

Ketamine Assisted Psychotherapy

Medical Informed Consent

What is ketamine and how does it work?

Ketamine is a Schedule III medication that has been used for some time as an anesthetic agent, and in recent years increasingly for mental health purposes. While intranasal esketamine has been FDA approved for treatment-resistant depression, we will be using a different formulation of ketamine **off-label** for your psychotherapeutic benefit. Although I believe in the effectiveness of ketamine for medical and psychotherapeutic use, **I cannot guarantee that you will benefit from ketamine.**

Ketamine is an NMDA receptor antagonist which impacts glutamate, an excitatory neurotransmitter in the brain. We believe that ketamine induces a cascade of effects in the brain involving this, and other pathways. We don't have a complete biochemical understanding of why ketamine works as it does to benefit mental health, but we do have a rapidly growing base of clinical data to support its efficacy, and multiple theories.

Ketamine is a dissociative anesthetic and you can expect to experience a sense of disconnection from your ordinary reality and from your usual self. We believe, and data suggests, that the dissociative experience is an essential mediator of therapeutic gains, as it disrupts the rigidity of one's personality and ordinary psychological defenses.

Eligibility for ketamine treatment:

At our initial visit I will be assessing whether ketamine is medically safe and appropriate for you. The history you provide on the attached forms is part of that process, as well as an in-person interview and mental status examination, assessment of vital signs, focused physical examination as may be necessary, and standardized symptom assessments.

Pregnant women and nursing mothers are not eligible for ketamine treatment due to the unknown impact on and potential harm to the fetus or nursing child.

Uncontrolled elevated blood pressure is a contraindication to ketamine use as the medication can itself lead to a rise in blood pressure. Similarly, a history of heart disease may preclude its use.

Information on ketamine's interactions with other medications is only partially available and it will be assessed as to your eligibility.

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

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

Potential risks of Ketamine Assisted Psychotherapy:

I will be observing you and assessing for the following side effects in person as well as by closed-circuit video throughout your session. Depending on your level of risk, I may assess your vital signs (blood pressure) during the treatment.

Your sense of balance and coordination will be adversely affected until the drug's effect has worn off—typically within about 3 hours. It is possible you may fall asleep.

You may have blurred and uncomfortable vision. You will be provided with an eye mask for use during the therapy.

There is a risk of nausea and vomiting. Because of this, you will be asked not to eat for 4 hours prior to the session. I will prescribe an anti-nausea medication (ondansetron) to have available on the day of the session should you experience nausea.

Ketamine generally causes a significant increase in blood pressure, but not usually heart rate. If monitoring reveals that your blood pressure is too high, you may be offered clonidine to remedy this. There are also reports of reduction in blood pressure during ketamine administration.

Agitation may occur during the ketamine session. I will prescribe lorazepam, a sedative-hypnotic, which you will be offered, if necessary, to help you relax.

Additional potential side effects include saliva production, slurred speech, mental confusion, excitability, anxiety, unusual movements, diminished ability to see things that are actually present, diminished ability to hear or to feel objects accurately including one's own body.

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.

Additional reactions that have been observed in anesthetic doses of ketamine include: loss of appetite, double vision, rapid eye movements (nystagmus), increased sense of pressure within the eyes, rash, seizure-like movements, breathing changes or difficulties, and changes in heart rhythm, or rapid heart rate. We will be using doses of about 40% of the anesthetic dose, or less, and expect these reactions to be rare.

Ketamine has been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia and other serious psychiatric disorders. It may also worsen psychological problems in people with severe personality disorders.

During the experience itself, some people have frightening and unusual experiences. These are temporary, and you will be assisted to integrate these experiences in psychotherapy. Often these experiences are precisely what needs to be dealt with on your path to recovery.

Driving or other hazardous activities must be avoided until the effects of the ketamine have abated. You will need to arrange for a driver to bring you home after the session, and you will be assessed before leaving.

Potential for ketamine abuse and physical dependence:

Ketamine belongs to the same group of chemicals as phencyclidine (PCP), classified as hallucinogens or psychedelics. Ketamine is a Schedule III controlled substance and medical evidence suggests that its abuse potential is equivalent to that of other hallucinogenic substances.

Ketamine and other hallucinogens are not widely observed to create physiologic dependence—i.e. tolerance or withdrawal. However, because they cause an alteration in feelings and thought processes, its use can result in cravings, psychological dependence, and the potential for abuse.

Ketamine should not be used except under the strict 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. In a similar population, we have also observed neurotoxicity and permanent changes in the brain. These effects have not been observed in medical use such as our framework.

You will be provided only the number of lozenges necessary for your treatment.

Alternative procedures and possibilities for treatment:

No other procedure is available in medicine that produces ketamine's effects. There are current and ongoing trials assessing the use of other psychedelics for mental health and therapeutic purposes, but these substances are not yet available for prescription as ketamine is.

Various psychotherapeutic modalities, medications including antidepressants, mood stabilizers, and tranquilizers, and interventions such as electroconvulsive therapy, transcranial magnetic stimulation are currently used in the treatment of trauma-related, mood, anxiety, and personality disorders.

Please note that if you cancel the in-office ketamine session with less than 24 hours notice, you will be charged the full fee for the session. If you arrive 30 minutes late, we will consider the session cancelled and charge the full amount.

By signing this document, you indicate that you understand the information provided and that you give your consent to participate in ketamine assisted psychotherapy treatment.

You may withdraw your consent at any time by communicating this with me directly.

_____ I have fully read this Informed Consent describing Ketamine Assisted Psychotherapy and agree to its terms. No oral or written statements or inducements have been made to cause me to enter into this agreement. I have had the opportunity to raise questions and have received satisfactory answers.

_____ I have fully understood that the ketamine sessions(s) can result in a profound change in my mental state and may result in unusual psychological and physiological effects.

_____ I consent to be monitored by Dr. Babbitt via closed-circuit camera during the session.

_____ I give my consent to the use of lorazepam if deemed necessary for agitation, to ondansetron for nausea, and for clonidine for high blood pressure.

_____ I have been given a copy of this Informed Consent paperwork, which is mine to keep.

_____ I understand the risks and benefits of the off-label use of ketamine, and I freely give my consent to participate in KAP as outlined in this form, and under the conditions indicated in it.

_____ I understand that I may withdraw from KAP at any time, up until the actual medication has been given.

_____ I understand that I will be charged the full fee for the KAP session if I cancel with less than 24 hours notice, or if I arrive more than 30 minutes late for the session.

_____ I agree that I will call Dr. Babbitt with any unusual or concerning symptoms. I understand and acknowledge that I will call 911 for any life-threatening symptoms I may experience.

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

Signature

Date

Printed Name

Physician Statement

I have carefully explained the nature of Ketamine Assisted Psychotherapy 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 KAP.

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

Kriste Babbitt, M.D.

Date