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Ketamine Assisted Psychotherapy Informed Consent

This document contains important information about Ketamine Assisted Psychotherapy (KAP), as well as about ketamine itself. Please read it carefully and ask any questions about the information it contains before you decide to participate in KAP. It is very important to us that you feel safe and respected throughout this process, and to address any concerns you might have.

What is Ketamine?

Ketamine is one of the most widely used anesthetics in modern medicine, and is on the World Health Organization's List of Essential Medicines. It was developed in 1963, FDA approved in 1970, and adopted by many hospitals and medical offices because of its rapid onset, proven safety, and short duration of action.

As an anesthetic, ketamine is most commonly used in surgical settings, including pediatric surgery, due to its excellent safety profile, particularly around breathing/airway management. It has also been utilized successfully in managing acute and chronic pain conditions due to its analgesic properties.

When a drug is approved for medical use, the manufacturer produces a "label" to explain its use as approved by the FDA. Once a medication is approved by the FDA, physicians may use it "off-label," or for purposes other than what is listed on the label, as long as the use is based on sound medical evidence.

In the last two decades, ketamine has been increasingly researched and used off-label to treat various chronic and treatment-resistant mental health conditions, such as depression, alcohol/substance dependencies, post-traumatic stress disorder, anxiety disorders, and other psychiatric diagnoses.

How Ketamine Works

Although it is not fully understood how Ketamine works pharmacologically, we do know that the mechanism of action is as an NMDA antagonist working through the glutamate neurotransmitter system, as well as an opioid receptor agonist. This is a different pathway than that of other psychiatric medications such as SSRIs, SNRIs, Lamotrigine, anti-psychotics, benzodiazepines, etc.

As a dissociative anesthetic, Ketamine causes a sense of detachment from one's body, environment, ordinary reality, and usual sense of self. This shift from your usual mindset and awareness presents an opportunity to disrupt negative patterns and gain new perspectives, often leading to significant shifts in overall well-being.

Dosing Strategies and Route of Administration

Ketamine can be administered in a variety of ways, including as an intravenous infusion (IV), intramuscular injection (IM), a subcutaneous injection (SC), intranasally, or sublingually/orally as a dissolving troche or tablet. Routes vary in the onset, bioavailability and duration of active effects for each person.

In my practice, ketamine is administered by sublingual (oral) dissolving tablets or intranasal spray, a strategy which may allow for psychotherapy during the treatment, and an easier experience for those who are hesitant about injections. I work collaboratively with your prescriber to use a range of dosing strategies to create a personalized approach for each client, adjusting the dose, frequency, and time in between sessions based on each individual's needs.

The choice of dose depends on multiple factors, including client preference, therapeutic goals, prior exposure to ketamine and other psychedelics, body height and weight, and sensitivity. Those without prior experiences are advised to begin with lower doses to reduce anxiety and build familiarity with ketamine's effects, while those who are experienced with psychedelics may begin with higher initial doses.

Research has demonstrated an antidepressant response to low doses that are minimally psychoactive or sub-psychedelic, and this effect tends to be cumulative, requiring repeated administrations over short periods of time. Some practitioners view the psychedelic and dissociative experiences that occur at higher doses provide a more robust and longer-lasting outcome.

The Ketamine Experience

Although the experience varies widely depending on multiple factors, there are common aspects that people experience. Generally, the ketamine experience is characterized by dissociation and the relaxation of ordinary consciousness and usual mindset.

At lower doses, you will likely experience mild physical numbing, reduced feelings of anxiety and/or depression, and some psychoactive effects. You might experience increased sensitivity to light and sound, as well as an altered sense of time. Some people experience a sense of emotional openness. This state may also enhance participation in therapy as defenses are relaxed and communication with others is still possible.

Higher doses are more likely to produce dissociative states that are largely internal journeys away from the external world. Body sensations are greatly diminished. Such experiences may provide a more robust treatment effect, often assisting in the resolution of existential concerns, accelerating psychological and (and possibly spiritual) growth, and promoting a positive change in outlook.

The sensory effects of ketamine may include distorted visualization of colors, feeling suspended in space or floating, experiencing out-of-body sensations, vivid imagery, and changes in visual, tactile and auditory processing. Synesthesia (a mingling of the senses) may occur. Familiar music may not be recognizable. An ordinary sense of time may morph into time dilation.

Acclimating oneself to this kind of experience may be challenging or uncomfortable and you may perceive parts of your experience with difficulty. However, I believe there is value to every experience in the healing process. I am trained to provide stability and guidance to help you make the best use of every part of your ketamine experience.

The effects of ketamine typically start 5 to 10 minutes after ketamine dosing. The peak effects typically last 20 to 30 minutes, and then slowly diminish for the next hour. Some alterations in sensory perception, speech, and motor ability may continue for approximately 5 hours.

Two to three hours after ketamine administration, clients can return home with another driver. Driving an automobile or engaging in hazardous activities should not be undertaken on the day of the administration, and not until all effects have stopped.

Why Ketamine Assisted Psychotherapy (KAP)?

The administration of ketamine may be most effective when paired with therapy. Ketamine assisted therapy emphasizes the potential for change, and such change is best facilitated within a structured, supportive therapeutic environment that includes preparation, guidance, and integration.

Just as the body can intuitively heal itself, so can the psyche. Ketamine as a medicine represents a mode to accessing the intuitive healing nature of the Self. Ketamine by itself is not the cure. Instead, it assists the healing process by creating an altered state of consciousness and openness towards change. The rest of the work towards healing lies in your ability to make these shifts and support life changes.

Preparation includes education about the medicine and potential experiences. We also discuss how support is provided, boundaries, and overall expectations. Therapeutic guidance during ketamine sessions is designed to ensure safety and support. Each experience is different and having a highly-trained therapist to assist you in moving through the experience creates an opportunity for greater healing.

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

These shifts may happen during treatment, in the aftermath, and/or in the days and weeks that follow. Some experiences may be temporarily challenging for you, and I will work with you in integration sessions to understand these in context of your healing process.

Ultimately, KAP is designed to assist you in changing patterns of mind, mood, and behavior that cause you difficulty and distress. This is a unique opportunity for growth and change, and your active engagement in the therapeutic process will shape lasting effects and maintenance of your own healing.

The Treatment Process

We will have an initial meeting to go over basic information and to assess whether or not KAP is a viable option for you. If we decide to move forward, I will refer you to a qualified professional for the medical evaluation and prescription. I have an established collaborative relationship with those in my referral network and this can also include any existing mental health care professionals you are currently working with. Dosage, frequency, and any medical concerns will be discussed at this time.

Preparatory Sessions

We will meet for at least two preparatory sessions before medicine sessions begin to prepare you for the experience, reflect on your goals for treatment, and set intentions for your experience. These sessions are important in building a connection with each other as I believe that the efficacy of this medication is tremendously enhanced by a safe setting in the context of trusting relationships.

Day of KAP

On the day of your ketamine administration, it is very important to follow the directions given on your KAP Preparation and Aftercare Guide about food and medication intake.

We will take some time when you arrive to discuss your current state, and remind us all of your intentions for this work. A small ritual that is individualized to your particular preferences and spiritual practices may be performed as a way to initiate and open the space for the day's work.

For sublingual dosing, we will begin treatment with one lozenge. It will dissolve slowly, and as the ketamine is being absorbed through the lining of your mouth, you will be asked not to swallow your saliva for 10-15 minutes. It is safe to swallow ketamine, although it may not be absorbed as well if you do so, resulting in less bioavailable medicine.

The first dose will give us a measure of your responsiveness to ketamine, and enable us to witness the effectiveness of the lozenges and adjust the dose if needed. Some people experience empathogenic effects in this dose range, and engaging in therapeutic exploration can be quite fruitful. Others find speaking too difficult and prefer an internal focus even at this lower dose. Your preferences for engagement will be respected.

After 30 minutes, you may have the opportunity to self-administer a second dose which you will be asked to keep in your mouth for 15 minutes. Each sublingual dose provides a peak effect of approximately 20 minutes.

For intranasal, you will begin with 1-2 sprays in each nostril and continue self-administering these every 5 minutes until the desired dose is reached.

Throughout the ketamine session, I will be present for support and to guide you through any recommended relaxation exercises, play soothing music, etc. During these sessions, you will be offered an eye mask to facilitate and enhance the experience, and to help you maintain an internal focus.

When you are ready and willing to communicate with the outside world, you will have the opportunity to share about the content of your experience. The moments following an altered state can be powerful in their ability to reshape perspectives and beliefs. I find that even the act of putting words to the experience can create positive momentum in your healing process.

Each ketamine medicine session will last approximately 2 hours. After two hours, we will check on how you are metabolizing the medicine and if you are safe to return home.

Please arrange for some trusted person to pick you up and take you home. We ask that you not drive at all on the day of your administration.

Integration Sessions

I can call you on the following day to check on your health and well-being, if requested. You will have at least one integration session between medicine sessions and these will be proactively scheduled during preparation in order to adequately support you during the entire KAP treatment process.

When Will I See Positive Effects, and How Long Will They Last?

Ketamine treatment can result in a number of benefits, and there are now many studies demonstrating its efficacy; however, it is still a relatively new and experimental psychiatric intervention, and there are no guarantees of your outcome.

Ketamine is distinguished from other psychotropic medications by its rapid onset, often producing relief in as soon as a few hours. The literature indicates a 70% initial response rate to ketamine, as well as a remission rate (return of symptoms) for people with treatment-resistant depression of 40-50%.

Durable improvement generally occurs with more than one administration, and is most robust when part of an overall treatment program. It may not permanently relieve your condition. If your symptoms respond to ketamine, you may still elect to be treated with other medications and ongoing psychotherapy to reduce the possibility of relapse.

If you do not respond to ketamine after the first administration, repeated treatment will be offered. If you do not respond after a series of 8 dosings, additional ketamine will not be offered. Studies have shown it is not effective to keep treating with ketamine in those who do not respond to the first 8 doses. The treatment team will discuss other available options at that time.

Medical and Psychiatric Eligibility for KAP

Before participating, you will be carefully interviewed to determine if you are a good candidate for ketamine treatment. This will include discussing your medical and psychiatric history, and review of your medical and psychiatric records if necessary.

You are required to be under the care of a primary care physician to evaluate your overall health, and in particular your respiratory and cardiovascular status. You are also required to be under the care of a mental health provider, either a current therapist, or someone you begin treatment with at the start of your ketamine treatment and will continue your care thereafter.

Some medical and psychiatric conditions need to be treated before you can safely take ketamine. These conditions include hallucinations, untreated mania, unstable angina (chest pain/heart disease), uncontrolled hyperthyroidism, increased intracranial pressure, or evidence of liver disease. A previously demonstrated allergy to ketamine excludes one from treatment.

An EKG may be required for those with a history of arrhythmia or a history of cardiovascular issues. Untreated or uncontrolled hypertension is a contraindication to ketamine use, as the substance causes a rise in blood pressure. This increase is typically comparable to normal increases in blood pressure that occur with heavy exercise.

Pregnant and nursing people are not eligible because of undetermined potential effects on the fetus or nursing child.

Those with a history of cystitis or other bladder issues may need to be cleared by urological consultation, due to the rare but potentially significant adverse effect of cystitis.

Those with a primary psychotic or dissociative disorder or who are currently in a manic or mixed episode are not eligible for treatment with ketamine. Please consult your treating clinician if you are taking

Lamotrigine (Lamictal) or an anxiety medication such as benzodiazepines, pregabalin, or gabapentin as they may blunt the antidepressant effects of ketamine.

Information on ketamine's interaction with other medicines is only partially available; any possible interactions will be assessed to help determine your eligibility for ketamine treatment.

Potential Risks of Ketamine

Ketamine has an extensive record of safety and has been used at much higher doses for surgical anesthesia, without respiratory depression. As with any other medication, there are also some potential risks and side effects to be informed of and consider.

The most common physical side effect is a short-term spike in blood pressure, pulse, or heart rate, which may be a risk to those with heart disease, and can be misinterpreted as a symptom of anxiety.

Other possible side effects include dizziness/lightheadedness, sedation, impaired balance and coordination, 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, headache, anxiety, nausea, vomiting, and diminished awareness of physical functions such as respiration. These effects are transient and resolve as the active phase of the medication ends (generally within 4 hours).

Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction or cystitis in individuals using the drug too frequently. These adverse effects are much less likely in medically supervised ketamine treatment populations, but might include more frequent, painful, or difficult urination. Please inform your providers immediately if you notice any of these side effects.

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 and dissociative disorders.

Management of Adverse Effects

It is very important to abstain from eating or drinking in the 4 hours prior to your treatment so as to avoid nausea or vomiting. Additionally, due to possible blurred and altered vision, we advise keeping your eyes closed or using the eye mask provided (as long as you are comfortable doing so) until the main effects have worn off. Excessive movement can exacerbate nausea and dizziness, so it is best to lie still during the active phase while balance and coordination are impaired.

Driving an automobile or engaging in hazardous activities should not be undertaken on the day of the administration, and not until all effects have stopped. You will be assessed for safety prior to leaving the office premises, and will be required to arrange for a responsible person drive you home.

Under your prescriber's direction, I will provide a blood pressure cuff and pulse oximeter to monitor vitals before, during, and after the ketamine experience.

I reserve the right to activate emergency response systems (such as calling 9-1-1) if it is determined by clinical judgment that your safety requires a higher level of care than can be provided in my setting.

Potential for Ketamine Abuse and Physical Dependence

Instances of addiction to ketamine resulting from medical treatment with ketamine can occur, but such cases are exceedingly rare. Non-medical use of ketamine, and ketamine addiction, does occur. Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction in individuals abusing the drug.

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 only be used under the direct supervision of a licensed prescriber.

Alternative Procedures and Treatments

No other procedure is available in medicine that produces ketamine's effects.

Psychotherapy without ketamine is available and can be effective. Major Depression (MDD), PTSD and Bipolar Disorders are usually treated with antidepressant medications, tranquilizers, mood stabilizers and psychotherapy. PTSD is often also treated with Eye Movement Desensitization and Reprocessing (EMDR). Electroconvulsive therapy (ECT) and Transcranial Magnetic Stimulation (TMS) are also in use for treatment-resistant-depression.

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.

Voluntary Nature of Participation

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. That effect generally occurs with more than one treatment and is most robust when part of an overall treatment program. It may not permanently relieve depression. Your decision to undertake ketamine is completely voluntary.

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

KAP INFORMED CONSENT ATTESTATION

By signing this form, I agree that:

- *I have fully read this informed consent form describing ketamine treatment.*
- *I have had the opportunity to raise questions and have received satisfactory answers.*
- *I fully understand that the ketamine session(s) can result in a profound change in mental state and may result in unusual psychological and physiological effects.*
- *I understand that difficult experiences are often part of the healing process and not every ketamine experience may be pleasant.*
- *I have been given a signed copy of this informed consent form, which is mine to keep.*
- *I understand the risks and benefits, and I freely give my consent to participate in ketamine treatment as outlined in this form, and under the conditions indicated in it.*
- *I understand that the Food and Drug Administration (FDA) has not yet established the appropriateness of Ketamine Assisted Psychotherapy and its use is considered off label, the only official 'indication' for use of ketamine being anesthesia*
- *I understand that I may withdraw from ketamine treatment at any time.*
- *I agree not to operate a motor vehicle until the morning after being administered ketamine, for the duration of my treatment.*

Signature

Printed Name

Date

Witness signature

Printed Name and Credentials

Date