



Informed Consent for Ketamine-Assisted Psychotherapy

Introduction

Our goal at Bird's Eye Wellness is to make your experience with Ketamine-Assisted Psychotherapy (KAP) as safe and informed as possible. This consent form contains information regarding the use of sub-anesthetic doses of ketamine for the purposes of treating mental health conditions such as depression or anxiety.

Bird's Eye Wellness utilizes ketamine, in combination with psychotherapy, as a holistic and integrative approach to treating mental illness. This is a newer, off-label treatment that is not approved by the FDA, despite compelling evidence that has emerged through clinical studies over the past few decades. Most of this research has been applied to treatment-resistant depression (TRD), though many studies have demonstrated efficacy in treating other disorders such as anxiety, trauma, OCD, mood disorders and certain substance use disorders.

It is important that you read the following information carefully and ask any questions that arise prior to your decision to participate in KAP.

What is Ketamine?

Ketamine is a dissociative anesthetic. It was approved for use by the FDA in the 1970's following attempts to synthesize a safer anesthetic with less risk of impacting respiratory and cardiac function. Today, ketamine remains one of the most commonly used medications for anesthesia during surgical procedures, pediatric procedures and emergency medicine. The safety record of ketamine, which is based on anesthetic doses used for surgical procedures, is robust and consistent. Doses used for KAP are considered sub-anesthetic and are much lower than surgical doses.

How Does Ketamine Work?

Ketamine is an NMDA receptor antagonist. It causes the release of glutamate, which is an excitatory neurotransmitter. This glutamate release is thought to trigger a cascade of effects resulting in a unique state of neuroplasticity (the brain's ability to change) and neurogenesis (the brain's production of new neurons). This is believed to play an important role in ketamine's therapeutic benefits and offers a different mechanism of action than most commonly used psychiatric drugs.

During ketamine use, most people experience some level of anesthetic, empathogenic, anxiolytic, antidepressant and/or, potentially, psychedelic effects. It is important to note that psychedelics, including ketamine, are non-specific amplifiers. This means, your experience may involve the enhancement of uncomfortable or painful feelings in addition to uplifting experiences. This highlights the importance of the set (your internal state) and setting (your environment) during KAP and the need to have adequate support following your medicine



session. Difficult or challenging experiences can be incredibly valuable and often a necessary part of healing when they occur in a safe and supported container, such as that offered by Bird's Eye Wellness.

Some people have “peak” experiences often described as “mystical”, “spiritual”, “out-of-body” or involve a sense of ego-dissolution. The dissociative effects of ketamine refer to a disconnection from one's ordinary reality and usual sense of self. This can involve a sense of disconnection between mind and body, an altered sense of time, space, and or a shift in the qualities and beliefs we hold on to in order to define who, what we are and how we relate to ourselves and others.

These “peak” experiences are more common with higher doses. Research links greater dissociative experiences with improved antidepressant outcomes, suggesting that these states are what offer people an opportunity to catalyze deep, transformative change. This may involve positive change in perspective, alleviation of existential fears, changes in habits or behaviors, and/or characterological change and growth. However, there currently is no consensus on exactly what mechanism of action is responsible for ketamine's effects.

Dosing and Administration

Ketamine has many routes of administration, each with their own advantages and disadvantages. At Bird's Eye Wellness, we use either oral or intramuscular administration. Other forms of administration, which may be available at other clinics, include intranasal and intravenous. Route is an important consideration because different formulations of the medicine have varying degrees of bioavailability. This impacts the onset/effect/duration of action of a given dose. What works best for you, your condition and your goals for treatment will be part of a shared decision-making process during the creation of your treatment plan, which will occur at the beginning of treatment.

- *Oral/sublingual*- either a dissolving lozenge or a liquid solution; offers a more gradual onset and can be a lower-dose strategy to gain comfort and familiarity with the medicine's effect and how to navigate them. This may be beneficial for an individual who is psychedelic naive, has significant anxiety entering into the experience, or has a history of trauma. Lower-doses can also be utilized to engage in psycholytic treatment, meaning advantage is taken of the empathogenic effects of the ketamine to deepen psychotherapy work.
- *Intramuscular (IM)* - an injection given in either the arm or the hip/buttocks; very high bioavailability and dosage control. It offers a rapid onset and generally a more dissociative experience with greater likelihood of “peak” psychedelic effects. For this administration, no clothing needs to be removed, simply a raised sleeve or a lowered waistband.

It is important to note that each individual is different and can respond to the medication in a nuanced manner. Dissociation can be experienced at any dose, with any type of administration. We will most often start with an oral dose to gradually familiarize participants with the medicine,



and how to navigate its effects. If the desired depth and effects of the medicine are not achieved with the oral dose, IM administration may be considered.

Our KAP Process

It is important that potential clients realize that ketamine is not a cure or a “silver bullet.” When administered outside of a safe and supported container, and in the absence of integration therapy, the opportunities the medicine offers for psychological growth and therapeutic gains may be lost. At worst, it could be harmful. Ketamine is a powerful tool that helps individuals reduce/remove psychological barriers to healing in order to access their own inner healing intelligence. It is meant to be an adjunctive treatment within a comprehensive treatment plan.

Our treatment team is made up of a board certified psychiatric mental health nurse practitioner and masters level licensed psychotherapists. All members of our team have completed training specific to KAP and other psychedelic-assisted therapy modalities. If you have other professionals already involved in your treatment that you would like to be involved in your care (e.g. therapist, psychiatric provider), we would be happy to coordinate care with them. Often, we will encourage it and reserve the right to require the involvement of other psychiatric professionals for eligibility in KAP based on individual circumstances.

Prior to any intake processes, it is important you read this informed consent carefully and in its entirety. The first step in the intake process is screening paperwork. This is an important step to be sure you are a safe candidate for KAP and avoid any unnecessary costs to you of meeting for a consult if ketamine is not a safe or appropriate intervention. Please answer these questions honestly and to the best of your ability as there can be serious health risks otherwise. If this screening indicates there are no contraindications to this type of treatment, then we will proceed to the initial consultation. This is a 90 minute session with the ketamine provider reviewing your current and past psychiatric, medical and social history. Treatment planning and preparation for the medicine session will also occur during this appointment.

During this initial session, we will discuss your goals for treatment, your strengths and areas requiring additional support, and together we will create an individualized plan for your KAP experience. This will include the number of treatments, route of administration and plans for dosing, any preferences you have for your experiences (e.g. invocation, ceremony, intention setting, therapeutic touch) and integration sessions, identifying and bolstering your external support network and incorporating other complimentary skills such as mindfulness/breathing exercises (if you desire). This plan is dynamic and can always be changed as you move through your KAP journey.

We will also review the KAP and general informed consents, and there will be ample time to discuss any questions or concerns you may have. We want you to feel as safe and informed as possible and these sessions provide an opportunity for you to build trust and rapport with your team prior to your medicine sessions.



Following your initial consult, a preparatory session will then be scheduled with the therapist facilitating your medicine experience. This is a 50 minute session during which you will receive more information about what to expect on the day of the medicine session, how to navigate the experience and guidelines around safely preparing for the medicine. This is also an important time to ask questions and gain trust and comfort with your therapist. Your first medicine session will be scheduled within a week of your prep session. You will be given a document outlining important instructions to follow in the days leading up to, and the day of, your medicine session.

The current data recommends 4-6 medicine sessions. At Bird's Eye Wellness, each session is accompanied by an integration therapy session. Integration refers to the solidifying of insights, making meaning from your experience, and weaving these new beliefs and changes into our day to day life. It is arguably one of the most important aspects in sustaining the benefits offered by KAP and why our model emphasizes this holistic and integrated approach, rather than offering ketamine as a stand-alone treatment. Some individuals may opt for "booster" sessions to support them in sustaining benefits gained or to seek additional growth/healing. This can be in either individual or group sessions.

Throughout your course of KAP treatment, it is important that you agree to remain in communication with your treatment team by attending scheduled appointments, responding to communication from providers, and notifying your team immediately of any worsening of symptoms or changes in suicidal thinking and/or utilizing local emergency services/crisis centers.

What to Expect During a Ketamine Session?

As outlined above, prior to your first medicine experience, there will be a preparation session when more detailed "flight instructions" will be reviewed with you. There will be time prior to administering the medicine to settle into the space and check in with your clinician.

The onset of the ketamine experience will be dependent on the route of administration. For oral, the onset is approximately 10-15 minutes and the effects have a more gradual onset. Often, we start participants at a lower dose to assess their initial response. Approximately 30 minutes later, a "booster" dose will be offered if the effect of the medicine is mild and you are keen to have a deeper experience. As the medicine takes effect, you may start to feel some numbness/tingling in your mouth and body. You may feel a reduction in anxiety or any body pains, a greater attunement to energy flow, changes in the way you experience your body (e.g. heavier, lighter) and/or an empathogenic or "heart-opening" sensation. Sometimes lower doses are used to achieve this state as an aid in psychotherapy.

For IM, onset is usually less than 5 minutes and dissociative effects occur more quickly. The "peak" effect usually lasts around 30 minutes and then tapers down over the following hour. Higher doses are more likely to produce "peak" psychedelic and/or dissociative states and the experience tends to be more internal. Articulating the experience at the time can be difficult, so it



is often useful to focus on integrating the experience during subsequent psychotherapy sessions rather than during or immediately after the medicine session.

In general, sensory effects of ketamine can include unusual physical sensations, emotions, visual effects. Often the body feels very relaxed or you may not have any body sensations at all. You may have the sensation of floating or feeling a separation of your body and mind, a distorted sense of time, a feeling of vivid dreaming, or synesthesia (crossing of senses) or changes in sensory processing. They may be pleasant or unpleasant and often people can experience both within the same medicine journey in waves. These sensations are common and expected.

Ketamine is a non-specific amplifier, meaning it can create euphoric sensations, but also intensify difficult emotions. It is important to be prepared for this potential as you enter into your ketamine experience. The opportunity to process and integrate difficult emotions in new ways is likely an integral part of the healing mechanism of ketamine and it is helpful to view this as an opportunity to be seized rather than to resist or avoid. In contrast to current psychiatric medications, KAP aims to create a safe container to heal deep wounds rather than suppress and manage symptoms. In KAP, we try not to assign judgment to our journeys (i.e. “bad” “negative”) and instead appreciate them as challenging or difficult.

During the medicine session, your blood pressure, oxygen level, and heart rate will be monitored to ensure your safety. Throughout your ketamine experience, one or both of your providers will be with you at all times to monitor you, offer support, or guide you through any challenging experiences that may come up. If you have consented to therapeutic touch, they may offer this if it could benefit you. There is no pressure to speak, and it is often most beneficial to maintain an internal focus, which your providers will support you in doing. With your permission, they can also scribe to help you recall moments from your medicine experience at future integration sessions. Please let us know of any allergies or sensitivities to smells/scents, and any history of spiritual or religious wounding, so we can adjust your experience accordingly.

Due to the mind-altering nature of ketamine, for your own safety, you must agree to follow the instructions provided by the therapist(s) until the effects of the medicine have worn off. You may be unsteady on your feet so the therapist will be there to offer support in going to the bathroom or moving around if necessary - but movement should be limited to reduce risk of falling.

As the effect of the medicine begins to wear off, your provider(s) will be there to help you “land” and acclimatize again to your surroundings. You are welcome to share any thoughts or feelings coming up for you regarding your journey during that time, but it is also common to remain internally focused, or journal/draw, and to discuss the experience later during an integration session.

The effects of the ketamine will gradually resolve. Medicine sessions are scheduled for three hours to support you through the most acute effects of the medicine, though residual effects may



occur for up to 5 hours after administration. You are unable to drive for the remainder of the day after receiving ketamine and will need to pre-arrange transportation following the session.

Video Recording KAP Sessions

In Psychedelic-Assisted Psychotherapy clinical trials, video recording of sessions is a standard practice for safety. Bird's Eye Wellness (BEW) records all Ketamine-Assisted Psychotherapy sessions in order to meet the standard of care and to provide the utmost safety for the experience in an altered state of consciousness. Video recordings are ONLY accessed and reviewed in the event of a concern arising from a KAP session. Recordings are NOT released to participants for any other use. Because we take your privacy very seriously, we have built the recording systems with state of the art HIPAA and privacy protections. The cameras record to a local, fully encrypted and locked hard drive. These recordings are not stored in your Electronic Medical Records system, and are not accessible through the internet, or any cloud-based application. BEW maintains these video recordings for one full year after the date of the recorded session.

Eligibility for Ketamine Treatment

Through our initial screening and intake process, we carefully review your medical and psychiatric history to be sure ketamine is a safe treatment option for you. This may also involve discussion with current providers (e.g. therapists, psychiatric providers, primary care providers, specialists etc.) and reviewing past treatment records. We may require that you have an established therapist for ongoing support once KAP services are complete. If you are taking psychiatric medications, we also may require that your care is being managed by a psychiatric provider.

Our screening form is used to assist in identification of individuals who are clearly not safe candidates for KAP. Your honesty on this form is essential to keep you safe and to prevent undue costs. It is important to note that an initial consultation does not guarantee eligibility for treatment.

You will be required to be an active patient with a primary care provider while undergoing ketamine treatment. There are certain conditions that may disqualify you, or need to be treated, before you can safely take ketamine. These conditions may include, but are not limited to, hallucinations/psychosis, hypomania or mania, Borderline Personality Disorder, Dissociative Identity Disorder, unstable angina (chest pain/heart disease), uncontrolled hyperthyroidism, uncontrolled hypertension, bladder disease, increased intracranial pressure, evidence of liver disease, or allergy to ketamine.

Those who are pregnant or breastfeeding are not eligible for KAP because of potential effects on the fetus/infant. The effects of ketamine on pregnancy, breastfeeding and the fetus are undetermined, and therefore, it is our policy that you protect yourself against pregnancy while exposing yourself to ketamine or in the immediate aftermath of its use.



Untreated hypertension is a contraindication to ketamine which can cause a rise in blood pressure. Similarly, a history of heart disease may make you ineligible to participate, unless your cardiologist approves your participation.

There is evidence of ketamine both helping and exacerbating migraines. If you have a history of migraines, please discuss the potential risks and benefits with the medical provider at BEW.

Certain medications will dampen your experience of ketamine and you may need to work with your prescriber to taper or discontinue these medications before treatment. These include, but are not limited to, benzodiazepines, lamotrigine, gabapentin, or pregabalin. If this is applicable to you, your treatment team will discuss recommendations further. Adequate data is not available regarding ketamine's potential interactions with other medications and your team will determine safety on a case by case basis using available information and discussion of risks versus benefits.

Opiate use is contraindicated with ketamine treatment. Stimulants can not be taken concurrently with ketamine administration.

Based on your unique circumstances and medical history, we may require further testing/screening procedures (blood work, urine drug screen, EKG) or require approval of other specialists involved in your care.

As we are a small clinic, certain individuals may not be appropriate for our services and may be better suited for a larger clinic with more robust support, higher level of monitoring or availability of intravenous ketamine.

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

Potential Risks of Ketamine Therapy

Many of the below effects were noted after rapid intravenous administration of ketamine or at high dose intramuscular injection ($>4\text{mg/kg}$) which is much larger than the sub-anesthetic ketamine doses used for KAP (typically 0.5mg/kg to 1.5mg/kg). The determination of dose will use a well-researched weight based protocol, and will depend on prior exposure to ketamine and other psychedelics, as well as general sensitivity.

Overall, any side effects experienced resolve once the effects of the medicine subside.

You may experience:

- Impaired balance and sense of coordination - usually occurring for two, but up to four hours after administration.
- Change in perception of sensory input (i.e. difficulty seeing something that is actually present, diminished ability to hear or to feel object accurately, including one's own body)



- Elevation in blood pressure, usually about 20 mm Hg systolic, which is similar to heavy exercise and usually resolves within 4 hours.
- Vision changes (e.g. blurred, double vision, nystagmus)
- Elevation of intraocular pressure (feeling of pressure in the eye)
- Loss of appetite
- Slurred speech
- Confusion
- Excitability
- Nausea, vomiting
- Anxiety
- Tachycardia (elevation of pulse)
- Lowering of blood pressure and/or pulse rate

Urinary tract symptoms, cystitis or permanent bladder damage can occur if ketamine is used chronically, at high doses. This is much less likely with medically supervised, sub-anesthetic doses. If you experience any urinary symptoms, please notify your provider.

Laryngospasm, which is a transient and reversible spasm of the vocal cords making it temporarily difficult to speak or breathe, is an extremely rare adverse effect of Ketamine occurring in approximately 1 in 100,000 people. This data is based on individuals receiving anesthetic doses of ketamine (4-5 times higher than sub-anesthetic doses used for KAP). However, if this occurs it is considered a medical emergency.

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.

Due to the nature of this type of treatment, it is possible you experience upsetting or disturbing content or memories which could result in temporary worsening of psychological symptoms or dysregulation/functioning. Though available data demonstrates rapid anti-suicidal effects of ketamine, it is also possible that the treatment may exacerbate suicidality. It is for these reasons we may require you to be established with an external therapist and commit to maintaining communication with your treatment team. By signing this form you agree that you understand these risks.



Largely, potential side effects or adverse effects of ketamine are mild, transient and resolve as the medication leaves your body (usually in appx 4 hours).

If you are prone to nausea or motion sickness, you will have the opportunity to premedicate with an anti-nausea medication (e.g. Zofran). Common reactions to Zofran include: headache, constipation, fatigue, diarrhea, hypoxia, fever, urinary retention, dizziness, agitation and pruritus. Serious reactions include: severe hypersensitivity and anaphylaxis, bronchospasm, Stevens-Johnson syndrome, toxic epidermal necrolysis, myocardial ischemia, QT prolongation, torsades de pointes, serotonin syndrome, extra pyramidal symptoms, oculogyric crisis, transient blindness.

Due to the risk of nausea, please refrain from eating 4 hours prior to your session. Hydrate well for up to 2 hours before your session, then stop drinking so you do not have to interrupt your ketamine session with bathroom trips.

We will also have anti-hypertensive medications available should you experience an elevation in blood pressure that is determined to be unsafe or is not resolving. Common reactions to these anti-hypertensive medications include: somnolence, headache, hypotension, abdominal pain, fatigue, nightmares, nausea, irritability, throat pain, dizziness, temperature elevation, diarrhea, otalgia, sexual dysfunction and constipation. Serious reactions include: syncope, bradycardia, hypersensitivity reaction, and angioedema.

The treating provider reserves 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 our setting.

Throughout the ketamine protocol, you must agree not to drive a car or motorized vehicle until the morning after being administered a dose of ketamine. This is a strict safety protocol to reduce the risk of harm to yourself or others and is non-negotiable. For this reason, you will be required to have someone pick you up from each ketamine session, or take a lyft/uber/taxi home. Transportation must be pre-arranged as some options above may not be accessible depending on location and time of day.

Please see KAP guidelines and pre-flight instructions for more details.

Potential for Ketamine Abuse and/or Dependence

Non-medical use of ketamine, and ketamine abuse, does occur. Repeated, high dose, chronic use of ketamine has caused urinary tract symptoms and even permanent bladder dysfunction in individuals abusing the drug.

The DEA classifies ketamine as a schedule III controlled substance. It is highly regulated and as such, our treatment plans space and dose ketamine sessions cautiously to reduce the theoretical risk of dependence, which is exceedingly rare in a controlled, medically supervised setting.

There is a growing body of literature that KAP has promising potential for treatment in certain substance use disorders and helping to maintain abstinence.



Positive Effects of Ketamine

While the potential benefits of KAP are quite exciting, as mentioned previously, it is not a cure. It is a powerful tool to reduce rigidity, offer new perspectives and insights where one may have previously felt stuck. In order to make meaning and lasting change, it requires a dedicated engagement to the integration therapy portion of your treatment. While there are many studies demonstrating ketamine's efficacy in treating depression and other diagnoses, it is still a relatively new and experimental treatment, and unfortunately outcomes cannot be guaranteed. Ketamine's antidepressant effects have a rapid onset, which distinguishes it from other traditional antidepressants. According to available literature, as many as 70% of patients experience an immediate response, and up to 40-50% achieve remission of symptoms. The response to initial ketamine treatment tends to last a few months, but the effects tend to compound and last longer with subsequent treatments and a dedicated participation to integration psychotherapy. If there has been no response after four doses of ketamine, further treatments will not be offered as current data does not support it.

Some individuals opt to continue current psychotropic medications and engagement in external therapy, despite improvements, in order to prevent future relapse. "Booster" ketamine sessions may be a good option for some to aid in sustaining positive effects.

Confidentiality

Your privacy and all other therapy records will be kept confidential. They will be maintained with the same precautions as ordinary medical records under HIPAA law. Only providers at BEW who are involved with your case will have access to your information. To allow others to access your records, you will need to provide a signed release form.

What if KAP is not right for me?

If KAP is not a safe or appropriate treatment for you based on the information gathered in the screening/intake process, or if it is not providing the desired improvement, there are other interventions which may help. Should this be the case, we will do our best to provide you with alternative resources and/or referrals. These may include Electroconvulsive therapy (ECT) and Transcranial Magnetic Stimulation (TMS) for treatment-resistant depression. Eye Movement Desensitization and Reprocessing (EMDR) is an intervention for trauma-related symptoms.

Voluntary Nature of Participation

Please be aware that the Food and Drug Administration (FDA) has not yet established the appropriateness of KAP and its use is considered off-label. The only official indication for use of ketamine is anesthesia. It is extremely important that you understand the off-label use of ketamine as it pertains to any liability associated with the use of ketamine. Your informed consent indicates you are aware of this situation.

Ketamine is a new psychiatric treatment—the primary studies researched effects on depression, bipolar disorders and alcoholism. There have also been studies on the effects of ketamine on



OCD, PTSD and anxiety with promising results. It is not yet a mainstream treatment, though there are now many studies that demonstrate 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 or you may benefit from “booster” treatments as described above. Your decision to undertake ketamine is completely voluntary. Before you make your decision about participating, you will be encouraged to ask any questions you may have about the process.

Even after agreeing to ketamine treatment, you may withdraw from treatment at any time. However, if you have ingested ketamine, we strongly encourage participation in integration therapy, even if you choose not to participate in any further medicine sessions.

Informed Consent Attestation

By signing this form, I agree that:

I have fully read this informed consent that describes ketamine-assisted psychotherapy treatment.

I have had the opportunity to raise questions and 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 or destabilizing psychological effects. Typically these symptoms are short term in duration, but rarely may last for longer periods of time.

I understand the physiological risks of taking ketamine.

I understand that difficult experiences are often part of the healing process and not every ketamine experience may be pleasant.

I give my consent to the administration of Zofran (Ondansetron), 4mg, 1-2 tablets as needed for nausea, at my request.

I give my consent to the administration of Catapres (Clonidine) in case of high blood pressure at my request.

I accept that the medical consultation is for evaluation of my medical condition only as it pertains to my participation in Ketamine Assisted Psychotherapy.

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 I may withdraw from ketamine treatment at any time.



I agree not to operate any type of vehicle or engage in any risky activities until the morning after being administered ketamine, for the duration of my treatment.

I consent to Bird's Eye Wellness video recording my Ketamine Assisted Therapy session.

I give my consent for providers at Bird's Eye Wellness to contact emergency services in the event of a medical or psychiatric emergency.

By signing below, you also agree to:

Maintain contact with your treatment team throughout treatment by attending scheduled appointments, responding to communications from your treatment team, and informing your treatment team promptly in case of aggravation of symptoms such as increase in suicidality. I agree to contact emergency services or crisis response with any increased suicidality.

Follow any direct instructions given by your treatment team until the effects of the ketamine have worn off.

Remain at the office until the therapist(s) determines that you are safely ready to leave, and have transportation previously arranged.

PRINTED NAME: _____

SIGNATURE: _____ DATE: _____