have as they prepare for the treatment. This review allows the subject to disclose his/her feelings about the process and provides the therapists with the opportunity to encourage, reassure, and guide the subject towards maintaining a therapeutic intention.

As the therapists give the medicine to the subject, they explain that MDMA is known to increase feelings of intimacy or closeness to others and reduce fear when confronting emotionally threatening material (Adams 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 subject that in the context of psychotherapy, a combination of drug effects may all serve to facilitate the therapeutic process and bring an individual closer to his/her treatment goals. These effects include enhanced positive mood, changed thoughts about meaning, increased access to distressing thoughts and memories, reduced anxiety and increased feelings of empathy or closeness to others, and decreased self-blame and judgment. This combination of drug effects should allow the subject to confront and examine memories of traumatic events and the effects these memories and related thoughts and feelings have had on his/her life without being overwhelmed by fear, anger, or shame. In preparation for the effects of the medicine, the subject is guided towards a relaxed state, encouraged

to focus his/her attention on abdominal breathing and to set aside any expectations about what will or should happen during the session.

## **Step 2: MDMA Session**

Onset of subjective and physiological effects begins 30 to 60 minutes after oral administration. During this period of treatment the subject is in a comfortable position and may find it helpful to focus on his/her breathing. The subject will have the option to use eye shades and have music playing. At the beginning of the session subjects will have been reminded of their intentions, such as exploring traumatic memories themselves, or exploring ways in which their response to the trauma has affected interpersonal relationships or life course decisions. During this stage of the session it is important that neither the subject nor the therapists be forceful about directing attention toward these goals. It is more useful for all involved to take a stance of openness to whatever unfolds, knowing that the subject's psyche is capable of discovering a route to deep healing that is apt to be more effective and ingenious than the rational mind could have devised. The subject may talk to the therapists at any time.

In some cases the subject may become anxious as they feel the early effects of the MDMA. If they tell the therapists this or if they appear restless during the first hour an interaction with the therapists might be as follows:

Subject: "I'm feeling scared, my heart's beating fast."

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. Let us be in charge of keeping you safe. What you're experiencing is a normal reaction to the MDMA effect starting. When people feel anxious at first it usually passes quickly. Would you like one of us to hold your hand to remind you we're here with you?"

Subject: "Yes, that would be nice."

Therapist: "Take some slow, deep breaths from your diaphragm the way we talked about before. Let your breath help you relax and open to the experience. The medicine will help you do that."

Peak effects are expected to occur 70 to 90 minutes after drug administration (Harris et al, 2002; Liechti & Vollenweider, 2001), and to persist for 1 to 1.5 hours. The therapists will check-in with the subject after 60 minutes if the subject has not talked since the administration of the medication. This check-in reminds the subject of the therapists' presence and provides the therapists with a cue as to the subject's inner status. This is a brief interaction that is followed by the therapist guiding the subject to return to an inner focus.

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

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

Subject: “I feel good. My body is kind of tingly with a lot of energy, and the music is really beautiful.”

Therapist: “Good, would you like a drink of juice?”

Subject: “Sure, I guess that would be a good idea.”

Therapist: “Then you can put your eye shades back on and go back inside if you want to, and we’ll check with you again in awhile. Tell us if you need anything or if you want to talk.”

The majority of the MDMA-treatment session consists of the subject attending to his/her intrapsychic experience and the therapists maintaining a clear empathic presence in order to attend to the process of the MDMA-treatment session. As the session progresses, the subject is likely to experience a positive mood and a sense of trust for both self and others, along with facilitated recall, which can result in the emergence of difficult and painful emotions and memories. Ideally the effects of the MDMA and the therapeutic set and setting will lead to catharsis and improvement.

The effects of MDMA-assisted psychotherapy are expected to assist the subject to face the traumatic memories and associated thoughts and emotions. Enhanced self-acceptance and decreased self-criticism may increase self-confidence, a sense of self-efficacy and control over unfolding memories, thoughts or feelings. A sense inner of calm, rather than extreme arousal, on confronting trauma-related material is expected to help the subject examine memories and thoughts more closely and objectively, while at the same time encouraging the subject to allow powerful emotions to surface. The sense of safety and the facilitated recall may work in concert to allow for a deeper or more intense exploration of the trauma-related events and/or their effects on relationships and other aspects of the subject’s life.

An MDMA-induced increased sense of closeness to others, trust, and intimacy may foster feelings of empathy and forgiveness for the self and others that may lead the subject to feel worthy despite the shame or distress caused by the traumatic event or events. In addition, changes in feelings of closeness to others may allow for enhanced rapport between the therapist and subject. While subjects are directed to focus on their inner experience during much of the MDMA session, enhanced interpersonal trust and feelings of closeness to others may make it easier to convey his/ her inner experience to the therapists. Greater rapport during the MDMA-assisted session may also increase compliance with instructions provided by the therapists that are intended to improve the therapeutic experience or to reduce avoidance of fully experiencing a particular element of the experience, such as a memory, insight or feeling.

The therapists will engage in listening and talking with the subject. Additionally, the therapists make judgments about when verbal interaction with the subject is indicated and when verbal interaction is an attempt by the subject to defend against difficult or painful emotional material. The therapists listen for cues that alert them to the subject’s intellectualizing which may indicate that the subject needs to allow his/her experience additional time to unfold within. This is sometimes referred to as “getting ahead of the internal emotional experience.” In this situation, it is necessary for the therapists to

intervene and guide the subject back to his/her internal experience. The therapists are also sensitive to the subject's need to share strong feelings of bliss and joy. The therapists recognize that these feelings may also be a significant aspect of the healing process.

It is essential for therapists to recognize and work with both the subject's underlying psychological processes and the experience produced by the medicine. Working with both of these components of the treatment involves supporting the subject in experiencing the negative effects of the trauma and experiencing the softening effects of MDMA simultaneously. The therapists' presence and the effects of the medicine provide a feeling of safety as the subject's barriers to perception open to allow increased access to memories, thoughts and emotions. The therapists continually create a safe space for the subject as he or she experiences increased access to memories or thoughts. The medicine may also produce in some subjects a feeling of loss of control. The therapists must be prepared to work with the subject to embrace these feelings and move through them as the subject is encouraged to surrender control and open to inner emotions which may previously have been too fearful to encounter.

The increase in sensitivity to interpersonal relationships and intimacy issues may draw people to consider ways in which their symptoms have altered or impaired their relationships with others. These MDMA effects may better equip subjects to view their interpersonal relationships, including relationship difficulties, without judging themselves or others too harshly. The increased focus on interpersonal relationships may assist people who have distanced themselves from others as a way of coping with the trauma or PTSD symptoms. Feelings of interpersonal trust may also assist subjects dealing with lack of support from significant others after the traumatic event or events. The therapists and the subject might explicitly seek to explore these areas during part of the MDMA session.

During the MDMA session, the subject may experience strong negative emotional reactions, including a feeling of loss of control. When the therapists become aware of the subject's distress, they intervene to encourage the subject to stay with deeper levels of emotion, 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 subject that he/she is in a safe place, orienting the subject to the "here and now", encouraging the subject to talk about his/her emotions, holding the subject's hand, or providing other nurturing touch. In this way, the therapists help the subject to stay with and move through his/her emotional experience, (i.e., the subject 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 subject may engage in some level of bodywork. Bodywork in MDMA-assisted psychotherapy will be addressed in more detail in the Integrative Follow-up Sessions and New Intentions for Daily Living section.

An example of helping a subject with a difficult experience:

Subject: (looking agitated) “I just keep having images of those men, I try to think of something else but I can’t make it stop!”

Therapist: “We’re right here with you. (Perhaps with some nurturing touch) I know this part is hard, but it’s coming up now for healing. If you can use your breath to stay with the experience instead of trying to make it stop that will help you move through it. Use your breath, just breathe into it and stay as present as you can with your experience. And express it in any way you need to, crying, making sounds, letting your body move, talking to us about it, however you can express it. We’re right here, and the medicine will help you with this too.”

As the subject makes the transition from the non-ordinary state of consciousness into an ordinary state of consciousness, the therapists may communicate with the subject more extensively about what she or he experienced. The therapists ask the subject for detailed feedback on his/her emotional and psychosomatic status (Grof, 2001). The therapist will encourage the subject to reflect upon and accept the experience, and to consider any newly experienced insights. If the subject indicates awareness of physical pain, tension, anxiety, or other manifestations of distress, the therapist may use this as an entry for bodywork, a method of psychotherapy involving manual therapy.

In preparation for bodywork the subject should be asked to use the word “stop” if there is ever any touch he or she does not want. He or she should be told that the therapists will always obey this command unless what they are doing 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 things the subject may say that are part of his or her inner experience.

There are specific measures for the therapists to take in the event that an individual is experiencing emotional distress that they are not able to process and move through spontaneously. 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 will help the subject 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 subject 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 subject is quite anxious (anxious affect, moving on the futon, opening eyes) it may be helpful to hold his or her hand, or for the therapist 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 subject’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 critical self-statements, fear and to increase trust. This will also be an opportunity for the therapists to help the subject 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 subject to “go back inside”, to focus on his/her own inner experience.
- 6) If there continues to be unresolved emotional distress or somatic tension or pain, bodywork of a more focused nature may be indicated. This is discussed in detail in Appendix A.

As the MDMA session draws to a close, the subject has the option of inviting his/her significant other into the consultation room to assist with re-entry and join the subject in his/her recovery process. The subject and therapists share with this individual information about the subject’s present condition as well as encourage the significant other to share any concerns or questions he/she may have. The therapists may educate the significant other about 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 subject remains in the treatment setting, accompanied by a trained attendant, overnight and may be given the option of having a significant other stay as well. Both the subject and the significant other (with the subject’s permission) will be given a means to contact the therapists. The therapists will be available to speak with the subject during this time, and they will be able to rapidly return to the clinic if requested to do so by the subject or the attendant.

After the therapists leave (when they have judged the subject to be emotionally and medically stable), the subject will spend the rest of the evening and night in the clinic or offices of the therapists, where he or she will have a private room to sleep in. The room will be an office designated for that purpose and will be furnished with comfortable furniture and a sofa-bed. The attendant will be on duty during this time and will have a separate room in which to rest. As is true for the current study, any place where MDMA-assisted therapy is performed should come equipped with rooms that can house the subject, an attendant, and a selected significant other. A kitchen and eating space should also be available.

The presence of the attendant, acting as an impartial and empathic listener following the session, may assist the subject in further approaching and considering material from the MDMA session. The attendant will also serve as a supportive caretaker and will monitor the mental and physical state of the subject. The nurse will contact the therapists if at any time the subject appears to be in distress or is experiencing any problem.

The subject may spend his or her time indoors or outdoors, so long as the attendant is nearby. However, the subject will be encouraged to use much of the time for rest and for a period of reflection and integration in a quiet atmosphere. The subject may also spend time with the selected friend, family member, partner or spouse as mentioned earlier.

A follow-up session is scheduled for the following morning. The attendant is instructed to page the therapists in the event the subject may need something throughout the night.

### **The Second MDMA-assisted therapy session**

The second MDMA-assisted therapy session will be conducted in a manner identical to that described for the first MDMA-assisted therapy session. The second MDMA therapy session will be scheduled to occur approximately three to four weeks after the first session. The subject and therapists will review the subject's goals at the outset of the session, and the subject will be encouraged to follow his or her inner experience throughout the session. As previously described, the therapists will guide and support the subject throughout this process.

The second MDMA session has the potential for facilitating a deeper emotional experience. This is due in part to the therapeutic alliance that has been established, familiarity with the effects of MDMA, and an increased openness to further exploration. The psychic material that has revealed itself from the first MDMA session and the therapeutic work that occurs in the follow-up sessions may afford the subject an increased sense of safety and security with the process. Feeling a stronger sense of trust and familiarity with the medicine, the subject is likely to move even further beyond his/her defenses during the second session. The subject and therapists integrate the progress and experience from the previous sessions to set intentions for the second MDMA session.

### **Therapist (Therapist) Role**

A primary role of the therapist is to create and maintain a safe therapeutic alliance with the subject. A key aspect of this therapeutic alliance is the self-awareness of the therapist. The therapists consider the psychological factors influencing the subject, including the subject's expectations of the therapist (Widmer, 1997). They are able to be fully present during the subject's processing of trauma and at the same time maintain healthy, appropriate boundaries. This ability on the part of the therapists provides support for the subject in remaining present with his/her inner experience and enhances the subject's willingness to explore new and unexpected perceptions that may arise during the healing process.

The therapeutic experience during the treatment session 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 subject may undergo. The therapists are caretakers of the goals that are set prior to the treatment session. As a caretaker of these goals, they maintain an awareness of the subject's intentions for the session while allowing for additional psychic material to emerge. In order to maintain the delicate balance between maintaining focus on the inner experience

and providing a safe space for exploring this experience, the therapists must be prepared to respect the natural healing mechanisms of the subject's own psyche and body and to be prepared to skillfully interweave interaction with the subject and periods of silent witnessing.

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 subject to focus on his/her goals when appropriate. This role may require redirecting behavior, as when subjects are requested to discontinue talking if it is felt that the communication represents either a defensive avoidance of material or a distraction from the opportunity to experience and benefit from the unique effects of the medicine on the subject's inner experience. These MDMA effects can lead to important insights and healing that arise through a non-linear process. This process is enhanced by an attitude of allowing the medicine to bring forth experiences rather than by any intervention and of acceptance rather than analysis. Another aspect of this role may require the therapist to follow the subject as he/she explores new and unexpected perceptions, even if they appear to be leading away from the primary agenda.

As nurturant figures, the therapists provide support and comfort to the subject and assist him/her in facing overwhelming and upsetting thoughts, memories or feelings, and encourage the subject to move toward reaching new perceptions or insights. This is accomplished through empathic listening, the offering and providing of verbal and physical comfort on request, and providing subjects with the means to relax and gain a sense of security in the face of trauma related feelings.

At other times, subjects may describe experiences of exhilaration, joy, resolution or self-affirmation. The therapists, as guides, provide the subject with room for these expressions and encourage the subject to accept and perhaps further explore these experiences. The therapists may inquire as to how the subject 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 subject.

Agreements concerning appropriate behavior during the treatment session are integral to the therapeutic and nurturing role of the therapists. Prohibiting any sexual behavior between therapists and subject assures subjects that their heightened vulnerability will not be exploited. It simultaneously fosters a safe environment for offering physical comfort during the treatment session. Insistence that the subject remain within the confines of the treatment area until the completion of the sessions is important for subject safety, and provides assurance that the therapists will not allow subjects to leave the safe space until the return of ordinary consciousness.

The therapists provide verbal and physical comfort upon request. This may include reminding the subject of the therapists' presence and reminding the subject that he/she can use breathing exercises or requests bodywork if needed. The therapists also maintain a safe space through the immediate discontinuation of any action, including verbal or

physical contact, when the subject says “Stop”. Support is also offered through reminding the subject 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, the therapists must attend to balancing their responsibilities as facilitators and as noninvasive participant observers. This may prove difficult at times, particularly when it is necessary for an individual to explore and confront his/her inner experience and when it is appropriate for the therapists to facilitate a particular avenue with the subject.

The therapists may also assist the subject in examining and negotiating ambivalent feelings toward the appropriateness of emotions or thoughts he or she is experiencing during the MDMA session. For example, the subject 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 inner experience facilitated by the medication while at the same time ensuring that subjects are safe and are not re-traumatized by it. Maintaining this balance requires an intense focus on the verbal and nonverbal communications of the subject, and an understanding of any potential difficulties the subject might be facing as a part of his/her healing process.

Toward the end of the session as the subject is making the transition from the non-ordinary to the ordinary state of consciousness, the therapists assess the subject’s emotional stability, alertness and whether or not the subject continues to experience altered perception. The therapists will only allow the MDMA session to end when they believe that the subject is stable and alert enough to leave the premises. In the event that the subject is experiencing residual emotional distress, the therapists will use clinical judgment to assess the apparent intensity of distress and to gauge what interventions should be employed. In most cases, the proper intervention will be to allow the subject 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 when they have concluded that the subject is emotionally stable and that most MDMA effects have subsided.

The subject should be reassured 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 subject is also assured that the therapists will continue to provide support and help in working through and resolving any difficulties. In addition, this would be a good time to review and practice the relaxation and self-soothing techniques that were taught in the introductory sessions. If the subject’s distress is not sufficiently decreased by the above measures, the therapists should consider focused bodywork as described in Appendix A.

If severe anxiety persists despite the above measures, a benzodiazepine may be used as a “rescue medication.” We anticipate that this will rarely, if ever, be necessary. If a

particularly severe panic reaction does occur during or after the first MDMA session, the therapists will make a decision about whether or not the subject is eligible to undergo a second drug session. This decision should not be made until after assessing the subject during the follow-up session the next day, and should subsequently be thoroughly explained and discussed with the subject.

If all means of reducing distress have failed and the subject 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. The first option is for a psychiatric nurse, therapeutic assistant or therapist (whose availability has already been pre-arranged) to stay with the distressed subject until the time of his or her appointment with therapists the next day. The therapists will then meet with the subject daily until the period of destabilization has passed. The second option is for the subject to be hospitalized until she or is in a stable condition. All subjects 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 prior to requiring the assistance of another or hospitalizing the subject.

As described above, the principal therapist/therapist is responsible for disqualifying any subject who had an adverse physiological or emotional response to MDMA during the first session sufficiently severe to indicate that he/she would be at risk during a second MDMA session. For all subjects who are eligible for a second session, the follow-up visits between MDMA sessions should include a discussion of their thoughts and feelings about undergoing a second session. The consequences of continuing MDMA-assisted therapy and the consequences of discontinuation are both frankly discussed, and the subject's decision about what he or she would prefer is respected.

At the end of the MDMA session or upon departing on the night of the session, the therapists may provide the subject 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 subject will also be encouraged to pay close attention to his/her dreams.

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

### ***Phase III: Follow-up and Integration Sessions***

The first integrative follow-up session occurs the day after the MDMA treatment session. The following section describes three steps involved in conducting the integrative follow-up sessions. The first step involves implementing a Safety Net; step two addresses the structure, nature, and goals of the follow-up sessions and step three considers the therapists' role during the integrative follow-up therapy sessions.

### **Safety Net**

The therapists provide a ninety minute follow-up session the day after the MDMA session. There are several aspects of the integrative follow-up session which contribute to the subject's felt sense of safety after his/her treatment session. These include, but are not limited to, the following:

- 1.) Knowing that he/she has access to the therapists at any time through their pager as well as during the scheduled appointment the day after the experience may reduce any anxiogenic thoughts the subject may have about his/her experience.
- 2.) Knowing that he/she will return to treatment less than 24 hours after the MDMA session for an opportunity to debrief and understand the intensity of his/her experience.
- 3.) Strengthening of the therapeutic alliance.
- 4.) Knowing that the therapists may have had an opportunity to work with or speak with members of the subject's support system.
- 5.) Knowing that the therapists may have had the opportunity to dialogue with subject's primary therapist if the subject is in therapy.
- 6.) Knowing it is an opportunity to connect with the therapists and process any experience they may have of a heightened state of vulnerability.

In the Safety Net stage of treatment, the subject is reminded that he/she has the commitment of the therapists to provide support throughout the study. The therapists review the procedure by which they can be contacted at any time should the subject or his/her designated support team need to talk with them about any difficulties or concerns. The protocol for other emergencies is also reviewed at this time.

### **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 begin the integration process. The therapists and subject begin the process of understanding the lessons and experiences of the previous day. The therapists schedule three to four additional sessions, generally one week apart, before the second MDMA session. These sessions are designed to assist the subject with integrating the events of the MDMA session through exploring the subject's psychological and physical response and to prepare him/her for the second MDMA session. The therapists engage in an active dialogue and elicit detailed disclosure as a means to accomplish the following:

- 1.) To examine the events of the MDMA-assisted treatment session and explore what is occurring for the subject on a psychological and physical level.
- 2.) To ensure that the subject understands that the experience catalyzed by the MDMA-assisted treatment will likely unfold and resolve over days or even weeks following the treatment session.
- 3.) To introduce bodywork into the therapy in the event that the subject is experiencing emotional distress that he/she are not able to move through spontaneously or with talk therapy.
- 4.) To assess how the subject tolerated the MDMA treatment session and process content of the MDMA treatment session. Based on this process, the therapists

discuss effects on PTSD symptoms, re-evaluate goals and discuss integration of insight and new perceptions gained from the MDMA treatment session.

- 5.) To assess any possible contraindications for the second MDMA-assisted treatment session.

In response to distress or upsetting thoughts, memories or feelings lingering after the MDMA session and those which may unfold over the course of time, the subject is reminded to perform the relaxation and centering techniques such as diaphragmatic breathing. 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 bodywork and breathing exercises can be reinforced in this session in preparation for the next MDMA session.

The content of the treatment session will cue the therapists to the likelihood of the subject requiring (or requesting) 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. Bodywork is only done under the condition of subject permission and is immediately discontinued if the subject requests “Stop.” Although bodywork may be an important part of the follow-up and integration sessions for some subjects, it should not be used prematurely in an attempt to resolve challenging emotions or their somatic manifestations if they are spontaneously being adequately experienced, emotionally processed and expressed. The 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. The therapists must exercise judgment about when body work is indicated to help facilitate the therapeutic process and when it is preferable to allow the process to proceed at its own pace.

For the purposes of this manual we will use the term “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 “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 A.

The ultimate goal of MDMA-assisted psychotherapy is the elimination of symptoms and the attainment of an improved level of functioning. This can be accomplished as the subject weaves all aspects of therapy together in order to develop a new relationship with self, others, and with his/her traumatic history. The integration phase of treatment brings these elements together, in a cohesive, harmonious way. Paradoxically, in some sense, integration begins at the onset of treatment when the subject and therapists discuss the subject’s intentions for therapy. Integration involves the ability to access and apply to daily life the lessons, insights, changes in perception, awareness of bodily sensations, and whatever else was revealed during the treatment experiences.

The therapists and subject 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 subject works with the therapists to understand and accept the changes he/she has undergone. It involves giving meaning to the memories, thoughts, feelings, and insights experienced during the MDMA and integrative follow-up sessions and determining how this new meaning will be manifested in daily living.

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

Each integrative follow-up session should begin with an invitation for the subject to talk about whatever is on his/her mind. This is so the subject's experience rather than the agenda of the therapists 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 subject 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 which aids 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 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 subject 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 subject 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 subject 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; Came et al, 2000; Grinspoon & Bakalar, 1986) at times when he/she may be confronted with cues of the traumatic event(s). This allows the subject to maintain a sense of calm security in the face of these anxiogenic stimuli. The ability to expand consciousness assists the subject with restoring a sense of intrapersonal safety while gaining mastery over the debilitating symptoms of PTSD.

The therapists recognize that the information revealed during the MDMA and integrative follow-up sessions serves as a starting point for enhancing the subject’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 subject 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 subject to do this between 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 validate the subject’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 MDMA-assisted treatment sessions provide the basis for constructing new meanings about self, others and his/her world. In turn, these newly constructed meanings 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 subject should feel less fearful, with a greater sense of self-control or insight when confronted with trauma-related triggers or memories. Strengthened interpersonal trust will allow the subject to further develop his or her social network. Greater insight into the whole range of thoughts and feelings about the trauma give the subject confidence in confronting his or her emotions and reduce the likelihood of emotional numbing. Maintaining and nurturing the 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 subject can confront anxiety-producing situations with more confidence and may be more comfortable with asking for assistance from his/her supportive network.

### **Therapists’ Role**

During Follow-up and Integration sessions the therapists are present to answer any questions relative to the subject’s experience and offer support and encouragement as the subject processes the intrapsychic realities and new perceptions gained through the MDMA session. The therapists take a supportive and validating stance toward the subject’s experience. They also facilitate the subject’s understanding of the trauma from insights and perspectives gained from the opening of new channels and the clearing of

other reactions and thoughts that may have outlived their usefulness. There may be times when the therapists offer insights or interpretations of the subject's experience, but care should be taken to do this sparingly. Subjects should be encouraged to exercise their own judgment about what they may or may not resonate with and apply their own experience.

The therapists work to maintain the subject's focus on his/her therapeutic goals, work through the memories of the traumatic event(s), and 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 subject's bodily wisdom in self-healing.

As empathic listeners, the therapists attend to the subject's account of his/her inner experience and create space for the subject's own meanings or for his/her ambivalent thoughts and feelings about the experience. The therapists offer the appropriate assistance needed for the subject to cope with any apparent ambiguity, while fostering the awareness that it is the subject 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. As was discussed at the beginning of this manual, it is hypothesized that MDMA will be a powerful ally for the subject and the therapists. It is further hypothesized that MDMA will assist the subject and therapists in restructuring the subject's intrapsychic realities in relation to the trauma so as to develop a wider behavioral and emotional repertoire with which to respond to anxiogenic stimuli. To reach this goal the therapists and subject embark on integration of the treatment process. The integration of these valuable lessons learned while experiencing a non-ordinary state of consciousness is an essential part of MDMA-assisted psychotherapy

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## Appendix A – Bodywork

For the purposes of this manual we will use the term “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 “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 A.

The subject of touch in psychotherapy is complex and, in some circles, controversial. There are psychiatrists and other therapists who believe that any physical contact with a client is contraindicated. On the other hand, there are numerous practitioners of various methods of “body centered psychotherapy” who consider the appropriate use of touch to be an essential part of the therapeutic process. (references) What follows is a description of our approach to the use of touch in MDMA-assisted psychotherapy. We believe that mindful use of touch can be an important catalyst to healing during both the MDMA sessions and the follow-up therapy. It 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. It is certainly clear that touch which has sexual connotations or which 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 which the therapist must be attentive to:

1. Touch could be motivated by the therapist’s own sexual desires or needs for physical contact.
2. The subject may misinterpret touch as being sexual or exploitative when it is not.
3. Touch may distract the subject 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 as a means of avoiding or moving attention away from an experience that is uncomfortable.
4. The act of intervening with bodywork may give the subject 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 subject and to help the subject avoid the misconception that the therapist is the source, rather than the facilitator, of his or her therapeutic experience.
5. 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 subject 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.

6. 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 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 bodywork and nurturing touch:

In considering the possible pitfalls listed above and the specific principles described below, it is important to understand that, in most cases, little or no bodywork will be required in the MDMA sessions themselves. It is more likely that bodywork will 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 bodywork than LSD psychotherapy, the principles underlying this approach are those developed by Stanislov Grof, MD in his LSD psychotherapy research. 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 individual 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 subject should be asked to use the word “stop” if there is ever any touch he or she does not want. He or she should be told that the therapists will always obey this command unless what they are doing 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 things the individual may say that are part of his or her inner experience.

There are specific measures for the therapists to take in the event that the subject is experiencing emotional distress that they are not able to process and move through spontaneously. In most cases, these steps should be taken sequentially, proceeding to the next step only if necessary:

- 7) Ask, “What are you aware of in your body?” This will help the subject 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.
- 8) Encourage the subject 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.”
- 9) If the subject is quite anxious (anxious affect, moving on the mat, opening eyes) it may be helpful to hold his or her hand, or for the therapist 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 subject's permission.
- 10) 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 will also be an opportunity for the therapists to help the subject explore connections between symptoms and past traumatic experiences, and to put these experiences into perspective in his/her current lives.
- 11) After this period of talking, and periodically throughout the session, encourage the subject to “go back inside”, to focus on his/her own inner experience.
- 12) If there continues to be unresolved emotional distress or somatic tension or pain, 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 pains 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).

- 13) If, during the massage, the subject's body responds spontaneously by pushing against the therapist's hand, the therapist should give resistance for the subject 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.
- 14) 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 subject's instructions about where the tension is) until the subject has a sense of 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 subjects as possible ways of working with their symptoms if they choose to. People should never be pressured to do body work or to be touched in any way, and any use of touch should be determined by the subject's choices. Subjects 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.