



Ketamine Assisted Mindfulness/Psychotherapy Informed Consent

Introduction

Ketamine is now an “off-label” treatment for various chronic “treatment-resistant” mental conditions. Ketamine is a Schedule III medication that has long been used safely as an anesthetic and analgesic agent and now, often effectively for treatment of depression, alcoholism, substance dependencies, PTSD and other psychiatric diagnoses as well as for existential, psychological and spiritual crises and growth.

How Does It Work? The current, most probable, understanding of ketamine’s mode of action is as an NMDA antagonist working through the glutamate neurotransmitter system. This is a very different pathway than that of other psychiatric drugs such as the SSRIs, SNRIs, lamotrigine, anti-psychotics, Benzodiazepines, etc.

Ketamine is classified as a dissociative anesthetic, dissociation meaning a sense of disconnection from one’s ordinary reality and usual self. At the dosage level administered to you, you will most likely experience mild anesthetic, anxiolytic, antidepressant and, potentially, psychedelic effects. While more recent work has demonstrated the possibility of an antidepressant response to low dosages of ketamine administered intravenously, intra-nasally, and sublingually (orally) that produce minimal psychedelic effects, this effect tending to be more sustained with repeated use - in other words, a cumulative effect - it is our view that psychedelic, ‘dissociative’ experiences may well be instrumental in providing a more robust effect. This may well include a positive change in outlook and character that we term a ‘transformative’ response. We employ intravenous, intramuscular, and soon sublingual.

Essential to any method are tie-outs from usual experience, this period being of varying duration, usually 30 minutes to 2 hours, that tends to be dose and method of administration related. Relaxation from ordinary concerns and usual mind, while maintaining conscious awareness of the flow of mind under the influence of ketamine is characteristic. This tends to lead to a disruption of negative feelings and obsessional preoccupations. It is our view that this relief and the exploration and experience of other possible states of consciousness are singularly impactful. At Satori Healing we will work closely with therapists to process the experience and its impacts before and after the sessions.

Monitoring:

It is essential that you be followed very closely during and after your treatment. This may include Blood pressure and pulse measurements, psychological measures before each session (We are very serious about understanding what we and ketamine are accomplishing). We follow up and support your treatment by telephone/text and email.

It is essential that you enter in and maintain a psychotherapeutic relationship with a licensed mental health professional to assist you in integrating your experience(s) afterwards.

How Long Before I Might See Beneficial Effects?

You may experience important positive changes in personality, mood and cognition during treatment, in the aftermath, and in the days and weeks that follow. Some experiences may be temporarily disturbing to you. The ketamine experience itself is designed to enable your own healing wisdom to be accessed and beneficial to you. Ongoing psychological support will aid you in making your experience(s) valuable and understandable to you.

Why Ketamine with Psychotherapy?

The literature indicates a persons rate to treatment resistant depression (TRD) (Information from the low dose intravenous method) Of 40-50% - the percentage of patients having remissions, this with multiple sessions. Relapses do occur and may require periodic additional sessions.

The purpose of the intramuscular ketamine experience is to create a non-ordinary (“altered”) state of consciousness in order to facilitate profound transpersonal peak experiences.

These experiences may prove to be auspicious in resolving your existential problems, accelerating your psycho-spiritual growth and leading to a deep personal transformation and optimization of your lifestyle. Such change, again, is best facilitated within a structured ongoing psychotherapeutic relationship.

As a byproduct of your experiences you may well feel improvement in your emotional state and reduction in symptoms that bother you such as depression, anxiety, and post-traumatic manifestations. You may well notice that you are a bit different after a ketamine experience and that difference may well be liberating and allow for new mindfulness and new behavior.

We understand that you are able to withdraw from our treatment at any time.

Your experience will be unique to you. And if you decide to have additional sessions using ketamine, each of your sessions will be different. The number of sessions varies based on personal needs and treatment responses. We cannot pre-program your experience. We do our best to give prognostic view as we learn with you how ketamine treatment affects you. All ketamine journeys are adventures that cannot be programmed. They evolve from your own being in relation to this substance. Journeys vary in intensity from IV to the IM experiences. While it is best to form an intention for your journey, you may or may not be able to hold onto that. Indeed, not holding on is best and the journey will flow whether or not you hold on and resist or follow the path that unfolds and relax into it. Holding on is the main source of anxiety in this and other related journeys. A ketamine session can be light, dark, or both. There will be concepts, visions, encounters, and you may well deal with your own death, mortality, and immortality. Some journeys are enjoyable and filled with awe and some are difficult, but everyone grows from their experience.

Eligibility for Ketamine Treatment

Before participating in ketamine treatment, you will need a formal referral from your licensed therapist or psychiatrist. The intake process starts with a telephone conversation. This screen is followed by a formal provider intake that can happen on the same day as your first treatment. This intake will include a medical, psychiatric, and anesthetic history, a physical exam, and administration of brief psychological tests to assess your state of mind.

Pregnant women and nursing mothers are not eligible because of potential effects on the fetus, or nursing child. The effects of ketamine on pregnancy and the fetus are undetermined, and therefore, it is advisable to protect against pregnancy while exposing yourself to ketamine or in the immediate aftermath of its use.

Untreated hypertension is a contra-indication to ketamine use as the substance causes a rise in blood pressure. Similarly, a history of heart disease may make you ineligible to participate.

Information on ketamine's interaction with other medicines is only partially available and it will be assessed as to your eligibility for ketamine treatment.

Ketamine should not be taken if you have untreated hyperthyroidism. There have also been reports of some decrease in immune function in patients receiving surgical doses of ketamine.

Ketamine has an extensive record of safety and has been used as much higher doses for surgical anesthesia, without respiratory depression.

Overview of Ketamine Therapy

During the a ketamine administration session, you will be asked to make two (2) agreements with your therapist or nurse to ensure your safety and well-being:

1. You agree to follow any direct instructions given to you by the therapist or nurse until it is determined that the session is over, and
2. You agree to remain at the location of the session until the therapist or nurse decides you are ready to leave.

The length of the ketamine sessions varies from person-to-person and from experience-to-experience. You will mostly internally focused for the first 45 minutes to 1 hour and a half following IM administration of ketamine. You will continue to remain under ketamine's influence at a lesser level for at least one hour.

Under our care, ketamine will be given as an intravenous infusion (doses of 0.5 mg/kg - 1.6 mg/kg) or an intramuscular injection into the shoulder or buttocks (doses of 50 mg - 100 mg). The choice of dose will depend on prior exposure to ketamine and other psychedelics, body weight, and sensitivity. Naive subjects will receive a lower dose initial session. It is always better to start with a lower dose to reduce anxiety and become familiar with what a substance may produce in you. There is always an opportunity to make a choice for a larger dose at a future date. It is more difficult to correct a bad experience because of too high an initial dose and the anxiety it may engender. Individuals experienced with psychedelics may receive a higher initial dose. Ketamine IM creates an unusual experience of formlessness and a dissolving of boundaries and has novel effects on the mind. Therefore, it is much better to have an initial learning experience.

Potential Risks of Ketamine Therapy

You will be asked to lie still during the ketamine administration because your sense of balance and coordination will be adversely affected until the drug's effect has worn off—generally two and up to 4 hours after IM, less so with IV. It is possible you may fall asleep. Other possibilities for adverse effects include blurred and uncomfortable vision (you are advised to keep your eyes closed until the main effects have worn off), slurred speech, mental confusion, excitability, diminished ability to see things that are actually present, diminished ability to hear or to feel objects accurately including one's own body, anxiety, nausea and vomiting. Visual, tactile and auditory processing are affected by the drug. Music that may be familiar is not ordinary. Synesthesia—a mingling of the senses may occur. Ordinary sense of time will morph into time dilation.

Because of the risk of nausea and vomiting, please refrain from eating and drinking for at least 3-4 hours preceding the session. And eat lightly when you do. Hydrate well in that same time frame.

If you are unduly nauseated, you may be offered an anti-nausea medication- ondansetron or reglan- in oral or intravenous forms.

Ketamine generally causes a significant increase in blood pressure but usually not pulse rate. If blood pressure monitoring reveals that your blood pressure is too high, you may be offered clonidine or metoprolol to remedy this.

Agitation may occur during the course of a ketamine session. If your agitation is severe, you may be offered midazolam to help you relax.

The administration of ketamine may also cause the following adverse reactions: tachycardia (elevation of pulse rate), diplopia (double vision), nystagmus (rapid eye movements), elevation of intraocular pressure (feeling of pressure in the eyes), and anorexia (loss of appetite). The above reactions occurred after rapid administration of ketamine or intramuscular administration of high doses of ketamine (in a range greater than 5 mg/kg used to surgical anesthesia. The dose to be used in this sub-anesthetic ketamine therapy is much lower (2 mg/kg or less).

Driving an automobile or engaging in hazardous activities should not be undertaken until all effects have stopped. All patient's undergoing ketamine therapy must have a driver. It is not felt you are safe to drive or operate heavy machinery until the following calendar day.

In terms of psychological risk, ketamine has been shown to worsen certain psychotic symptoms in people who suffer from Schizophrenia or other serious Mental Disorders. It may also worsen underlying psychological problems in people with severe Personality Disorders.

During the experience itself, some people have reported frightening and unusual experiences. These frightening experiences, however, may be of paramount value to your transition to recovery from suffering that brought you to seek ketamine therapy. They will stop! This again is why it is so important to have an ongoing relationship with a licensed therapist or psychiatrist.

Potential for Ketamine Abuse and Physical Dependence

Ketamine belongs to the same group of chemicals as Phencyclidine (PCP, 'Angel dust'). This group of chemical compounds is known chemically as Arylcyclohexylamines and is classified as Hallucinogens ('Psychedelics'). Ketamine is a controlled substance and is subject to Schedule III rules under the Controlled Substance Act of 1970. Medical evidence regarding the issue of drug abuse and dependence suggests that ketamine's abuse potential is equivalent to that of phencyclidine and other hallucinogenic substances.

Phencyclidine and other hallucinogenic compounds do not meet criteria for chemical dependence, since they do not cause tolerance and withdrawal symptoms. However, "cravings" have been reported by individuals with the history of heavy use of "psychedelic" drugs. In addition, ketamine can have effects on mood (feelings), cognition (thinking), and perception (imagery) that may make some people want to use it repeatedly. Therefore, ketamine should never be used except under the direct supervision of a licensed physician.

Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction in individuals abusing the drug. This has not been reported in therapeutic settings using ketamine at sub anesthetic doses.

Alternative Procedures and Possibilities

No other procedure is available in medicine that produces ketamine's effects. Major Depression (MDD), PTSD and Bipolar Disorders are usually treated with antidepressant medications, tranquilizers, mood stabilizers and psychotherapy. Electroconvulsive therapy (ECT), and the recently introduced Transcranial Magnetic Stimulation (TMS) are also in use for treatment-resistant-depression. Ketamine has also been used in the treatment of addictions and alcoholism as part of a comprehensive and usually residential treatment programs, primarily abroad.

Confidentiality

Your privacy and all therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records. To allow others access to your records, you will have to provide a signed release form. The results of this ketamine therapy may be published in clinical literature. Published reports will not include your name or any other information that would identify you.

Voluntary Nature of Participation

Please be aware that the Food and Drug Administration (FDA) has not yet established the appropriateness of Ketamine therapy for mental health conditions and its use is considered off-label, the only official 'indication' for use of ketamine being anesthesia. Your awareness of this situation is key to understanding any liability associated with your use of ketamine. Your informed consent indicates you are aware of this situation.

Ketamine is a new psychiatric treatment— the primary studies have been with depression, bipolar disorders and alcoholism. It is not yet a mainstream treatment, though there are now many studies that demonstrate that it may be an effective treatment. There is an expanding array of ketamine clinics across the country, primarily administering ketamine intravenously, and usually without a therapy component. At Satori Healing, we feel the ongoing relationship with a therapist during and after ketamine treatment is a key element in the effectiveness of ketamine therapy. That therapeutic effect generally occurs with more than one treatment and again, is most robust when part of an overall treatment program. It may not permanently relieve depression. If your depressive symptoms respond to ketamine therapy, you may still elect to be treated with medications and ongoing psychotherapy to try to reduce the possibility of relapse. Over time, you may also need additional ketamine treatments or other therapies to maintain your remission.

Your decision to undertake ketamine treatments is completely voluntary. Before you make your decision about participating in ketamine therapy, you may ask and will be encouraged to ask— any questions you may have about the process.

Withdrawal from Ketamine Therapy is Always Your Option!!

Even after agreeing to undertake ketamine treatments, you may decide to withdraw from treatment at any time.

I understand that I am to have no food or drink 4 hours prior to my ketamine treatment

I understand that I need to have someone drive me home from the treatment sessions, and not engage in any driving or hazardous activity for at least 4 hours or more— depending on the continued presence of effects after my session has concluded.

Eligibility for Ketamine Therapy

This consent form contains information about the use of sub-anesthetic dosages of ketamine for mental health purposes including depression. Ketamine was approved by the FDA for use as an anesthetic agent several decades ago. The administration of ketamine in lower, sub-anesthetic doses to treat pain, depression, or other mental health disorders is a newer, off-label use of ketamine. Psychiatric and Pain specialist use of ketamine has become relatively wide spread in recent years, has been studied and promoted by researchers at the National Institute of Mental Health, and has had front-page publicity as the newest antidepressant with its own novel pharmacological mechanism of action. Ketamine has been administered by intravenous (IV), intramuscular (IM), sublingual, oral, rectal, and intranasal routes. Often, it has been used only after other treatment approaches have been unsuccessful.

Once you indicate that you have understood the benefits and the risks of this treatment, you will be asked to sign this form in order to participate in this treatment. You will be given a signed copy of this form to keep for your own records. This process is known as giving *Informed Consent*.

By signing this document, you indicate that you understand the information provided and that you give your consent to the medical procedure to be performed during your participation in ketamine treatment.

Please read this consent form carefully, and feel free to ask questions about any information in it.

Informed Consent

By signing this form I agree that:

1. I have fully read this Informed Consent form describing Ketamine Therapy and agree to its terms holding harmless the practitioner(s) involved in my care—waving, releasing and discharging all claims, rights, and or causes of action, which may arise out of or in connection with my participation in ketamine therapy. No oral or written statements, representations, or inducements have been made to cause me to enter into this agreement.
2. I have had the opportunity to raise questions and have received satisfactory answers.
3. I fully understand that the ketamine sessions(s) can result in a profound change in mental state and may result in unusual psychological and physiological effects.
4. I give my consent to the use of midazolam if deemed necessary for agitation, to ondansetron for nausea and clonidine or metoprolol for high blood pressure.
5. Upon signing I will be given a signed copy of this Informed Consent form, which is mine to keep.
6. I understand the risks and benefits, and I freely give my consent to participate in ketamine therapy as outlined in this form, and under the conditions indicated in it.
7. I understand that I may withdraw from ketamine therapy at any time, up until the actual injection or infusion has been started.

I voluntarily sign my name evidencing acceptance of the provisions of this agreement.

Signature _____

Date _____

Printed Name _____

Physician/Provider Statement

I have carefully explained the nature of Ketamine Therapy to _____.
I hereby certify that to the best of my knowledge, the individual signing this consent form understands the nature, conditions, risks, and potential benefits involved in participating in ketamine treatments.

A medical problem or language or educational barrier has not precluded a clear understanding of the subject's involvement in ketamine therapy.

Signature provider/physician_____. **Date**_____