



A Manual for MDMA-Assisted Psychotherapy in the Treatment of Anxiety Associated with a Life-Threatening Illness

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1.0 INTRODUCTION

The Multidisciplinary Association for Psychedelic Studies (MAPS) is sponsoring clinical trials to explore the potential risks and benefits of 3, 4-methylenedioxy-N-methylamphetamine (MDMA)-assisted psychotherapy for PTSD, social anxiety in autistic adults and for anxiety associated with a life-threatening illness. This manual provides researchers with a method of MDMA-assisted psychotherapy to be used as a model in conducting trials for anxiety associated with a life-threatening illness. This manual is intended only for use with subjects of an approved clinical trial who have provided their informed consent.

1.1 MDMA for Anxiety Associated With a Life-Threatening Illness

Individuals facing, or who have faced a life-threatening illness contend with more than just the physical symptoms of their condition. Anxiety, depression, anger, and despair often exacerbate the distress already caused by the illness itself, even after a remission or cure is achieved. A significant increase in caregiver distress may occur as well (Grunfeld, et al., 2004; Wolfson, 2011). The trauma of a devastating illness is often deep and difficult to integrate into one's life moving on, with persistence of fear of recurrence, or relapse--with the potential attendant medical procedures, the fatigue and illness, and reduction in the quality of life. The past illness and the set and setting in which it was experienced may well be perceived as having been traumatic and thereby create anxiety about future negative possibilities including death itself, as that specter is raised by the very nature of such illnesses. For those individuals who have had a post-traumatic response of numbness, the denial may be broken and distress be felt as overwhelming and difficult to process and pass through.

End-of-life problems, including pain management, are increasingly recognized by caregivers and the public as significant public health concerns (Potter, et al., 2003; Randall-David, et al., 2003; Shvartzman, et al., 2003). Research suggests that diagnosis of, and living with a life-threatening illness can result in symptoms similar to those seen in Posttraumatic Stress Disorder (PTSD), and that these symptoms may persist even if the individual recovers, or their illness goes into remission (Jacobsen, et al., 1998; Cordova, et al., 1995). These symptoms may include emotional avoidance and numbing, difficulty relating to or connecting with friends or loved ones, difficulty sleeping, a sense of foreshortened future and fear of its possibilities, anxiety, insomnia, anhedonia, depression, despair, grief for the past life lived, and intrusive thoughts or memories related to the illness.

While efforts to improve palliative care for the terminally ill have led to advances over the last several decades, and significant strides have been made in reducing individuals' physical pain and discomfort, less progress has been made in helping individuals reduce or come to terms with the psychological and existential issues raised by their condition. Fears of loss of autonomy, helplessness, and death itself are also often accompanied by challenging internal family dynamics that surface around the end of life. In a 2003 report, McClain et al. support developing additional palliative care interventions to improve the

well-being of people with terminal illness by “...keeping the psychological distress of patients who are facing death to a minimum. What is less clear, however, is whether interventions exist that can help raise a terminally ill individual’s sense of spiritual well-being.” However pessimistic that sounds, for there are practitioners and methods available that are potentially beneficial, the medicalization of terminal care tends to leave out the humanistic and spiritual in favor of the technical and is too often isolative.

The situation is somewhat different for those individuals and their families who have not been moved imminently towards death by a terminal illness but instead face that possibility due to recurrence or relapse and feel this at some varying degree of emotional/psychological distance. Their challenge is to function at an intense level often in the presence of significant anxiety. Arising are choices of how to live; what to do for prevention or maintenance; balancing desires with diminished capacities; a focus on future treatment choices that may be potentially frightening, challenging and debilitating; the balancing acts between hope and resignation, passion and giving-up, ambition/achievement and letting go; love and isolation, and so on. This is the human condition with difficult circumstances that induces an awareness (or denial, which in this case is a kind of negative awareness) of the possibility of the shortening of lifetimes and the hovering realization that life may soon end.

Given that in this situation, spiritual, familial, psychological, and existential concerns all take a position of primary and intense importance for many people, the development of new treatment modalities to meet these needs is a clear imperative. Enabling individuals to face life-threatening illness and the attendant fears and quandaries with dignity, passion, emotional openness to self and others, creativity, love, openness to support, and kindness is the primary impetus for this research study.

1.2 Treatment Approach

The foundation for this therapeutic approach was laid by: Stan and Christina Grof, Leo Zeff, George Greer and Requa Tolbert, Ralph Metzner, Phil Wolfson and many others [8, 14-17]. The basic premise of this treatment approach is that the therapeutic effect is not due simply to the physiological effects of the medicine; rather, it is the result of an interaction between the effects of the medicine, the therapeutic setting and the mindsets of the participant and the therapists. MDMA produces an experience that appears to temporarily reduce fear [14], increase the range of positive emotions toward self and others, and increase interpersonal trust without clouding the sensorium or inhibiting access to emotions. MDMA may catalyze therapeutic processing by allowing participants to stay emotionally engaged while exploring the meaning and implications of their illness without being overwhelmed by anxiety or other painful emotions. Participants are able to experience and express fear, anger, and grief as part of the therapeutic process with less likelihood of either feeling overwhelmed or feeling guilty for these emotions, or of avoiding them by emotional numbing. In addition, MDMA can enable a heightened state of empathic rapport that facilitates the therapeutic process [18] and allows for a corrective experience of secure attachment and collaboration with the

therapists. At some point during the MDMA experience feelings of empathy, love, and deep appreciation often emerge in conjunction with a deeper sense of meaning in the face of illness and death and a heightened awareness of the potential for support and emotional safety that exists in the present. A renewed connection to one's body, the unraveling of trapped emotions and muscular armoring that comes directly from the traumatic aspects of having a life threatening illness, these all may occur and enable catharsis and healing and a return of sensation as sensual and vital. Research participants have said that being able to successfully process painful emotions during MDMA-assisted psychotherapy has given them a template for feeling and expressing pain that has "changed their relationship to their emotions".

MDMA may also provide access to meaningful spiritual experiences and other transpersonal experiences, release of tensions in the body, and a sense of healing on a non-verbal level that are incompletely understood, but are considered important by many participants.

The successful use of MDMA in therapy depends on "the sensitivity and talent of the therapist who employs [it]" [19]. The therapists work with the participant to establish a sense of safety, trust, and openness, as well as to emphasize the necessity of trusting the wisdom of the participant's innate capacity to forge deeper meaning and confidence in the face of illness and death. Greer and Tolbert [14] suggest that "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). Establishing these conditions requires that the therapists carefully set the parameters of treatment and prepare the participant before each MDMA-assisted session, and then provide appropriate support following the session so that the experience can be successfully integrated.

1.3 Goals of this Manual

This manual provides researchers with a largely non-directive method of MDMA-assisted psychotherapy to be used in conducting a scientific study (see study protocol) in order to develop and test an investigational form of drug-assisted psychotherapy. In this manual, the therapists are also referred to as "investigators" and the people who participate in the experimental psychotherapy sessions are referred to as "participants" rather than as "patients" (NOTE: throughout this manual, quotations from study participants are printed in *italics*.) The manual is used in conjunction with an approved study protocol, a separate document describing the study design. The design typically involves several experimental sessions with associated preparatory and integrative sessions. Non-drug sessions range from one to one and a half hours of interaction and MDMA-assisted therapy sessions range from six to eight hours of interaction with a team of two co-therapists, generally one female and one male.

The specific goals of this manual are to:

- 1) Delineate the core elements of the MDMA-assisted psychotherapy method used in MAPS sponsored studies of anxiety related to life-threatening illness.
- 2) Educate therapists about the phases and steps involved in conducting MDMA-assisted psychotherapy for the treatment of anxiety related to life-threatening illness.

This manual is to be used as the basis for the controlled clinical trials that are required to standardize and validate MDMA-assisted psychotherapy as an approach to treatment for anxiety related to life-threatening illness. As it is intended, the therapy:

- Encompasses the essential elements described in the manual and adherence measures.
- Avoids interactions that are proscribed by the manual and adherence measures.
- Allows individual therapist teams to include therapeutic interventions based on their own training, experience, intuition, and clinical judgment, provided interventions are compatible with the tenor of the method and appropriate to the participant's unfolding experience.

1.4 Elements of the Therapy Method

Elements of this therapeutic method build upon the therapists' background and training while incorporating specific concepts to be used across therapy teams. This approach is intended to establish a standardized approach to treatment and at the same time to provide creative latitude for individual therapist teams to apply their own intuition and training. Core elements and important concepts that will be discussed throughout the manual are highlighted below.

- Participant **safety and well-being** are always prioritized ahead of any scientific goals of the study.
- A qualified therapist with the appropriate **training and experience** relevant to the methods in the manual is required.
- Providing adequate participant **preparation and orientation** to the therapy is vital.
- Creating an appropriate **set, setting, and support system** during MDMA-assisted sessions and follow-up is essential.
- The development of **therapeutic alliance and trust** over the course of therapy is essential.
- A **nondirective approach to therapy** based on **empathetic rapport and empathetic presence** should be used to support the participant's own unfolding experience and

the body's own healing process. A non-directive approach emphasizes invitation rather than direction.

- It is essential to encourage the participant to trust her/his **inner healing intelligence**, which is a person's innate capacity to heal psychic distress or trauma. It is important to highlight the fact that the participant is the source of her/his own healing. The MDMA and the therapists are likely to facilitate access to, but are not the source of, the healing process.
- **Intervention** in the form of guidance or redirection, when deemed appropriate, can be used to facilitate the participant's processing. Therapists must attend to balancing their responsibilities as facilitators and as noninvasive empathic witnesses.
- The therapy should enable the **processing of anxiety or distress** rather than the avoidance of these experiences; however, this should be done with respect for protective mechanisms, which are referred to in different models of therapy as "resistance", "defenses", "protectors" etc. The therapists should facilitate awareness of and curiosity about any apparent resistance that arises rather than simply attempting to overcome it. The goal is to enable participants to know themselves at ever deeper levels of understanding with compassion and insight.
- Therapists seek to **maximize the benefits of the inner experience catalyzed by MDMA**, while at the same time **ensuring that the participant is safe and is not further traumatized** by internal conflicts that may arise.
- Therapeutic techniques should be available to **address somatic manifestations of emotion** that arise. These may include one or more approaches such as nurturing touch, focused bodywork, breathing techniques, or other approaches to somatosensory processing.
- It is important to include various tools such as music, focused bodywork, breathing, guided meditation that is participant specific, humor, or other techniques in the therapeutic setting to **evoke and support emotional experience** while avoiding distraction from the participant's experience.
- **Integration** is viewed as an **essential and ongoing process** as experience unfolds and resolves. Follow-up contact with the therapists by phone and during scheduled integration visits is necessary to support successful integration. During non-drug follow-up psychotherapy sessions the therapists aim to address any difficulties that may have arisen following MDMA-assisted sessions and to anchor the lessons gained in a non-ordinary state of consciousness so they can be integrated into daily life.
- The therapy requires a **thorough understanding of the nature of MDMA effects** and the **non-linear manner** in which they can lead to healing effects.

1.5 Empathetic Presence & Listening, Non-Directive Communication, and Inner Healing Intelligence

Empathic presence includes providing a non-judgmental environment which offers psychological permission to talk openly and honestly. It requires listening beneath and beyond the spoken words for deeper meanings, acknowledging the other's suffering, and validating her/his feelings. Empathic presence also involves appreciating and even rejoicing in another's accomplishments at a level of genuine sincerity that conveys to the other person her/his importance. Empathic presence decreases feelings of abandonment and isolation.

Empathetic listeners are relaxed but engaged, ask questions and explore without prying. The listener maintains appropriate eye contact and offers reassuring, appropriate touches if culturally acceptable. Empathetic listeners may be required to admit they don't have answers.

Important components of empathetic listening and active listening:

- Minimal encouragement, verbal and non-verbal
- Invitation rather than direction
- Paraphrasing
- Reflecting
- Emotional labeling
- Validating
- Reassurance and waiting
- Allowing participants to come to conclusions themselves.

Non-directive communication also uses invitation rather than direction. For example:

- “We encourage you to ...”
- “This might be a good time to ...”
- Use the gerund of a word: instead of “breathe” say “breathing” because it is suggestive rather than directive.
- Reflecting back to the participant what they are saying in order to continue conversation without being directive.

Inner healing intelligence is a concept used throughout the manual to help put the participant in touch with their innate ability to heal and grow. The following analogies may be helpful in explaining the concept:

- The body knows how to heal itself: if someone goes to the emergency room with a laceration, a doctor can remove obstacles to healing (e.g. remove foreign bodies,

infection, etc.) and can help create favorable conditions for healing (e.g. sew the edges of the wound close together), but the doctor does not direct or cause the healing that ensues. The body initiates a remarkably complex and sophisticated healing process and always spontaneously attempts to move toward healing. The psyche too exhibits an innate healing intelligence and capacity.

- Seeds want to become a plant; it is the natural way.
- A tree always grows toward the sun; it is the tree's natural inclination.

1.6 Adherence to the Therapeutic Approach

Adherence to the essential elements of the treatment manual will be measured by independent review of session videos against adherence criteria. The adherence measures for each type of session can be found in the Adherence Manual.

2.0 THERAPIST FOUNDATION

Therapists will receive specific training in the MDMA assisted therapy method, approved study protocol and latest version of the Investigator Brochure in order to participate as investigators in the clinical trials. Training on the method consists of reading the manual and participating in a training program that includes watching videos of research sessions. Training may also include other modules such as observing a session, role play or attending supplemental trainings given by MAPS or applicable outside trainings such as Holotropic Breathwork [20]. In addition to this specific training, it is required that participating therapists have a proper background, education and experience as therapists. An important element of this background in the prior PTSD studies has been experience with the various therapies for PTSD, which generally have included Prolonged Exposure (PE), Cognitive Processing (CPT), Eye movement desensitization and reprocessing (EMDR) and psychodynamic psychotherapy. In addition to these modalities which may well have relevance for working with those with life threatening illnesses as many such people do suffer with PTSD or the elements of PTSD, there are other approaches that offer valuable experience for MDMA researchers in the present study. These include: Internal Family Systems (IFS), Voice Dialogue, Psychodrama, Psychosynthesis, Hakomi, Sensorimotor Therapy, Holotropic Breathwork, Family Systems approaches, Gestalt Psychotherapy, Guided Meditation, Jungian psychology, Buddhist psychology, and Virtual Reality. Elements of each of these psychotherapeutic approaches may occur within MDMA-assisted therapy for those with life threatening illnesses.

2.1 Essential Therapist Background

The therapists should have a client centered orientation so they are comfortable following and supporting whatever course the participant's own emotional process takes, rather than trying to impose upon it a predetermined course or outcome. This relatively nondirective approach may require a challenging adjustment for some therapists with training and experience in other methods. It is an inherent, ongoing challenge for any

therapist undertaking this approach to strike a skillful balance between allowing the participant's process to take its unique course and offering guidance or direction when appropriate. In conjunction with this challenge therapists are charged with maintaining a high level of empathic presence throughout the therapy session. This empathic presence helps the participant stay with her/his inner process when it is important to do so, and also enhances the therapists' ability to appropriately respond to the participant's non-verbal behavior, have a dialogue with the participant when necessary, and offer nurturing touch or other supportive methods when indicated. It is required that at least one therapist on the team be prepared to teach a method of stress inoculation such as diaphragmatic breathing and to be well versed in a method of addressing somatic manifestations.

2.2 Specialized Therapist Skillsets

The MAPS training program is designed to teach competency in applying the essential elements of this method of MDMA-assisted psychotherapy. Other tools that each therapist uses to help participants move through emotional blocks, address somatic manifestations of distress, and integrate the MDMA experience will be determined by that therapist's preexisting skill sets. Some of the therapist training that has proven helpful are as follows:

- Holotropic Breathwork training is an excellent preparation for therapists because it provides experience working with non-ordinary states of consciousness (in this case induced by breath, music, mindset and setting) as well as training in the cartography of non-ordinary states, the use of music to support non-ordinary states and the ethical use of focused bodywork and nurturing touch [20]. Throughout this manual, "focused bodywork" is used to refer to touch in the form of giving resistance for the participant to push against. "Touch" will be used as a broader term, including both "focused bodywork" and "nurturing touch".
- Therapists may benefit from training and experience in Internal Family Systems Therapy (IFS) or some other model (e.g. Voice Dialogue or Psychosynthesis) that recognizes and addresses the multiplicity of the psyche [3, 21-23]. Training in these methods provides an understanding that multiplicity in the absence of high degree dissociation is a normal phenomenon. This is applicable because multiplicity often becomes more apparent during MDMA-assisted psychotherapy. During and after MDMA-assisted sessions, the participant may have a heightened awareness of different parts of his/her psyche, and it is essential that such experiences not be pathologized by the therapists.
- Therapists may also benefit from training or background in Sensorimotor Psychotherapy or other techniques recognizing sensorimotor-level psychological influence. Through "connecting psychological symptoms and physiological states" [24], the participant can be encouraged to work with her/his body to process anxiety and fear. Other forms of training or background that include mindful use of touch, somatic oriented therapies and focused bodywork can provide important therapeutic

tools that are compatible with this treatment method and can facilitate energy movement and release of body tensions.

- Training or background in Hakomi and other mindfulness based approaches that focus on present moment experience is applicable to this treatment method. Practitioners of Hakomi view people as self-organizing systems, organized psychologically around core memories, beliefs, and images [25]. Through working with core material and changing core beliefs, people can transform their way of being in the world.
- Training or background in Family Systems theories enables a wider systemic view of individuals in their actual psycho-social contexts, especially the immediate and extended family clusters. This enables a centered view of conflicts and opportunities as relational elements involved in handling and healing from illnesses.
- Experience with Gestalt Therapy, Psychodrama, and other enactment centered techniques enable a vitalization of experience and relationships in a here-and-now presence thereby highlighting conceptual structures and offering possibilities for movement and re-structuring/reframing that are potentially creative of new behavior and solutions.

Although this description of therapists' backgrounds is not meant to be prescriptive or exclusive, some experience with these or similar methods of treating anxiety is desirable. Strictly behavioral or cognitive behavioral approaches, while applicable to some extent, are likely to be limiting in the context of MDMA-facilitated psychotherapy if they are not balanced by other approaches.

3.0 SUPPORTING THE PARTICIPANT'S PROCESS

Before therapy starts, important considerations should be addressed with regards to providing the set and setting necessary to support the participant's therapeutic process. These considerations include: preparing the physical setting, assessing the participant's social support network, preparing programs of music, and preparing a co-therapy team that can work together effectively. During the entire therapeutic process the therapists must continue to create and communicate a setting of safety and support.

3.1 Preparing the Physical Setting

Establishing a safe and therapeutic physical setting and mind set for the participant requires that the therapists take an active role in creating an environment that is conducive to the MDMA therapeutic experience, and which will allow the participant to fully attend to her/his internal experience.

The physical setting should generally be:

- Private, with freedom from interruption.

- Quiet, with minimal external stimuli.
- Comfortable, with a futon, couch, or similar furniture that is off the floor for the participant to either recline or sit up with support from pillows. There should be blankets and good ambient temperature control. There should be room to position two comfortable chairs for the co-therapists on either side of the participant.
- Aesthetically pleasing, with fresh flowers and artwork. Images with powerful negative or disturbing connotations should be avoided. To whatever degree possible, the setting should be similar to a comfortably furnished living room rather than a medical facility. However, the participant should be aware of all safety measures and equipment in place to respond to the unlikely possibility of a medical complication.
- Well furnished, with sleeping arrangements to accommodate the participant, a selected significant other if desired, and an attendant, in a separate area. An eating space should be available and good quality, easily digested food that suits the participant's dietary preferences should be provided. The participant's preferences regarding food and types of hydration drinks should be discussed with them in advance. A snack (such as fruit and/or cheese and crackers) is recommended in the late afternoon. Even if they do not feel hungry because of the MDMA effects it is helpful to encourage participants to have a snack because their mood and energy level later in the day may be adversely affected by their having fasted since midnight.
- Equipped with art supplies, which can provide the opportunity for nonverbal expression that may facilitate the continuing unfolding and integration of the experience at the end of the day.
- Have a stereo, video recording equipment and required medical equipment.
- Have a locked area for protocol materials and records.

Maintaining physical safety includes providing access to treatment for possible reactions to the medicine during or immediately after each treatment session. Most reactions can be dealt with through supportive care, but some, such as a cardiovascular complication, could need additional intervention. Although there have not been any emergencies requiring medical intervention during any MDMA research sessions, MDMA-assisted psychotherapy should be done in a setting where Basic Cardiac Life Support (BCLS) is immediately available and Advanced Cardiac Life Support (ACLS) can be summoned reasonably quickly in the unlikely event of an acute medical problem. The clinic or office should have a means of readily assessing blood pressure and heart rate during the MDMA-assisted session.

When providing beverages, the therapists should ensure that participants do not consume more than 3 L over the course of the MDMA-assisted session, and they may wish to

provide electrolyte-containing beverages (such as Gatorade) or juices instead of water as a means of reducing risk of hyponatremia.

During MDMA-assisted sessions, therapists should ensure participant's physical safety by asking participant to sit on the edge of the futon before rising and by protecting the participant from falling when standing or walking.

3.2 Preparing Social Support

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

- It can be valuable to share the experience with someone who is supportive and willing to listen, especially if they've been briefed ahead of time about the concept that the healing process may at times involve an increase in painful emotions and this does not represent a worsening of the underlying problem. Inviting a partner or other important support person to meet with the therapists and participant during one or more of the introductory or integrative sessions can be helpful in this regard.
- Some people may have preconceived notions about the use of drugs like MDMA because of its illegal use as "Ecstasy", and they may not understand that "non-ordinary states" may be beneficial in a therapeutic setting. Participants should be advised to consider this possibility before discussing their experience. This is especially true immediately following experimental sessions when they may be emotionally vulnerable and may feel particularly open and eager to talk about their experience in the session. Under the right circumstances this can be an important part of the healing process. However, participants should be cautioned to use careful judgment about with whom they want to share this sensitive information.
- Having a period of quiet time alone after the MDMA-assisted session for journaling or introspection. Participants should be encouraged to make allowances for this so they don't become overly engaged in social interaction and receiving outside feedback. Taking time alone at this stage can be a valuable beginning of the integration process, and can provide a template for fostering the continued unfolding of the healing process that is expected to occur over the ensuing days and even weeks.

The participant may choose to invite a significant other (friend, family member, or partner) to spend time with them at the close of at least one MDMA-assisted session. This can be a valuable experience that enhances the supportive relationship. However, it

should be cleared in advance with the therapists based on the same clinical judgment they would use in considering the therapeutic value of an overnight stay by a significant other.

3.3 Planning for the Therapeutic Use of Music

Music is selected to support emotional experience while minimizing suggestion [15]. During MDMA-assisted sessions, the participant is provided with eye shades, headphones, and a pre-selected program of music. The participant may elect to forgo eyeshades and/or headphones at any time. The participant also has the option to request periods of silence and the therapists have the option to make adjustments in the musical program to fit the unfolding experience. Therapists use music to support the experience without being intrusive.

Music selections should be culturally appropriate to the population participating in a particular study. The individual selections within a program of music should vary in tempo and overall volume, so that the program has relatively quiet and tranquil sections as well as relatively active and dramatic sections. The sets can be a progression from music that is relaxing at first, then in succession more active, more emotionally evocative and later quieter and more meditative. The order of play can be changed as needed to fit the general mood and flow of the session.

It is important for at least one of the therapy team members to be very familiar with the music so it can be used effectively to support each individual's process. It may be helpful to have some multi-hour play lists prepared, providing a semi-standardized music set. Instrumental music is generally preferable to music with lyrics in a language that the participant understands, but this is not a hard-and-fast rule. There should be a variety of music on hand in case a change is needed from the pre-recorded set. Participants may bring in their own music for the therapist to incorporate during MDMA-assisted sessions. However, it is important to consider the reasons for the music selected to ensure that it is serving to support and deepen the process, rather than to distract from feelings or other experiences that may be emerging.

3.4 Supporting Somatic Manifestations of Anxiety

For those with life-threatening illnesses, many issues related to the body and body consciousness may emerge--including loss of physical ability, physical degradation, pain, and body image distress. Individuals may also have experienced certain traumas due to surgery, chemotherapy, hospitalization, prolonged invalidism, or accidents related to their illness. There may well have been adverse impacts on vitality, cognition, self-expression, movement, sensation, sensuality and sexuality. The therapists should be prepared to help participants address somatic manifestations of anxiety or fear by becoming aware of, expressing and releasing any blocks, pains or tensions in the body that may arise. This concept should be introduced during the integration sessions and built upon subsequently. There are many methods that can be used. The following is a discussion of some methods for dealing with somatic manifestations including nurturing touch, focused bodywork,

and breathing techniques. The therapists may employ other methods from their own backgrounds that are compatible with this therapeutic approach.

In MDMA-assisted psychotherapy, mindful use of touch can be an important catalyst to healing during both the MDMA-assisted sessions and the follow-up therapy. Touch must always be used with a high level of attention and care, with proper preparation and communication, and with great respect for the participant's needs and vulnerabilities. Any touch that has sexual connotations or is driven by the therapist's needs, rather than the participant's has no place in therapy and can be counter-therapeutic or even abusive. By the same token, withholding nurturing 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 participant as abuse by neglect. If the participant wants to touch one of the therapists, the therapist allows for and/or provides touch as long as it is appropriate and nonsexual. Nurturing touch that occurs when the participant is deeply re-connecting with times in life when they needed and did not get it can provide an important corrective experience. Another kind of touch that can be therapeutic is focused bodywork, usually in the form of giving resistance for the participant to push against. This is aimed at intensifying and thereby facilitating release of blocks, tensions or pains in the body that arise during therapy.

Despite the likelihood that MDMA-assisted psychotherapy will involve less focused bodywork than LSD psychotherapy or Holotropic Breathwork, the principles underlying this approach are those developed by Stanislov Grof, M.D. in his research with LSD psychotherapy:

“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 she/he is experiencing discomfort, such as depression, anxiety, blocked aggression, feelings of guilt, circular thinking, headaches, nausea, muscular pains, intestinal cramps, or difficulties in breathing, this is the time to suggest active intervention. The possibility of this happening should have been discussed during the preparation period. The first step is to find out exactly what type of experience is involved ... It is also important to encourage the subject to scan his or her body for signs of physical pain, tension, or other forms of distress indicating energy blockage. There is, in general, no emotional distress or disturbing and incomplete psychological gestalt that does not show specific somatic manifestations. These concomitant psychosomatic symptoms then become the entry points for ... intervention” [15, p. 144].

An important principle of MDMA-assisted psychotherapy is that the healing process is guided by mechanisms from within the participant's own psyche and body. Since the act of intervening with focused bodywork may give the participant the unspoken message that something from outside her/him is required for healing, the therapists must be careful to take their cues about touch from the experience of the participant and to help the participant avoid the misconception that the therapists are the source, rather than the facilitators, of her/his therapeutic experience.

Another important principle of MDMA-assisted psychotherapy is that healing often comes as a result of bringing conscious attention to difficult feelings, memories or body sensations, and staying present with awareness during these challenging experiences rather than attempting to avoid or escape from them. The therapists should let the experience unfold for the participant, being mindful not to present any unnecessary distractions. They should avoid using focused bodywork prematurely, in an attempt to resolve challenging emotions or their somatic manifestations before allowing participants to adequately experience, and process them. Therefore, the therapists must exercise judgment about when focused bodywork is indicated to help move the therapeutic process forward, as well as when it is preferable to allow the process to proceed at its own pace.

In preparation for the session, the participant should be asked to use the word, “*Stop*” (or some comparable alternative word if it is preferred by the participant) if there is ever any touch she/he does not want. The participant should be told that this command will always be obeyed by the therapists unless the touch is necessary to protect the participant from physical harm. This convention will avoid confusion between communications that are meant to be directed to the therapists and statements that are expressions of the participant’s inner experience.

3.5 Use of the Breath

Elements of Holotropic Breathwork or other techniques utilizing the breath may be useful at different times in the therapeutic process. Diaphragmatic breathing should be used to aid relaxation (“stress inoculation”) near the beginning of the MDMA-assisted session if anxiety comes up during the onset of the MDMA effect. The therapists explain that some people feel anxious during this time and others do not. For those who do, the anxiety will be transient and it can be eased by use of the breath to release tension from the body and, as much as possible, to relax into the experience. Later in the MDMA-assisted session, if anxiety or any other intense emotion comes up, rather than trying to relax, it is often most helpful to use the breath to “breathe into” the experience and stay as present with it as possible in order to fully experience, process, and move through it.

Sensorimotor and somatic psychotherapy or other techniques can be used for “connecting psychological symptoms and physiological states” [24], the participant should be encouraged to work with her/his body to process their emotional distress. Helping the participant become aware of what her/his body wants to do in reaction to difficult memories or emotions, and encouraging the participant to allow that action, can be the beginning of liberating what was once a natural process (movement) and integrating the related experiences that are unprocessed. It is important to help the participant begin to befriend her/his body instead of regarding it as a source of danger and unpredictability. Describing emotions as being about fluid movement and anxiety or depression as being about frozen movement, the therapists help the participant move through and past the somatic consequences of their illness so that she/he can trust her/his body again. Therapists should inquire about participant’s bodily sensations and encourage release of

pains, tightness or energy in the body through movement in whatever way feels appropriate to the participant. Participants recovering from a life-threatening illness are encouraged to become friends with their new and changed body, to explore feeling and sensation, and to move beyond blocks that are the products of illness and medical treatment.

3.6 Supporting Transpersonal Experiences

It is important for the therapists to be prepared for the possibility that, during experimental sessions, the participant may have transpersonal experiences [15] that might transcend conventional Western concepts of consciousness and its relationship to the physical body. Such “transpersonal” experiences that are common during MDMA-assisted therapeutic sessions extend beyond biographical memory and may include unusual sensations in the body, as well as perinatal and/or spiritual experiences. There may be perceptions that are felt to extend well beyond the usual sense of self, such as feelings of oneness in which the participant experiences an openness and enhanced connection to his or her own humanity and to the surrounding environment. Such experiences can be difficult to interpret and in some cases, may challenge the therapists’ own belief system. The therapists are not required to understand or even have an opinion about the ontological status of these experiences, but it is essential that they accept them as real and important aspects of the participant’s experience and convey respect for and openness toward the participant’s own view of them without dismissing or pathologizing any experience based on its unusual content. If necessary, the therapist should help the participant integrate these experiences into their ordinary lives. These experiences may provide the participant with a perspective that goes beyond identification with their illness and even beyond their usual sense of self, affording the opportunity to foster awareness of an innate ability to integrate their difficult experiences and move forward with their lives.

3.7 Supporting Multiplicity

In MDMA-assisted psychotherapy, it is important that therapists understand that manifestations of the multiplicity of the psyche are a normal phenomenon but may be more pronounced in people who have experienced life-threatening illness and/or trauma. This can be thought of as “dissociation”, “regression” or as the appearance of different “parts”, “selves” or “sub-personalities”. The participant may talk about inner experience in terms of awareness of different parts of the psyche and it is essential that such experiences not be pathologized by the therapists.

The approach to each of these categories of experience is consistent with Stan Grof’s general approach to phenomenon arising during psychedelic or Holotropic Breathwork sessions, which is to think about whether the material can be worked with instead of pathologizing it [15].

4.0 CONDUCTING PREPARATION VISITS

The therapy consists of a preparatory period with screening and introductory sessions followed by experimental sessions interspersed with integrative sessions and follow-up evaluations. The screening and preparatory period is the time to gather participant history and to begin establishing an effective therapeutic alliance. It provides an important opportunity for the therapists to address the participant's questions and concerns, and to prepare the participant for MDMA-assisted sessions by familiarizing them with the logistics of the sessions and the therapeutic approach that will be used. This should be done with the intention of helping the participant feel a sense of safety and comfort in the therapeutic setting.

4.1 Prerequisites and Contraindications

Prior to conducting screening activities, participants must be provided with written information about the clinical trial in which they are interested in enrolling. Participants must be provided with ample time to ask questions and discuss the informed consent with therapists or other qualified study personnel, prior to signing. If the protocol requires video recording of psychotherapy sessions, the therapists should explore the participant's feelings about being video recorded during the consent interview. The therapists should make it clear that the informed consent gives permission for the recordings to be used only for research or training purposes. It is also advisable to tell each participant that, while the recordings are important for research purposes and much can be learned about the therapeutic process from review of videos during the most difficult periods, the therapeutic process is the primary focus of each session. If there is ever a time when the cameras are inhibiting the participant from talking about some aspect of their experience, they can ask for the cameras to be turned off temporarily, and that request will be respected. Therapists should be aware that video recordings will be used to assess adherence to this Treatment Manual and competence in conducting MDMA-assisted psychotherapy, therefore they should suggest that video recording be resumed when it is appropriate to the participant's therapeutic process. Participants may request to view video recordings.

Participants should be aware that clinical trials of MDMA-assisted psychotherapy are likely to generate attention from the media. Some participants in past studies have expressed the desire to speak to the media in order to inform the public and other people with conditions similar to their own. The therapists should be respectful of a participant's desire to share their experiences, but should emphasize several caveats about doing so and should offer to help them consider the decision carefully when and if they do consider speaking to the media. It will be the participant's decision whether or not they wish to publicly disclose their participation or any information about their experience in the clinical trial. However, they are asked to refrain from doing so until after outcome assessments are complete. Participants should inform the therapists of their intent to do so in advance of releasing their personal information, including video recordings. They should also be prepared for the possibility that engaging with the media may be emotionally challenging and could have unwanted psychological effects.

4.2 Commitments Required of the Therapist and Participant

Since MDMA can have profound emotional and physical effects, its use requires thorough assessment and preparation of the participant. To foster a therapeutic mindset and contribute to a collaborative therapeutic alliance, the therapists and participant discuss the parameters of each session and make several specific agreements during the preparation sessions:

- The therapists commit to providing adequate preparation time during non-drug sessions, giving careful attention to the set and setting during MDMA-assisted sessions, and ensuring adequate follow-up therapy [14].
- The participant must commit to attending all preparatory therapy and follow-up sessions, completing the evaluation instruments, and complying with dietary and drug restrictions. The only exception to this would be if the participant has notified the therapists of a decision to withdraw consent and drop out of the study. If a participant does not withdraw consent but withdraws from treatment then follow-up assessments should be performed.
- The therapists and participant discuss the possibility of physical contact with the participant in the form of nurturing touch or focused bodywork. The therapists and participant should negotiate a comfortable physical distance from each other during the experimental sessions, and the therapists should remain attentive to any possible changes in the participant's comfort level with their degree of proximity.
- The role of the therapists is clarified and strengthened by agreements concerning appropriate behavior during and after the treatment session. Any sexual behavior between therapists and participant is explicitly prohibited. This agreement assures the participant that her/his heightened vulnerability will not be exploited, while simultaneously fostering a safe environment for offering physical comfort during the treatment session.
- The participant must agree to refrain from self-harm, harm to others, and harm to property. The participant agrees that she/he will comply with the therapists' request to stop if, in the judgment of the therapists, the participant is engaged in any dangerous behavior.
- The participant must agree that she/he will remain within the treatment area until completion of each session (In many protocols, this includes the experimental session per se and the overnight stay and follow-up visit the next morning). At the end of the session it is the responsibility of the therapist to assess the participant's emotional stability and the degree to which the MDMA effects have subsided before permitting the participant to leave.
- At least one of the therapists is present in the room at all times throughout the entire MDMA-assisted session. Except for occasional brief periods in which one therapist

at a time may leave the room, both therapists commit to remain in the room with the participant throughout the duration of the MDMA-assisted sessions until the acute emotional and physical effects of the MDMA have worn off, as determined by examining physiological signs, by ascertaining the degree of self-reported distress (Subjective Units of Distress (SUD), which must be even with or below baseline), and by clinical judgment concerning stability.

- For the therapy session to conclude effectively, the therapists and participant must agree that the participant is in a safe and stable condition. If required by the study protocol, the participant must commit to an overnight stay in the treatment facility, accompanied by an attendant. The participant must also agree to accept transport home from the integrative follow-up session following the MDMA-assisted session, either from a partner or friend or arranged by the therapists.
- The therapists and participant commit to daily telephone contact for up to a week after each MDMA-assisted session. The therapists will be available by telephone twenty-four hours a day during this period and the entire period of study enrollment.
- The therapists should be aware of and agree to the extensive time commitment that may be required beyond the length of the sessions stated in the study protocol if the participant needs additional support.

4.3 Establishing a Therapeutic Alliance

The screening and preparation phase begins with informed consent followed by determination of whether the participant meets all inclusion and exclusion criteria for the study. This period also provides adequate time in non-drug therapy sessions to begin establishing a safe and positive therapeutic alliance, which is an absolute prerequisite for treatment [29], and will continue to develop throughout the study. The participant must feel assured that her/his wellbeing will be attended to with utmost care, including ensuring physical and psychological safety and supporting their intention to gain maximum benefit from the MDMA-assisted sessions. The therapists make it clear that participation in the study remains voluntary throughout the study and that the participant's safety and wellbeing always takes precedence over the scientific objectives of the study.

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

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

During the initial visits, the therapists introduce themselves, explain their interest in this work and describe their experience in treating anxiety associated with life-threatening illness. This interaction establishes a basis for the participants to develop trust in the therapists' experience and their commitment and ability to support the participant throughout the process. Greer and Tolbert note that self-disclosure on the part of the therapist creates a context for collaboration, intimacy, and trust [14]. It also can give the participant a sense of shared identification with the therapists, which can increase personal comfort as the participant enters a state of heightened vulnerability.

(Vignettes from MDMA/PTSD study)

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

Therapist: "You are not in that position anymore."

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

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

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

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

Participant: *(Inhalation ... Exhalation)*

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

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

4.4 Gathering Information

In these initial screening and preparatory visits, the participant will undoubtedly be experiencing reactions to the screening and enrollment process. Therapists should acknowledge the considerable logistical and emotional challenges involved in

participating in a clinical trial, and should give the participant the opportunity to discuss their reactions to it. In addition to inquiring about specific historical information that is needed, the therapists should ask open-ended questions, provide feedback to the participant about the results of her/his psychological testing and medical evaluation, and encourage the participant to share what she/he believes is personally significant information. These interactions will continue to build the relationship and provide additional information about the participant's history and current challenges and resources.

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

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

Therapist: "MMMmmm"

Participant: *"... He's not in the dreams, but she's in the dreams. And how she's not this kind, compassionate mother like she used to be. How she's changed. It's really interesting. I've tried to resolve my anger towards her ... so it's kind of a ... so it's interesting that the process is already starting to work even though I haven't had any therapy." (Laughs)*

Therapist: "Well that is typical."

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

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

The therapists guide these interviews to gather information about the participant’s present symptoms, history of their illness, previous treatment and outcome, other psychiatric history, and medical, social, and family history.

Therapist: “We’d like to talk in more detail about the sessions and we’d also like to hear more detail about your history and the anxiety around the illness in particular. We can do that in any order you want. Do you feel like talking more about yourself and the anxiety now or would you like to hear about the sessions?”

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

4.5 Administering Study Related Measures

The study design may involve administering measures during preparatory, experimental, or integrative sessions. Measures may include safety measures, additional measures of anxiety or other symptoms, and exploratory measures addressing subjective effects. These measures are not a part of MDMA-assisted psychotherapy, but are an element of many studies of MDMA-assisted psychotherapy.

The therapists will remind participants of any self-report measures they will need to complete during preparatory sessions or at the start or end of experimental sessions. The study protocol will give general times for administering any study related measures. Study-related measures will be administered at a time when they do not interfere with or interrupt therapeutic processes. Measure administration can be delayed to allow therapeutic engagement to continue. Participant safety and conducting psychotherapy will be given precedence over the precise timing of measure completion. However, the therapists will make all efforts to administer measures as close to scheduled times as possible.

Safety measures such as the CSSRS should be given as close to specified times as possible without interrupting the flow of the therapeutic process. The therapists will use clinical judgment and observation of drug effects to decide the appropriate time for administering self-report measures.

4.6 Preparatory Visits After Completion of Screening

In this stage, the participant has passed screening and is continuing the process of preparing for the MDMA-assisted sessions. The therapists describe the kinds of experience that can be expected during MDMA-assisted session, they enquire further about the participant's expectations, motivations, and concerns, and emphasize their own commitment to support the participant's innate capacity to heal and process their anxiety. 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 her/his inner experience. The participant should be encouraged to cultivate an attitude of trust in the wisdom and timing of the inner healing process that is catalyzed by this approach.

The therapists encourage an attitude of curiosity and openness toward whatever occurs during the MDMA-facilitated experience. The therapists explain that often the deepest, most effective healing experiences take a course that is quite different from what might be predicted by the participant's or the therapists' rational minds. The participant is encouraged to welcome difficult emotions rather than to suppress them, as much as possible operating from the assumption that whatever arises is being presented at that moment by the inner healing intelligence as an opportunity for healing. Fully feeling exploring and expressing whatever emotions, memories, images or body sensations arise can lead to the resolution of deep-seated patterns of fear, powerlessness, guilt, and shame.

It is important to discuss the possibility that the participant will be randomized to an inactive placebo. It should be made clear that the therapists will provide the same degree of support, and will work to help participants derive maximum benefit from the session regardless of whether or not they receive a placebo or MDMA.

The therapists prepare the participant for the likelihood that emotions related to their illness—past or present, and anxiety at the possibility of their illness returning or worsening or resulting in death--will be part of the therapeutic process. They encourage participants to be as open as possible to fully exploring, expressing, and understanding the anxiety, trauma, depression and other symptoms and life impacts their illness has had on them. The therapists explicitly agree to provide support, safety, and guidance for the participant in working with any emotions and memories that may arise. It is important that the therapists be personally prepared to maintain empathic presence in the face of the participant's distress. Under the influence of MDMA, a participant can be especially attuned to non-verbal communication and to sensing the therapist's discomfort. Failure to recognize and acknowledge this can bring up feelings of distrust and fear.

Therapist: "We want to emphasize our commitment to you to be available for you. It is a privilege to support you as you do this work. And if there's any time you feel we are not doing that in a way that is helpful, or we say or do something that feels like we haven't understood you, we really encourage you to let us know. We won't take it personally, and what helps us the most is for you to be honest with us and let us know how you're doing during the sessions and afterward, including how you're feeling toward us."

It is essential that the therapists use clinical judgment and personal awareness to ascertain when to take action to facilitate the participant's process versus when to silently witness the participant's experience. The participant is encouraged to feel free to request support from the therapists during times of intense emotion or painful memories. Such support can take the form of being touched or held, receiving reassurance, or simply talking about what they are experiencing. There are times when this kind of support is extremely helpful. There are other times when silent witnessing provides optimal support by conveying trust in the participant's own healing capacity.

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

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

During preparation sessions there will likely be opportunities to tailor preparatory remarks to an individual participant's particular process. Consider the following example:

Participant (a combat veteran who was struggling with outbursts of rage since returning from Iraq): *"I feel like there's a monster in my chest trying to come out and I've got my hands around its neck trying to strangle it."*

Therapist: "Uumm... you may find as we go along in this process, that it's more a matter of getting to know this part of yourself and having a different relationship with it rather than having to strangle or get rid of it."

No more was said about this that day until, during an MDMA-assisted session after a long period of inner focus, the participant returned to the topic.

Participant: *"I just had an amazing experience! There was a campfire with three figures around it, a wise old man, a little boy and a warrior – it wasn't a monster after all it was the warrior part of me. These are all valuable parts of me and they're sitting around the campfire in council."*

4.7 Preparation Just Prior to the MDMA Experimental Session

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

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

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

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

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

Therapist: (Long silence)

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

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

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

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

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

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

Therapist: "So the MDMA may help you not have to run away, help you face things you've felt you had to move away from. There may also be times when it magnifies

the experience of wanting to hide or of disappearing. We trust that however that comes up will be part of the healing process.”

The participant is made aware that she/he will be in a heightened state of vulnerability and will likely experience a range of emotions, thoughts, and physical sensations. The therapists discuss the process of helping the participant gain relief from difficult, intense emotions or distressing thoughts and remind the participant that she/he is in a safe environment, under the care of experienced clinicians.

Participants are taught diaphragmatic breathing and other techniques to aid in the relaxation and self-soothing process. They are also encouraged to use their awareness of the breath as a technique for staying present with experiences, especially difficult experiences from which they might otherwise attempt to distance themselves.

It is important to convey to participants that the experiences catalyzed by MDMA-assisted therapy will likely continue to unfold and resolve over days or even weeks following the MDMA-assisted sessions. After therapy sessions, particular symptoms may even seem to get worse before improving.

5.0 CONDUCTING MDMA PSYCHOTHERAPY SESSIONS

The overall goal of an MDMA-assisted session is to reduce the symptoms of anxiety and improve overall functioning, wellbeing, and quality of life of the participant. This goal is accomplished by allowing each participant’s experience to unfold spontaneously without a specific agenda about its content or trajectory. While anxiety symptoms are the primary focus of outcome measures in this research, and processing emotions related to the life-threatening illness is an essential part of the psychotherapy, it is highly likely that the scope of the sessions will go beyond processing anxiety to include exploration of other psychological, interpersonal and spiritual aspects of life. The therapists’ responsibility is primarily to follow and facilitate rather than direct the experience. At times, this will best be accomplished by silent, empathic presence and listening. At other times, the therapists will provide more active support and occasionally guidance if the participant encounters emotional or somatic blocks or has undue difficulty processing anxiety-related memories or any other painful memories, thoughts, and feelings. The therapists work to support the participant’s intentions and therapeutic goals, and to help the participant work through anxieties and fears to arrive at emotional resolution and new perspectives about the meaning of their illness. The therapists are also there to help explore and validate new perspectives about other life experiences as well as to join with participants in appreciating joyful or affirming experiences and enjoying moments of beauty, heart opening, and humor. In helping to accomplish these diverse goals the therapists act as empathic listeners, trustworthy guides, facilitators of deep emotional expression and catharsis, and supporters of the participant’s own inner healing intelligence. Renewing life and one’s connections to self and others, assessing the damage and visualizing what can be done, vitalizing the choices for a life after a life threatening illness, these are potent possible outcomes of this therapy.

5.1 Therapist's Role During MDMA-Assisted Sessions

To create and maintain a safe and collaborative therapeutic alliance with the participant it is crucial that the therapists maintain self-awareness. The therapists must be empathically present during the participant's processing of their experience, and at the same time, maintain healthy, appropriate boundaries. In so doing, the therapists encourage the participant to stay present with her/his own inner experience and they create a safe environment that fosters willingness to explore new and unexpected perceptions that may arise during the healing process.

The strength of the therapeutic experience depends heavily on the therapists' level of comfort with intense emotions, and their skill in remaining empathically present and open to a range of emotional experiences. As empathic listeners, the therapists attend to the participant's account of her/his inner experience, the meanings it has for her/him, and any ambivalent thoughts and feelings she/he may have about the experience. When needed the therapists offer appropriate assistance for the participant to cope with any apparent ambiguity or difficulty, while fostering the awareness that the participant is the source of her/his own healing. The therapists keep in mind any intentions for the session that the participant has identified during introductory sessions, while also allowing for additional, perhaps unexpected, psychic material to emerge. They also consider individual psychological factors, such as attachment style, that may impact the therapeutic relationship (transference and countertransference) and influence the degree and specific nature of therapeutic intervention that will be best suited to that individual [30].

To maintain the delicate balance between focusing on the inner experience and providing a safe space for exploring this experience in an open-ended way, the therapists must respect the inner healing intelligence of the participant's own psyche and body, and skillfully interweave periods of interaction with periods of silent witnessing. At times, after periods of silence, it is important for the therapists to inquire about the participant's experience in order to maintain supportive contact and to determine whether suggestions, encouragement or further inquiry may be beneficial. At other times the therapists may encourage the participant to discontinue talking and focus on her/his inner experience. There are several situations in which this is particularly appropriate: when the participant seems to have encountered an impasse, after periods of talking that seem to represent defensive avoidance, or during the emergence of an emotionally charged issue that may benefit from the opportunity for deeper self-exploration during the period of strong MDMA effects.

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

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

Participant: *"Yeah."*

Therapist: (After a long silence) “How is it going in there?”

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

Therapist: “It’s OK not to put it into words at this point. Just stay as present with it as much as you can.”

Participant: “OK.”

Participants naturally want to get maximum benefit from their sessions, so they often need reminding of the paradox that this is usually best accomplished by surrendering to the process rather than trying to direct it. They should be reminded that, in MDMA-assisted psychotherapy, important insights and healing often arise through a non-linear process that may shift and resolve in unexpected ways. This process is enhanced by the participant’s trust that the inner healing intelligence in conjunction with the medicine will bring forth whatever experiences are needed for healing and growth, so anything that arises is viewed as part of the healing process. In this vein, the participant is encouraged to surrender to the process as fully as possible and not to “get ahead of the medicine” with efforts to direct it. The therapists’ role is often to follow, rather than guide, the participant, as she/he explores new and unexpected perceptions and realizations. At other times it may be helpful for the therapists to remind the participant that facing painful experiences is actually a path toward healing.

The therapists may provide verbal reassurance when needed and nurturing touch if requested when the participant is facing upsetting, potentially overwhelming thoughts, memories, or feelings. However, care should be taken not to interrupt the participant’s process unnecessarily or to convey a lack of trust in the participant’s own inner healing ability. The therapists should track their own emotional reactions and refrain from intervening in response to their own needs. The therapists’ ability to be present without needing to intervene, other than perhaps with a gentle reminder of their presence, can convey a strong message of compassionate support and trust in the healing process.

“We’re right here with you, use your breath and stay with it as much as you can. We know this is difficult, but we also know from experience that this is an important part of the healing. Fully experiencing and expressing this, moving through it instead of away from it is the way to really heal it.”

With a combination of empathic listening, questions, and observations the therapists facilitate two complimentary aspects of processing these challenging experiences: facing and even amplifying the experience in order to allow the spontaneous unfolding of the

healing process on the one hand and on the other hand, clarifying, understanding, and gaining new perspectives about past experience and painful emotions.

Therapists must attend to balancing their responsibilities as facilitators and as noninvasive observers. Attaining and maintaining this balance may prove challenging at times, particularly when the therapists must decide when it is desirable to allow the participant to explore and confront her/his inner experience without any interaction and when it is more appropriate to interact with the participant in order to facilitate a particular avenue of experience. There is no formula for achieving this balance, and the amount of time spent in interaction may vary considerably from one session to another. Maintaining an effective balance requires a focus on the participant's verbal and nonverbal communications, as well as an understanding of the specifics of her/his psychological history and the nature of her/his particular healing process. For example, if someone is known to have a tendency to isolate, then the therapists would have a lower threshold for checking in with them and asking about their experience. On the other hand, if someone has a tendency to defend against painful feelings by talking and intellectualizing, the therapists would more readily encourage them to put the eyeshades and headphones back on and focus attention "inward". For many individuals, both avoidance and withdrawal may be observed at different times. Maintaining a skillful balance also requires a thorough understanding of the nature of MDMA effects and the non-linear manner in which they can lead to healing.

The principal therapist, in consultation with the medical monitor, is responsible for disqualifying any participant who has had a sufficiently adverse physiological or emotional response to MDMA during the first MDMA-assisted session that a subsequent MDMA-assisted session would present an unacceptable risk.

5.2 Initiating Therapy

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

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

Therapist: "It's really natural to be anxious about that. One of the challenges of this approach is being willing to go into it and work with whatever comes up. Your reactions are common. I think it is helpful to remember nothing is going to come up that is not already there. Whatever comes up is something you are walking around with already but maybe not fully conscious of. I know it can be scary. The paradox

is, although this approach could stir up memories or even flashbacks, temporarily, it allows you to move through them in a way, so that you are actually more apt to be free of them and less likely to have them be a problem for you in the long run. It's possible you could have more symptoms temporarily, like we talked about."

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

Therapist: "You'll remember this. One of the qualities of MDMA is that it makes it easier to face memories and not be overwhelmed and actually work through them and the painful emotions in a way that is healing rather than just painful. In everyday life flashbacks and memories can come up spontaneously and overwhelm you. We are trying to change this by inviting whatever comes up to come up in a safe setting, with the medicine helping you approach it without being overwhelmed. The idea is to approach your memories with less fear and less defensiveness."

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

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

Participant: *"Uh huh."*

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

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

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

Therapists and the participant will talk about their past reactions to anxiety and discuss a plan for ways the therapists can help if anxiety arises.

Participant: *"I curl up in a ball and repeatedly say "stop". Please do not touch me because I am afraid that I will hurt you when I am in this state. Just let me rest."*

Therapists encourage the participant to set aside expectations and remain open to whatever emerges ("beginner's mind"), viewing any experience as presenting an opportunity to heal and developing trust in their own inner healing intelligence.

Therapist: “We encourage you to approach whatever comes up as something that’s coming up as part of your healing process. We trust that your inner healing intelligence will bring you what you need for healing and that’s much more reliable than anything you or we could figure out ahead of time with our rational minds.”

The therapists explain that MDMA is known to increase feelings of intimacy or closeness to others and to reduce fear when confronting emotionally threatening material [14, 17, 31-34]. They remind the participant that in the context of psychotherapy, a combination of drug effects serves to facilitate the therapeutic process by allowing the participant to explore their illness and mortality without feeling overwhelmed by the fear or despair that may have overwhelmed her/him in the past. These effects can include enhanced positive mood, novel thoughts about meaning of objects, events or memories, also increased access to distressing thoughts and memories, reduced anxiety, increased feelings of empathy or closeness to others, and decreased self-blame and judgment [11, 34-40]. This combination of drug effects can support the participant in overcoming the feelings of victimization, hopelessness, hurt and anger, or the emotional numbing associated with the illness and allow her/him to be more fully open to experiencing their full range of emotions (grief, fear, rage, as well as joy, happiness, love, comfort).. MDMA can be expected to make it easier to process feelings and memories in a helpful way, but the therapists should make it clear that this does not mean it always will be easy, and they are there to offer support if there are times when it is difficult.

The participant should have an understanding of what to expect about the onset of effects. Onset of subjective and physiological effects of MDMA begins thirty to sixty minutes after oral administration. These may include heightened sensation and perceptual changes, including visual distortions, alteration in the brightness of the room or of colors, changes in the quality or apparent location of sounds, altered perception of time (especially slowing), and changes in the meaning or significance of perceptions, thoughts, and memories [34, 38, 39, 41, 42].

When the MDMA is administered, it should be offered to the participant in a bowl or other small container for the participant to pick up and swallow with water. This presentation symbolizes the nature of the therapeutic relationship in which the therapists are offering the participant a tool and the participant retains the ability to choose whether or not to use it.

Shortly after MDMA administration the participant is guided towards a relaxed state and may find it helpful to focus on abdominal breathing. Within approximately fifteen minutes of ingesting the MDMA, the participant is encouraged to recline on the couch, use eye shades and headphones, if they are comfortable doing so, and relax into the music selected for the session. The therapist softly reminds the participant to be open to whatever unfolds and trust her/his innate healing capacity. From this point on, the MDMA-assisted session consists of periods of inner focus during which the participant attends to her/his intrapsychic experience without talking, alternating with periods of interaction with the therapists. The ratio of inner focus to interaction is typically

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

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

Participant: “OK. *I feel good about that.*”

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

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

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

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

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

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

Participant: “*I need direction. I’m just going every which way. I need something to focus on. I need something to think about ... too many thoughts.*”

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

5.3 Period of Peak Effects

Peak effects typically occur seventy to ninety minutes after drug administration [38, 39, 42, 43] and persist for one to three hours [34, 38, 42, 43]. The therapists check-in with the participant after sixty minutes if the participant has not talked since the administration

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

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

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

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

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

As the session progresses, the participant is likely to experience a positive mood and a sense of trust in both self and others. During some sessions, this shift occurs relatively early in the session and seems to provide a platform from which the participant is then able to approach the emergence of painful emotions with a greater sense of strength and safety that comes with an empathic shift in consciousness. This expansion in consciousness aids the participant in developing a new sense of mastery over the painful emotions. During other sessions, participants may be confronted by difficult experiences relatively early in the session before they have affirming experiences. In this case, affirming experiences are likely to come later in that session, or even in subsequent sessions, and contribute to a sense of resolution and healing and a shift in perspective about the world. As Grof said of work with LSD, MDMA functions to some extent as a "nonspecific amplifier" of mental processes. It is possible that what is usually experienced as difficult may come to feel intensely sad, frightening or enraging, what is typically pleasant or affirming may become associated with intense joy.

Consider the following example of an affirming experience early in the session. In her first MDMA-assisted session, this particular participant started with a Subjective Units of Distress (SUD) rating at 7/7. She reported being very anxious about the unknown, including fear that flashbacks would be triggered. Forty-five minutes after MDMA administration she said:

"My legs are a little heavy and my chest is a little hot, not a bad thing, I'm not nervous anymore. I feel warm and fuzzy I'm not stressed at all." At the one hour point, her SUD was 0 (actually, she reported it as "minus 15"). *Colors are bright, I feel warm inside, there's lots of energy... My thoughts are coming fast. I need some*

direction. Love, I'm seeing blocks to it." The therapists suggested she focus her attention back inside. After a few minutes she said, *"I just heard, 'You're the greatest!'... I see the link between the derealization and the rape."* She talked briefly about the rape and became aware of anger, self-blame, and feeling alone, and then said, *"There has been desperation under the numbness. I feel protected now, I finally feel loved and protected. (Tears) It's good to have someone who cares."* She went on to talk some more about the rape in this session with realizations about how experiences in childhood had made her vulnerable. She spent much of the session appreciating being able to really feel, for the first time, how much love and safety there was in her marriage. In the follow-up sessions she said, *"Now I have a map of the battlefield. I think next time I'll be able to go deeper processing the trauma,"* which she did.

Consider the following example of an experience of being confronted by painful memories relatively early in the session:

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

It is common for participants to make mental connections spontaneously between their illness and earlier life experiences. Often, they arrive at insights about how earlier experiences may have left them more vulnerable to being fearful, anxious or hopeless later or may have affected their response to their illness.

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

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

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

Participant: *"I guess so."*

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

Participant: *"Not long at all."*

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

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

(Long silence)

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

MDMA-assisted psychotherapy helps the participant face the existential and day to day distress associated with a life-threatening illness. As illustrated above, there are often insights about longstanding emotional and behavioral patterns based on early protective responses to underlying rage, grief and shame. With more self-acceptance and less self-criticism, the participant gains clarity and self-confidence, a sense of self-efficacy, and a less fearful, more open and curious, relationship to unfolding memories, thoughts, and feelings. A sense of inner calm, rather than anxious arousal is expected to help the participant examine memories and thoughts more closely and objectively, while at the same time, allowing powerful emotions to surface. The sense of safety may work in concert with facilitated recall to allow deeper exploration of their illness and its effects on relationships and other aspects of the participant’s life. This mechanism is consistent with observations from other methods of therapy that require trauma processing, to be effective, be accompanied by a degree of emotional engagement or “fear activation,” while avoiding dissociation or overwhelming emotion [1]. This strategy has been referred to as working within the “optimal arousal zone” or “window of tolerance” [4, 44, 45].

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

Therapist: “Hmmm.” *(Long silence/soft piano music)*

Participant: *“I’ve kept all this inside for so long. It feels so heavy, these emotions ... it’s like I was trained this way ever since I can remember. Children were to be seen and not heard. From that point on, I sought to make myself as insignificant as*

possible. Then after the rape happened, I was headline news. I knew everyone at the hospital. I was ashamed, like I had a scarlet letter.”

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

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

As the participant experiences a greater sense of closeness to others, with more trust and intimacy, she/he may also feel greater empathy and forgiveness for self and others.

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

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

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

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

Sometimes the invitation is to expand on verbal discussion:

- “Would you like to tell us more about that?”

Or to direct attention to non-verbal or indirect communication:

- “I just noticed that your voice changed. Is there something going on that you notice?”

At other times the invitation is to focus inward:

- “Would you be willing to experiment with not distracting yourself that way for a few minutes just to see what you might discover?”
- “Maybe this would be a good time to put the eye shades and headphones on and go back inside to let the medicine help you with this?”

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

Therapist: “Where do you feel that in your body?”

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

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

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

Participant: *“I feel really restless.”*

Therapist: “Just try to go with the flow with that energy for a little while.”

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

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

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

In many cases, simply bringing attention to the body by inquiring about the present moment physical experience and encouraging the participant to allow spontaneous movement or expression will be all that is needed for further discovery and release of tensions or blocks in the body. If further facilitation is needed, the specific approach will vary according to the therapists’ training and experience, but must always be presented as a suggestion or invitation to further exploration, rather than an instruction or requirement.

If the participant “resists” a suggestion, recognize that this is probably not deliberate, or even conscious, and that it is usually better to accept and follow whatever direction she/he takes, rather than to further challenge or interpret the resistance at that point. An exception to this approach is when someone appears to be avoiding something repeatedly. In such a situation, if the therapist decides to directly address the resistance, it should be done gently, as a collaborative exploration, and with respect for the fact that the underlying intent of a defense is self-protection. As in other therapies, processing the resistance itself, rather than trying to push past it, should be the approach. With a gentle, minimally directive approach, given time, the participant is likely to come back to the issue spontaneously later in the session or in subsequent MDMA-assisted sessions or integrative follow-up sessions.

Participant: *“I’ve just been realizing that every time I started to think about that time in the hospital I decided to go to the bathroom. Now I’m ready to talk about it.”*

At this point, the participant may have valuable insights about the resistance, as well as the underlying issue. This is a situation in which there is room for flexibility for the therapists’ intuition and judgment. Insights which are formulated spontaneously are likely to be of greater benefit, but sometimes, direction from the therapist may help create a valuable opportunity for healing. It is important to strike a good balance: weighted more toward self-direction than direction from the therapists.

The therapists must recognize and attend to both the participant’s underlying psychological processes and the experience produced by the medicine. This responsibility involves supporting the participant in processing the negative effects of their illness and simultaneously supporting the softening effects of MDMA. The therapists’ presence and the effects of the medicine can provide a sense of safety, as the participant’s barriers to perception open to allow increased access to memories, thoughts, and emotions with greater clarity and compassion and a greater sense of interpersonal connection. Having survived the illness, the participant can open to the possibilities for life ahead and create an orientation to its pursuit, whatever the probable, or imagined duration.

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

Therapist: “Your derealization takes all of your attention.”

Participant: *“My perception is off.”*

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

Participant: *(Breathing softly)*

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

Participant (during an agreed-upon phone call to the participant’s husband near the end of the session): *“Did you tell Tom that I love him?”*

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

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

An increased focus on interpersonal relationships may benefit participants who have distanced themselves from others as a way of coping with their illness. Feelings of interpersonal trust may also help participants who have experienced a lack of support from significant others since receiving their diagnosis. The therapists and participant may explicitly seek to explore these areas during part of the MDMA-assisted session.

During the MDMA-assisted session, the participant may experience strong “negative” emotional reactions, including feelings of loss of control. When the therapists see that the participant’s distress is interfering with her/his ability to stay focused on the inner experience, they intervene, encouraging the participant to stay present with deeper levels of emotion, including distressing feelings, and to trust that it is safe to face the experience. Reminding her/him that in this supportive setting it is not only safe, but beneficial, to experience the fear of losing control and to experiment with relaxing the

need to control, without actually being out of control or in danger. They encourage the participant to surrender control and fully experience and express her/his feelings, including any fear of losing control. The therapists' guidance may take the form of:

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

During difficult periods, one or both therapists offer a supportive touch (if culturally and personally acceptable for the participant) by asking permission (e.g. "would you like me to hold your hand?").

In these ways, the therapists help the participant stay with powerful emotional experiences, including fear, anxiety, shame, guilt, helplessness, despair etc., rather than trying to suppress or avoid them. The therapists remind the participant that this is a natural progression of the therapeutic process, opening up to and moving through inner territory which she/he may have previously been afraid or unable to fully face.

Therapist: "I encourage you to just be as present as you can with that confusion (stuck feeling, fear, etc.), feel it as fully as you can, and express it in any way it may come."

Consider the following example of helping the participant with a difficult experience:

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

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

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

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

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

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

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

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

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

Therapist: “One option for working with this would be for us to work with that place in your body. It’s totally optional, and if you decide to do it we’d do it without any agenda, not trying to make anything happen, just to see if there’s something your body wants to do or something there to release. And you can always say stop any time.”

Often participants have vivid images that may depict some aspect of their healing process. Consider the following examples:

- *“I felt deeply connected to painful feelings about the illness as I saw them go by in spheres, but it didn’t cause anxiety. I felt deep sadness in my heart, [crying] but also deep happiness that I was healing it and letting it go.”*
- *“It’s like, every time I go inside I see flowers and I pick one, and that’s the thing to work on next. And there are things that are hard to take, but each time I move through them it feels so much better.”*
- *“It’s like there have been ropes tied around me and now they’re loosening.”*
- *“I’m a huge pile of fertilizer composting and turning into beautiful rich soil. It’s a perfect time to have rain. I’m a converter, I’m the earth, I am. Leaves, rain, even acid rain hit me, and I have a powerful ecosystem, all can be absorbed. What we’re doing here is turning compost.”*
- *“I see huge white doors with beautiful white glass, so huge and heavy, but a master has engineered them so you can open them with one hand. It’s only without the fear that the doors are so light. How interesting! If I go up to them with all the fears it makes me weak. I’m taking those fears out of different parts of my body, looking at them and saying ‘it’s OK but I’m leaving you here.’ The fear served me well at one time, but not now for going through these doors.”*

5.4 Later Part of the Session

As the effects of the MDMA subside, the therapists may talk with the participant more extensively about what she/he experienced during the session. The therapists ask if the participant would like to give more detailed feedback on her/his emotional and physical status [15]. However, there should be no pressure to do so at this point; it may be left for follow-up sessions.

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

The therapists encourage the participant to reflect on and accept the validity of the experience, including any new insights. If the participant expresses any regrets or self-judgment about what occurred during the experimental session the therapists help them to normalize these feelings and provide reassurance.

Therapist: “You know, today you’ve faced and talked about a lot of difficult experiences in ways you haven’t been able to before. It’s really important to your healing process that you did, it’s definitely a good thing, and it’s also really understandable that there would be some second thoughts or judgments about it as the medicine wears off. This is common for people doing this work, and part of our role is to help you process these thoughts and feelings too, and respect that there are parts of you that may not trust the validity of the experience yet, it’s all part of the process. How do you see it? Was it a genuine experience or just a drug experience that wasn’t really valid or real.”

Participant: “*No, it was a real experience. It was my own experience, the drug made it possible, but it was my experience.*”

If the participant indicates physical pain, tension, anxiety, or other signs of distress, the therapists may use focused bodywork (See Section 6.3).

When a participant’s emotional distress persists toward the end of the session and they are not able to process and spontaneously move through something difficult, the following steps may be helpful. In most cases, these steps should be taken sequentially, proceeding to the next step only if necessary:

- 1) Ask: “What are you aware of in your body?” This question helps the participant become conscious of the link between distressing emotions and any somatic manifestations. Making this link and making the suggestion to “Breathe into that area and allow your experience to unfold” may be the only intervention that is needed.
- 2) Encourage the participant to “Use your breath to help you stay as present as you can with this experience. Go inside to allow your inner healing intelligence to work with

this.” If the participant is still under the influence of the MDMA add, “The medicine will help that happen.”

- 3) If the participant is quite agitated (anxious affect, moving on the mat, opening eyes), it may be helpful to hold her/his hand or to put a hand gently on the participant’s arm, chest or back, or on an area where she/he is experiencing pain, tension or other physical symptoms. This nurturing touch can be reassuring and help refocus attention on inner experience, but should only be done with the participant’s permission.
- 4) Ask, “Is there any content (specific images, memories, or thoughts) coming up with these feelings?” If so, the therapists may encourage further discussion. The opportunity to put the experience into words may in itself be therapeutic, especially in this safe setting. This juncture may also be an opening for the therapists to help the participant articulate some of the deeper fears and concerns they have associated with their illness, and further to explore possible connections between their current emotional state and earlier life experiences such as illnesses in childhood, or knowing close relatives or friends whose illnesses and deaths they may have experienced that moved and influenced them..
- 5) After this period of talking, and periodically throughout the session, encourage the participant to “go back inside,” to focus on her/his own inner experience.
- 6) If the participant continues to express or exhibit emotional distress or somatic tension or pain, bodywork of a more focused nature may be indicated, according to the therapists’ training and experience in this area.

5.5 Ending the Session

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

If a significant other is invited to visit, there should be an agreement that he or she will wait in the waiting room until one of the therapists comes out to talk to her/him. If, as is sometimes but not usually the case, the significant other has been asked to come before most of the MDMA effects have worn off, she/he should be prepared to wait until the therapists and participant decide it is a good time to invite her/him into the session room. He or she should be encouraged not to take it personally if, because of the nature of the session, they are not invited in until later than anticipated. When the significant other arrives one of the therapists (with prior permission from the participant) should meet briefly with him or her outside the session room to explain the participant’s present

condition, to ask about any concerns or questions the significant other may have, and to assess his or her capacity to be empathically present with the participant in their current state of mind. Inasmuch as this study also focuses on the relationships with close caregivers and the reciprocal impact on lives lived with illness, treatment and recuperation, inclusion of the caregiver and understanding the impact of MDMA assisted psychotherapy on that relationship is of great interest and import to the therapists and the study..

Consider the following example (This example is about interaction between a woman and her husband conversing about her sexual trauma. The tendency for couples to avoid talking about painful subjects applies to many situations)

Therapist (outside the session room with a participant's husband who has come four hours after MDMA administration): "Hi, thanks for coming. She's having a very good and powerful session. She would like you to come back, but wants me to get an agreement with you first, and will also understand if you decide you can't give that agreement and she'll be OK whatever you decide. She wants to talk to you more about her abuse, but she's afraid you may confront and harm her abuser. That's why she hasn't talked to you more about it in the past. So she wants to know if you'll agree that, no matter what you hear, you won't act on it that way. And I can totally understand if you can't honestly agree to that, and she can understand that too. And we can also understand if you just aren't prepared to hear more about her abuse, because I'm sure it will be difficult to hear. We want you to be really honest about what you can agree to, and what you feel is OK for you to do."

Significant other (after some reflection): "I can agree to that. I know it would be good if we both stopped avoiding talking about it. I've been avoiding bringing it up because I didn't think she wanted to talk about it."

The significant other and participant went on to have a beautifully connected conversation about the abuse. They were able to talk and listen to each other with empathy and understanding, and to process each of their feelings about it in a very healing way.

Toward the end of the session, the therapists discuss with both the participant and significant other some of the after-effects of the MDMA experience and what might be expected over the course of time as the healing process unfolds. This can be a good time to review understandings about how they may best support each other during this time.

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

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

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

If all means of reducing the participant's distress have failed and the participant remains severely anxious, agitated, or in danger of self-harm or suicide, or is otherwise psychologically unstable at the end of a two-hour stabilization period, the therapists may decide between one of three options: 1) one or both of the therapists may stay with the participant until they are stable, 2) the therapists may meet with the participant daily until the period of destabilization has passed, or 3) the participant may be hospitalized until she/he is in a stable condition. The therapists would use the option of hospitalization only under extreme conditions, attempting all other viable options first. Hospitalization is likely to be indicated only very rarely, and would typically be utilized only if the individual is significantly clinically disorganized, unable to care for herself/himself, or posing a potential danger to herself/himself or others.

Barring the need for any ongoing treatment or attention from the therapists, the participant spends the rest of the evening and night in a comfortable private room in the study site.. An attendant is on duty during this time and has a separate room in which to rest. The attendant can function as an impartial and empathic listener, if desired, but primarily serves as a supportive caretaker and monitors the mental and physical state of the participant. Attendants must have the capacity to be present with other people's emotions without becoming emotionally reactive themselves. They are instructed to respect any desire the participant may have for quiet time alone, or to listen

compassionately if the participant wants to talk. Attendants should not interpret the participant's experiences or otherwise act as therapists. Attendants see to the participant's need for food or liquids and offer companionship by sitting or taking a walk with them, according to the participant's desires. The attendant contacts the therapists if at any time the participant seems to be experiencing undue distress.

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

It is quite common for participants to have difficulty sleeping the night following the MDMA-assisted session, in part because of residual amphetamine-like effects of MDMA. It is reasonable for the responsible physician to prescribe a sedative/hypnotic, such as zolpidem or a benzodiazepine such as lorazepam or temazepam, if the participant desires and there are not any contraindications.

A follow-up integrative session occurs on the morning following each MDMA-assisted session.

If a particularly severe panic or other problematic psychological reaction (e.g. suicidality), does occur during or after the first MDMA-assisted session, the therapists will decide whether or not the participant should undergo a second MDMA-assisted session as scheduled in the protocol. This decision should only be made after assessing the participant during the follow-up sessions and should subsequently be thoroughly explained and discussed with the participant. In many cases, if the participant is willing, it is beneficial to proceed to another MDMA-assisted session as an opportunity to process and resolve underlying causes of the anxiety, rather than reinforcing the idea that it must be avoided.

5.6 Subsequent Experimental Sessions

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

Typically, for participants who are offered more than one MDMA-assisted session, the sessions will occur two to three weeks apart. All of the principles and procedures that apply to the first MDMA-assisted session also apply to subsequent sessions, although explanations and reminders at the beginning of the session can be briefer in subsequent sessions. In addition, when preparing for subsequent sessions, the therapists should inquire about and explore any intentions the participant might have for the subsequent session based on their experiences in the previous session or sessions. In accordance with these revealed intentions, the therapists and the participant may make agreements

that the therapists will remind the participant of an issue they want to explore, will help her/him notice if they are avoiding certain subjects, and may be prepared to use or refrain from focused bodywork according to the agreement. Having recognized and discussed these intentions, the participant should also be encouraged to “hold the intentions lightly,” meaning not to be heavy handed in trying to direct or control her/his experience. Therapists and participant should strive to strike a balance between making use of what they have learned from the previous experience and taking the opportunity to build on it, versus maintaining a large measure of “beginners mind” and remaining open to the natural unfolding of the next experience

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

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

Participant: *“Oh yeah. I think that’s what’s got me so nervous.”*

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

Participant: *“All I can really tell you is that I’m not the ‘beat around the bush’ type of person.”*

Therapist: (Laughs)

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

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

Participant: *“Sure”*

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

6.0 CONDUCTING INTEGRATIVE FOLLOW-UP SESSIONS

The ultimate goals of MDMA-assisted psychotherapy are to eliminate symptoms, reduce the impact of past trauma(s) and attain an improved level of wellbeing and functioning. The process of accomplishing these goals continues well beyond the MDMA-assisted sessions themselves, and is supported by the follow-up integration sessions. The importance of integration is emphasized during the introductory therapy sessions, when the participant and therapists discuss the likely trajectory of the therapeutic process. The challenges during the integration stage are to facilitate continued emotional processing and address any difficulties that arise as the experience from the session continues to unfold, and at the same time to help the participant apply the benefits gained in the MDMA-assisted sessions to daily life. These are likely to include valuable insights and perspectives, a broader emotional range and resilience, and deepened interpersonal skills. The therapists help the participant weave all aspects of the therapeutic experience into a new relationship with self, with others, and with her/his illness. This phase of treatment brings these elements together in a cohesive, harmonious way.

Since it is difficult to predict how much difficulty a given participant will have with the integration process, it is important to be alert to possible problems, such as shame and self-judgment about having revealed secrets, or challenging shifts in relationships and family systems as the participant heals and changes. Conversely, the therapists should be open to the possibility of an easy integration that requires minimal intervention beyond empathic listening and sharing appreciation for the participant's healing and growth. The therapists should therefore remain flexible in their response to each participant's particular needs.

6.1 Therapist's Role During Integrative Follow-up

During follow-up integrative sessions, the therapists are present to answer any questions the participant may have, and to offer support and encouragement as the participant processes the emotional responses and new perceptions resulting from the MDMA-assisted session. The therapists take a supportive and validating stance toward the participant's experience. They also help the participant further explore and develop new insights about their illness, and its impact on their life, new perspectives about life and relationships, shifts in their relationship to their own emotions and the clearing of old thought patterns and reactions that may have outlived their usefulness. They may discuss the meaning of the memories, thoughts, feelings, and insights experienced during the MDMA-assisted sessions and how this new meaning will be manifested in daily living. The therapists may offer insights or interpretations regarding the participant's experience, but this should be minimized. Participants should be encouraged to exercise their own judgment about whether any given comment by the therapists may or may not resonate for them, and to apply their own discernment about what may be applicable and useful to understanding to their experience.

The therapists encourage the participant to make time in daily life to reflect on the MDMA-assisted sessions in order to bring valuable elements of the non-ordinary experience into ordinary consciousness. They will suggest ways to facilitate this, such as: listening to music from the sessions, listening to audio or video recordings from the MDMA-assisted sessions, practicing breathing techniques, or drawing, singing, dancing, yoga, exercising, spending time in nature, painting, or other forms of creative expression. The use of creative endeavors for recalling and retaining memories, thoughts, feelings or insights from MDMA-sessions may provide the participant with a new set of coping skills with which to restructure anxious thoughts and feelings and to be at greater ease with the uncertainty and fear associated with their illness. The therapists encourage these activities that allow restructuring to emerge from the participant's own thought process, ongoing emotional processing, and continuing self-exploration. In this way, the clarity of thought and the ability to safely and effectively process difficult emotions that are catalyzed by MDMA-assisted sessions can serve as templates of corrective experience to be accessed in daily life.

6.2 Integrative Follow-up Sessions

The integration process, begins with an initial ninety minute integrative follow-up treatment session scheduled for the morning after the first experimental session. It provides an opportunity to discuss the participant's experience during the experimental session and to process any thoughts or feelings that have come up since the session, including difficult reactions, such as anxiety or self-judgment. After the initial session, several more integrative sessions are scheduled prior to the next MDMA-assisted session or before entering into long-term follow-up. There is also a week of brief daily phone contact to assess the participant's general well-being and possible need for more therapist contact prior to the next scheduled visit.

During integrative follow-up sessions, participants should be invited, but not required, to talk more about some of the details of their experience during the experimental session, to direct attention toward any insights or emotional shifts that may have resulted, and to consider how these changes may be integrated into daily life. Each integrative follow-up session should begin with an invitation for the participant to talk about whatever is on her/his mind. The purpose is to ensure that the participant's experience rather than the therapists' agenda will direct the session. After allowing sufficient time for this open-ended discussion and exploration, the therapists should consider directing the session into other potentially useful areas. The therapists facilitate an active dialogue and elicit detailed disclosure as a means of allowing them to accomplish the following:

- Assess how the participant tolerated the MDMA-assisted session and discuss the content of the MDMA-assisted session and the participants emotional, intellectual, and physical response to it. Processing includes discussing the effects on anxiety symptoms and creating ways to integrate new perceptions and insights gained from the MDMA-assisted session.

- Ensure that the participant understands that the experience catalyzed by the MDMA-assisted session will likely continue to unfold and resolve over days or even weeks following the treatment session. This unfolding often happens in “waves” of memories, insights and/or emotions, some of which may be very affirming and pleasant and some may be difficult and challenging. It is important that the participant be prepared for this unfolding and make time in their daily life to attend to the unfolding process.
- Process any emotional distress or cognitive dilemmas that may arise.
- Work with relationship issues and develop tools for healthy connections.
- Introduce focused bodywork into the therapy in the event that the participant is experiencing emotional or somatic distress that she/he is not able to move through spontaneously or with talk therapy.
- Validate any affirming experiences and insights that occurred during the experimental session and help participants learn to re-connect with and continue to gain from these experiences.
- Encourage the participant to stay connected with their support system, but also to be prepared for the possibility that other people may not understand the depths of their experience and insights. For that reason it is advisable to be discriminating about with whom to share this sensitive material.
- Determine any possible contraindications for the subsequent MDMA-assisted treatment session.
- Discuss and reinforce activities, such as journaling or other creative expression, meditation, yoga, or other activities that, on a regular basis in daily life, will provide time for the quality of attention that is conducive to ongoing healing and self-awareness.

The therapists remind the participant that they have two options for dealing with upsetting thoughts, memories, or feelings lingering after the MDMA-assisted session. One is to set aside time to experience them as fully as possible, feeling free to call the therapists for support, if necessary. An important basis of this approach is the perspective that waves of difficult experience may recur for some time as a part of the healing process. A second option is to perform relaxation and centering techniques, such as diaphragmatic breathing. This option may be chosen if a given situation does not allow for the first approach. On occasion a medication such as a benzodiazepine can be helpful, but should always be used sparingly as a tool to aid in temporarily managing painful emotions in order to tend to daily responsibilities or to allow for sufficient rest and relaxation to balance the ongoing emotional processing. Information on the utility of focused bodywork and breathing exercises can be reinforced in integrative follow-up

sessions in preparation for the next MDMA-assisted session and as tools for the participant to use at home.

Consider the following example sessions:

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

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

Participant: *(Laughs)* “That’s what I got. It wasn’t in the brochure.”

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

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

Therapist: “Yes.”

Participant: *“I’m trying to train my brain to enjoy it. I have all these tools. I just need to remember to use them.”*

Strengthened interpersonal trust helps the participant further develop her/his social network. Greater insight into the whole range of thoughts and feelings that can emerge around life-threatening illness and the possibility of death gives the participant confidence in confronting emotions, reducing the likelihood of emotional numbing. Relying on the new perspectives gained from the MDMA-assisted session, the participant can confront anxiety-producing situations with more confidence and may be more comfortable with asking for assistance from her/his supportive network.

The therapists may use a variation of the following comments, always in the spirit of offering something for the participant to consider and with respect for the fact that what is offered 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 society in general. Is this something you’ve noticed?”
- “Since the MDMA experience is quite unique, it can be hard to explain to other people, and it can be painful if such an important experience is misunderstood or

judged by other people in your life. It may be important to exercise judgment about how and when you talk about your experience.”

- “Often people have very valuable insights and corrective emotional experiences with the help of MDMA that aid in decreasing fear and judgmental thinking. Sometimes the next day, the judging mind can get active again and start doubting the truth of these experiences, or sometimes, people can have emotional reactions the next day that didn’t come up during the MDMA-assisted session. This can sometimes be confusing or upsetting, but it doesn’t mean something has gone wrong or that you’re losing the gains you made. It’s a common aspect of this kind of work and the way the process unfolds. It’s really helpful to acknowledge and talk about it if you’re having any experiences like this. It’s part of the healing and we’re here to help you process it.”
- “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 individuals with life-threatening illnesses in any therapy, including MDMA-assisted therapy, can stir things up so that symptoms of anxiety or despair may temporarily get worse. These feelings 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-assisted sessions. It’s important to let us (and your other therapist) know about it if you have any difficulties like this.”
- “Sometimes people have powerful insights and a sense of comfort and peace that they’ve rarely or never experienced before. It’s natural to want to hold on to this, and sometimes people tell us that when some of the old painful experiences return, it feels like a failure or that it means they didn’t really have any healing. It is helpful to anticipate that painful feelings are bound to come sometimes and some of the old patterns of thinking, feeling, and reacting are bound to reconstitute themselves, even after you’ve seen past them so clearly. That’s a natural part of the process and what happened in the MDMA experience is likely to help you recognize and step out of these patterns sooner even when you do get caught. People often tell us that being able to think back to the experience can change their relationship to these painful emotions.”
- “It may be helpful to write about your MDMA experience and your thoughts and feelings since the session. It’s best to write this for yourself without the thought of doing it for anyone else, but, if you want to bring it in to share with us, that could be useful as well. It may also be helpful for you to listen to the recordings of the session in connection with this.”
- “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 that we can recommend that address some of the experiences you’ve been talking about.”
- “If a lot of feelings or images are coming up for you after the MDMA-assisted session, it’s good to allow them to unfold and to 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 by yourself when you have the time and energy. Hot baths, walks in nature, physical exercise, being with friends, working in the garden, cleaning the house, creative activities, nourishing food, or playing with a pet are all activities that can help to ground you in the present.”
- “If there are tensions left over in the body, yoga or a massage can be helpful.”
- “This is not a ‘no pain, no gain’ situation. Sometimes moving through waves of painful feelings and memories is part of the unfolding process, but connecting with easy, affirming, pleasurable experiences is part of the healing too and is at least as important as willingness to be with the painful ones.”
- “Sometimes during MDMA-assisted sessions, there are very rapid shifts and people feel that something difficult has really resolved. It’s good to be open to that possibility, but often, it’s more that people feel they’ve gotten past some big obstacles and made important steps along their path of healing and growth so they’re in a better position to keep working with it and continuing to heal and grow.”

Detailed discussion of this kind is often useful during the initial integrative follow-up session. On the other hand, at this point, sometimes participants have a sense that they would rather allow their inner experience to continue unfolding without attempting to put it into words. If this is the case, the therapists should validate that choice, but should ask for enough information for them to be aware of the participant’s emotional state and any difficult feelings or thought patterns that should be addressed before the participant leaves the office.

The therapists recognize that the MDMA-assisted sessions and integrative follow-up sessions serve as starting points for enhancing the participant’s emotional and behavioral repertoire in response to future emotional triggers related to life threatening illness. In the days between the MDMA-assisted sessions and integrative follow-up sessions, the participant is encouraged to be mindful of any changes in her/his perceptions, thoughts, feelings, interactions, and other experiences.

Some of the challenges during the integration period stem from the fact that symptoms may increase temporarily as part of the healing process. It is important to anticipate and prepare the participant for this possibility. It may be helpful to involve a significant other in preparing to support the participant if this challenge should arise. Normalizing, exploring and processing these reactions is usually all that is needed for them to resolve,

and additional insights, healing and growth typically arise as a result. Consider the following participant testimonials of experiences reflecting incomplete integration:

- *“The anger feels like a volcano, I’m afraid of being a one man wrecking crew, I feel such sadness, loneliness, nausea.”*
- *“Since I’ve realized how shut down I had been I don’t ever want to go back to being that way, so I’m having a hard time in business situations or with my father knowing when not to say everything I’m feeling.”*
- *“After all these years of not talking about it, was it really safe to reveal that I felt physical pleasure along with horror when I was abused?”*
- *“Now that the medicine has worn off I sometimes feel guilty for saying the things I did about my parents not being emotionally available. I know it wasn’t about blame, but there’s still that judging voice that says we don’t talk about any of this.”*

Suicidal thoughts may be present in those with life-threatening illness and in some cases may increase temporarily after the MDMA-assisted sessions. In this case, close communication is needed and may entail longer phone support or additional visits. The Columbia Suicide Severity Rating Scale (CSSRS) [46] should be used through the treatment (per study protocol and required by FDA) to monitor for suicidality.

When confronting emotionally threatening material, in addition to taking time to reflect upon it and fully feel and express any associated emotions, the participant should be encouraged to remember and reconnect with valuable aspects of their experience during the MDMA-assisted sessions such as: new insights, feelings of closeness to others, and the ability to process painful emotions without being overwhelmed. The participant can then ask herself/himself, “How can I best use my new knowledge in this situation?”

6.3 Focused Bodywork During Integration

Content from the MDMA-assisted session and integration sessions will cue the therapists to the likelihood that focused bodywork would assist in working with physical tension or pain or intense emotion that has somatic manifestations such as psychomotor agitation or retardation. A common example of this is when participants are more in touch with anger after thinking about their illness during an MDMA-assisted session, and are struggling to contain it for fear of acting out in a destructive way. Focused bodywork catalyzes the healing process by providing a safe way to express intense emotions and impulses in order to release tensions that may be contributing to somatic complaints and blocking energy flow within the body. Focused bodywork is only done with participant permission and is immediately discontinued if the participant requests that it stop. Although focused bodywork may be an important part of the follow-up integrative sessions for some participants, it should not be used prematurely if challenging emotions or their somatic manifestations are being adequately experienced, processed, and expressed spontaneously. The focused bodywork is most appropriate in situations in

which emotional or somatic symptoms are not resolving because their full experience and expression appears to be blocked.

Consider the following example of focused bodywork in an integrative follow-up session:

Therapist: “How are you today?”

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

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

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

Therapist: “MMMmmm.”

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

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

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

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

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

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

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

Therapist: “So maybe just use your breath and breathe into that feeling in your stomach. I encourage you to remain present with whatever comes up and if your body wants to express it in any way, shake, move, or if you want some resistance from us.” (As the focused bodywork was performed, the participant breathed into it and experienced a deep sobbing.)

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

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

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

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

6.4 Ongoing Integration

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

As the treatment program draws to a close, participants may differ in their response to its conclusion, from anxiety upon leaving the study and the therapists to relief at completing the course of psychotherapy. The therapists can use general well-being ratings, CSSRS scores, and clinical judgment to adapt to different responses to having the final integrative follow-up session. The therapists and participant will discuss ongoing issues or concerns participants may have about the end of integrative follow-up sessions and no longer meeting with the therapists. They will discuss the participant’s existing social support network. If necessary, they can review any procedures that have helped the participant cope with distress during the study, such as written expression, visual arts or movement, use of breathing, or other stress reduction methods. The therapists can remind participants to continue practicing any activities and maintaining relationships

that have supported and strengthened them. Participants who are seeing a therapist outside the study are encouraged to discuss the approaching end of the study with that therapist, and, if in their judgment it is warranted, the study therapists may provide participants who are not in ongoing therapy with a referral for contact with a therapist after the final integrative session. In addition, the therapists may recommend experiential therapies such as Holotropic Breathwork, Internal Family Systems Therapy or Somatic Processing as methods that can facilitate the ongoing unfolding of the process that was catalyzed by MDMA-assisted psychotherapy. The therapists will also share their perspectives about any changes, accomplishments and achieved goals they've observed over the course of the study.

As the integration progress continues to unfold, participants may come to gain novel perspectives on their own situation. Consider the following participant testimonials of experiences reflecting deeper integration:

- *“I have respect for my emotions now (rather than fear of them). What’s most comforting is knowing now I can handle difficult feelings without being overwhelmed. I realize feeling the fear and anger is not nearly as big a deal as I thought it would be.”*
- *“I don’t think I would have survived another year. It’s like night and day for me compared to other methods of therapy. Without MDMA I didn’t even know where I needed to go. Maybe one of the things the drug does is let your mind relax and get out of the way because the mind is so protective about the injury.”*
- *“It has felt like growing up, I feel wiser, more emotionally mature.”*
- *“Now I have a map of the battlefield.”*
- *“I got a glimpse of more of what I’m capable of growing into ... I’m motivated to keep practicing openness until it gets more developed.”*
- *“Last night I had a clear sense that I got where I needed to get. What was missing has been found. What I needed, I’ve gotten. I don’t feel like I need to do it again. I think there are still other issues in my life that I can work on with less intense methods.”*
- *“I feel like I’m walking in a place I’ve needed to go for so long and just didn’t know how to get there. I feel like I know myself better than I ever have before. Now I know I’m a normal person. I’ve been through some bad stuff, but...those are things that happened to me, not who I am...This is me, the medicine helps, but this is in me.”*

6.5 Reunion at Long-term Follow-up

Many sponsor-supported studies contain a long-term follow-up visit occurring at least a year after the final experimental session—in the case of this particular study at one year.

Though most of the long-term follow-up visit involves assessment with the independent rater, the therapists also meet with the participants to complete an exploratory questionnaire, to discuss any changes in their life or anxiety and other symptoms over time and to process any feelings the participant and therapists have had about termination.

The degree of rapport at the time of the long-term follow-up visit may depend in part upon existing symptom levels at the final integrative follow-up session and on any intervening events between the final integrative follow-up session and the long-term follow-up visit. The study's termination after months of deep work is often perceived by both the participant and therapists as a "bitter sweet" occasion.

Beyond assessing participant general well-being and possible suicidal ideation and behavior, the long-term follow-up visit will be less structured than preparatory or integrative follow-up sessions. The discussion will be guided primarily by the participant and any observations or concerns about her/his current state and any gains or difficulties that have resulted from study participation. The therapists may reaffirm accomplishments, review and discuss the usefulness of the techniques and procedures presented during MDMA-assisted psychotherapy, inquire about and discuss any insights or new techniques the participant has learned or discovered to improve psychological well-being.

7.0 THERAPIST SELF-CARE

Therapists should engage in some form of regular self-care in order to process their own emotional responses to discussing issues of illness, fragility, mortality, death, and loss. It is important that therapists continue doing their own inner work and that they take time for regular debriefing with the co-therapist. This should include an opportunity to process their own emotional responses to working with participants as well as peer supervision and discussion about the optimal application of the therapeutic method in specific situations. It is also an opportunity for developing and maintaining their skills as a therapeutic team by reviewing their interactions during study sessions.

The following are some simple methods of self-care to keep in mind:

- Listen to your body- pay attention to what it is telling you. It is the best guide to staying healthy. Use your body to inform your own process - are you holding your breath, is your body tense or numb, are you cold or hot?
- Use either diaphragmatic breathing simple breathing that expands your ribs front to back and side to side. Do a "body scan" and send breath to the areas of your body that feel tight or numb.
- Give yourself enough time before you start a session to gather your thoughts, ground yourself, and shift roles. Take enough time to feel "inner stillness".

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- Listen to your expectations and be realistic about your goals.
 - Know who the people are that have the ability to support you if and when you need it. Invite them into your process as constructive advocates for your own growth and development. Seek feedback about your concerns and feelings and choose your intimates well.
 - Take time after the session to release your role. Shaking your arms and body is a good way to get rid of any energy that has gotten stuck.
 - Have a good nutritious meal after a session and do something grounding and enjoyable.
 - Using water in the bath, shower or hot tub and reflecting on the archetypal qualities of water to dissolve and cleanse on many levels.
 - Consider having your own ongoing psychotherapy and/or supervision with another therapist.

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9.0 Internal Family Systems Therapy (IFS) and MDMA-Assisted Psychotherapy Compared

Elements of IFS therapy: recognition of and un-blending from parts, increased access to “Self energy”, acknowledgment of and respect for protectors, and witnessing and unburdening of past traumas often occur in MDMA-assisted psychotherapy with little or no direction from the therapists. One way to describe the effects of MDMA is that it facilitates access to a high level of self energy, and thereby brings courage to face painful experience and provides clarity and compassion for one’s own parts and the burdens they have carried.

9.1 Somatic Processing and MDMA-Assisted Psychotherapy Compared

Both Sensorimotor psychotherapy and MDMA-assisted psychotherapy aim to bring awareness to somatic experiences and can be used for “connecting psychological symptoms and physiological states” [24]. In both methods the participant is encouraged to work with her/his body to process trauma. Helping the participant become aware of what her/his body wants to do in reaction to traumatic memories, and following that action, can be the beginning of liberating what was once a natural process (movement) and integrating the experiences that are unprocessed. In both methods therapists inquire about participant’s bodily sensations and encourage release of pains, tightness or energy in the body through movement in whatever way feels appropriate to the participant. A goal is to help the participant begin to befriend her/his body instead of regarding it as a source of danger and unpredictability.

10.0 APPENDIX B: Suggested Reading List

Angeles Arrien, Ph.D.

The Four-Fold Way: Walking the Paths of the Warrior, Teacher, Healer, and Visionary

Stanislav Grof, M.D.

Psychology of the Future

The Adventure of Self Discovery

Judith Herman, M.D.

Trauma and Recovery

Richard Schwartz, Ph.D.

Introduction to Internal Family Systems Therapy

Pema Chodron

The Places that Scare You: A Guide to Fearlessness in Difficult Times

When Things Fall Apart: Heart Advice for Difficult Times

Pat Ogdon, Kekuni Minton, Claire Pain, and Daniel Siegel

Trauma and the Body

Peter Levine and Ann Fredrick

Waking the Tiger: Healing Trauma

Peter Levine and Gabor Mate

In an Unspoken Voice: How the Body Releases Trauma and Restores Goodness

Jalal al-Din Rumi

“The Guest House” (a poem that can be found online or in *The Essential Rumi* translated by Coleman Barks, Harper Collins 1995)

Phil Wolfson

Noe—a father-/son song of love, life illness, and death

North Atlantic Books 2011n