



CLARITY

INTEGRATIVE PSYCHIATRY

Consent to Treatment Ketamine Assisted Psychotherapy

Please read and review the following form carefully **prior** to your initial appointment. Please bring any questions you have to your medical prescriber and therapist. **A clinician will review the Consent to Treatment form with you at your initial appointment at which time you will be asked to initial every page and sign and date the client informed consent page.**

Ketamine Assisted Psychotherapy (KAP) is a unique approach to traditional psychotherapy. KAP applies the medicine ketamine within the context of psychotherapy. The intention of utilizing ketamine in psychotherapy is to promote an altered state of mind with lowered negative psychological defenses that allows for more efficient healing than traditional talk therapy.

The administration of ketamine in lower, sub-anesthetic doses to treat pain, depression, or other psychiatric diagnoses is a newer, off-label use of ketamine. Psychiatric use of ketamine has become relatively widespread 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 anti-depressant with its own novel pharmacological mechanism of action.

Ketamine is administered by intravenous, intramuscular (IM), sub-lingual, oral, and intra-nasal routes. Often, it is used after other treatment approaches have been unsuccessful.

KAP sessions last longer than traditional therapy and are conducted with medical support and psychological counseling to ensure you are well cared for throughout your experience.

Before and after KAP treatment sessions, we require preparation and integration work. We consider this an integral part of the treatment process. Preparation for KAP sessions requires assessment by your clinician of your eligibility and readiness. Integration is the therapeutic process of assisting you with integrating the insights of your ketamine experience into your life.

To get the most out of this experience, you should plan on taking at least a few hours break from your daily obligations before and after your sessions.

You may withdraw from treatment at any time, except in a session after you have been administered ketamine.

After taking ketamine in each session, we will support you if difficult experiences arise. Your experience will be unique to you and each of your KAP sessions may be different. KAP experiences cannot be pre-programmed and will vary in intensity. A KAP session can have

Client/Patient Initials [_____]
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aspects that are light, dark, or both. Some sessions are enjoyable and filled with awe and some are difficult, but it is our experience that the holistic therapeutic and mental health benefits of KAP outweigh any temporary discomfort experienced in any one ketamine session.

Because everyone has a unique experience, there is not a one size fits all treatment protocol. Some individuals may need additional treatments to maintain remission of symptoms. Your clinician will work with you to determine what treatment regime is appropriate for you.

What is ketamine's legal status?

- In the context of mental health and psychotherapy treatments, ketamine is used as an “off-label” treatment for a range of mental conditions and disorders. “Off-label” ketamine is currently being used in the medical context to treat depression, alcohol and substance dependence, trauma, and several other psychiatric disorders, however, the only official indication for use of ketamine is anesthesia.
- Since 1999, the U.S. Drug Enforcement Administration (DEA) has labeled ketamine a Schedule III non-narcotic controlled substance with accepted medical use and safety in the United States under medical supervision. Traditionally ketamine has been used as an anesthetic and analgesic.
- The U.S. Food and Drug Administration (FDA) considers ketamine to be an investigational drug and its prescribed use and administration in the mental health context to be “off-label.” Ketamine’s efficacy in treating post-traumatic stress disorder, major depressive disorder, treatment resistant depression, post-partum depression and other mental health disorders is currently being evaluated in FDA approved clinical trials.

How does ketamine work?

- While the medical understanding of ketamine’s mode of action is incomplete and still under investigation, Ketamine, as currently understood, likely works as an NMDA antagonist in the glutamate neurotransmitter system and in a way quite different from many other psychiatric medications.
- Ketamine is believed to exert antidepressant effects by enhancing neuroplasticity, or the ability of brain cells to form new connections with one another. The



glutamate pathway of ketamine is very different from that used by other psychiatric drugs (*e.g.*, SSRIs, SNRIs, lamotrigine, antipsychotics, benzodiazepines), which is part of what makes ketamine's antidepressant effects novel and unlike other forms of treatment.

- Medically, ketamine is classified as a dissociative anesthetic. Dissociation is typically understood as the disconnection from one's ordinary reality, environment and usual self.
- Recent medical understandings of ketamine's efficacy suggest the possibility of an anti-depressant response to low dosages of ketamine administered intravenously, intra-nasally and sublingually (orally) that produce minimal psychedelic and dissociative effects, this effect tending to be more sustained with repeated use under medical and therapeutic supervision.

What are the effects of ketamine?

- We employ both sublingual (under the tongue/oral) and IM (intramuscular injection) generally beginning with the sublingual.
- The higher the dose of ketamine, the more likely you are to experience ketamine's dissociative sensations and psychedelic effects.
- At the dosage level administered to you, you will likely experience mild anesthetic, anxiolytic, antidepressant and, potentially, psychedelic effects.
- Relaxation from ordinary concerns and usual states of mind, while maintaining conscious awareness of the flow of mind, is characteristic. Being under the influence of ketamine can lead to a disruption of negative feelings and obsessional preoccupations.
- Ketamine creates an unusual experience of formlessness and a dissolving of boundaries and has novel effects on the mind.
- The psychedelic and dissociative effects of ketamine are short-lived, and most people return to their ordinary level of awareness and state of mind within 45-60 minutes following administration.



Am I eligible for KAP?

- Before participating in KAP, you will be carefully screened to determine whether KAP is an appropriate and safe treatment for your medical condition.
- Screening may include a medical history, a physical exam including bloodwork if deemed necessary, review of your medical/psychiatric records, and psychiatric history.
- While information on ketamine's interaction with other medicines is only partially available, screening will assess various indications and contraindications for ketamine in the context of your physical, psychological and pharmacological history and presentation.
- We reserve the right based on our medical and clinical judgment to determine if you eligible for KAP or excluded from this treatment.
- Pregnant women and nursing mothers are not eligible for ketamine treatment.
- Contraindications that require further evaluation to determine severity and treatment to move forward with treatment include:
 - Untreated hypertension
 - History of heart disease
 - Untreated hyperthyroidism
 - Active mania
 - Active suicidality
 - Active Psychosis
 - Alcohol or substance use disorders in which cessation for treatment would risk severe withdrawal symptoms
 - History of severe dissociation
 - Severe personality disorders

What should I expect during a KAP session?

- During a KAP session, you will be asked to make four (4) agreements with the clinic to ensure your safety and well-being:



1. You agree to abstain from food or drink (other than water) four (4) hours prior to your KAP session.
 2. You agree to follow any direct instructions given to you by your clinician and any other clinic staff until it is determined that the session is over.
 3. You agree to remain at the location of the session until the clinician decides you are ready to leave the clinic.
 4. You agree to not drive after your ketamine session. If leaving from the clinic, you must have prearranged transportation and are not allowed to leave via walking, bicycle, etc. You will also agree to not engage in any driving or operation of heavy machinery for a minimum of six (6) hours after your session is finished.
- Low dose KAP sessions are generally conducted in more of a talk therapy and interactive fashion, whereas moderate to higher dose sessions are conducted in part with music guidance and eyeshades with longer periods of going inwards due to increase psychedelic and dissociative effects.
 - Typically, the effects of ketamine last 45 - 90 minutes, with approximately a 5-minute onset for intramuscular injection, and a 15-20 minute onset for lozenge.
 - The length of ketamine sessions varies from person-to-person and from experience-to-experience. You will mostly be internally focused for the first *45 minutes to one-hour-and-a-half* following administration of ketamine. You will likely 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 oral lozenge or an IM injection at doses determined specifically for you. The choice of dose (oral or IM) will depend on prior exposure to ketamine and other psychedelics, body weight, and sensitivity. KAP sessions could include oral only, IM only, or a combination of oral and IM Ketamine depending on medical judgement.
 - If you are receiving ketamine in lozenge form, we ask that you place it under your tongue and let it dissolve for 10 minutes. The ketamine lozenges dissolve slowly and will penetrate the oral mucosa-lining of your mouth, absorbing rapidly into your system.



- Do not use alcohol preceding ketamine sessions as this may have negative emotional and physiological consequences.
- Your consent to receive ketamine may be withdrawn by you at any time up until the actual dose of ketamine has been given.
- We reserve the right to end KAP if we determine in our sole medical and professional judgment that KAP is not medically appropriate or right for you.

What are the potential risks of KAP?

- Risks vary between low and high doses of ketamine.
- The higher the dose, the increased risk of disorientation issues including temporary lack of spatial or temporal awareness, loss of recognition of environment or self, and/or loss of coordination or balance.
- Other temporary adverse effects are possible and include:
 - Blurred/uncomfortable vision
 - Slurred speech
 - Mental confusion
 - Excitability/agitation
 - Diminished ability to see things that are actually present
 - Diminished ability to hear or to feel objects accurately
 - Anxiety
 - Nausea/vomiting
 - Senses processing is affected by the substance
 - Elevation of pulse
 - Double vision
 - Rapid eye movements
 - Feeling of pressure in the eyes
 - Loss of appetite
- Typically, ketamine causes a significant increase in blood pressure. This can sometimes be mitigated through blood pressure medication.



- At extremely high dosages, ketamine can cause adverse effects that include hypoxia, apnea, hypotension, dysphoria, and dysrhythmia
- Ketamine may result in temporary adverse psychomimetic, cardiovascular, hepatic and gastrointestinal adverse effects from its action on several receptors including NMDA, acetylcholine, opioid, monoamine, and histamine.
- 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 been shown to worsen certain psychotic symptoms in people who suffer from schizophrenia or other serious mental disorders.
- Ketamine may also worsen underlying psychological problems in people with severe personality disorders. During the experience itself, some people have reported frightening and unusual experiences that could exacerbate underlying disorders.
- Patients with moderate to severe hepatic dysfunction (cirrhosis), high-risk coronary artery disease and poorly controlled psychosis are at increased risk for adverse events following ketamine infusion.
- As a Schedule III substance, ketamine is understood to have moderate to low psychological and physiological dependence. Ketamine belongs to the same group of chemicals as phencyclidine (Sernyl, PCP or Angel Dust). This group of chemical compounds is known chemically as arylcyclohexylamines and are classified as hallucinogens. 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.

- Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction in individuals abusing the drug. This does not appear to occur within the framework of clinical studies using ketamine as a medical treatment procedure.

Is my medical information confidential?

- Your identification and all medical information is legally protected by HIPAA, the same as any medical or psychiatric clinic. This information will be kept confidential, on HIPAA protected, encrypted programs. If you wish to have others access these records, you must sign a release of protected information form.
- We do collect clinical data from your sessions that may be published in clinical literature, with all of your identifying information removed. The purpose of this data collection is to further validate this treatment and bring more evidence to the field of ketamine assisted psychotherapy.
- If your emergency contact person(s) is contacted without your permission, it is for safety purposes only and only the minimal information will be provided in order for your treatment team or emergency services to ensure your safety.

What should I know and understand about my “off-label” use of ketamine?

- Ketamine for use in treatment in the mental health and psychotherapy context is considered an “off label” use by the FDA, the only official indication for use of ketamine being anesthesia. Off-label use means that the FDA believes there is no data available to support safety and efficacy for other uses at-this-time.
- Your awareness of the administration of ketamine off-label is key to understanding any liability associated with your use of ketamine.
- KAP is a new psychiatric treatment. Ketamine’s efficacy in treating post-traumatic stress disorder, major depressive disorder, treatment resistant depression, post-partum depression and other mental health disorders is currently



being evaluated in FDA approved clinical trials but has not been approved by FDA.

- Your decision to undertake KAP is completely voluntary. Before you make your decision about participating in KAP, you may ask and will be encouraged to ask any questions that you may have about the treatment.
- If you believe KAP is not right for you, you have the right to discuss alternative treatments with your clinician including treatment with alternative medications, use of psychotherapy, and/or other alternative health modalities.
- In signing this Consent to Treatment form, you acknowledge that you fully understand ketamine's off-label designation and agree to waive any-and-all liability associated with your voluntary participation in ketamine assisted psychotherapy and off label prescriptive treatment with ketamine.

What is informed consent?

- After reviewing this document and indicating your understanding, you will be asked to sign this document in the presence of a clinician before participating in KAP.
- You will have access to 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 herein and give your informed consent to participate in Ketamine Assisted Psychotherapy treatment.

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CLIENT INFORMED CONSENT

Please check each box and sign below:

- I have fully read this Consent to Treatment form describing Ketamine Assisted Psychotherapy and agree to its terms holding harmless the practitioner(s) involved in my care--waiving, releasing and discharging all claims, rights, and or causes of action, which may arise out of or in connection to my participation in this treatment. No oral or written statements, representations, 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 fully understand that the sessions can result in a profound change in mental state and may result in unusual psychological and physiological effects.
- I give my consent to the use of lorazepam if deemed necessary for agitation, to ondansetron for nausea, and clonidine for high blood pressure.
- I have been offered a signed copy of this Consent to Treatment, which is mine to keep.
- I understand the risks and benefits and I freely give my consent to participate in this ketamine treatment as outlined in this form, under the conditions indicated in it.
- I understand that I may withdraw from the ketamine treatment at any time, up until the actual injection or lozenge has been administered.
- I understand and will adhere to the four (4) agreements for participating in KAP and will otherwise follow the advice and instruction of the clinician during a KAP session.

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

Patient Signature: _____ Date: _____

Patient Printed Name: _____



**CLINICIAN ATTESTATION OF PATIENT'S
ABILITY TO CONSENT TO TREATMENT**

I have carefully explained the nature of Ketamine Assisted Psychotherapy to the above-named and undersigned patient. I hereby certify that to the best of my knowledge, the individual signing this consent form understands the nature, conditions, risks, and potential benefits in participating in this treatment. A medical problem or language or educational barrier has not precluded a clear understanding of the subject's involvement in Ketamine Assisted Psychotherapy.

Clinician Signature: _____

Date: _____

Clinician Printed Name: _____