

Informed Consent for Ketamine-Assisted Psychotherapy (KAP)

Introduction

Ketamine has long been used safely as an anesthetic and analgesic agent, and has been found to have rapid antidepressant effects. A form of ketamine (esketamine, under the brand name “Spravato”) was approved for use in treatment resistant depression by the FDA in March 2019.

Ketamine is also considered by some to be a psychedelic substance; that is, a substance that has psychedelic, or “mind-manifesting”, properties. A psychedelic dose of ketamine, the dose used in Ketamine-Assisted Psychotherapy (KAP), is significantly lower than the dose used for anesthetic purposes. KAP may also involve a “psycholytic” dose of ketamine – that is, a dose that does not produce psychedelic effects, but decreases psychological defenses in order to facilitate talk therapy.

The vast majority of research thus far has been done with intravenous ketamine. By contrast, your KAP treatment will be administered via the sublingual route; that is, by means of a lozenge that you will place in your mouth. Accordingly, this usage of ketamine is considered “off-label”; see the section on limitations, below. The dosage of ketamine for your treatment will depend on a variety of factors, and will be determined in collaboration between you, your provider, and your prescriber, but will generally be between 25mg and 400mg for a single session.

Will KAP help me?

The therapeutic use of ketamine has been associated with a decrease in depression, addiction, bipolar symptoms, and PTSD symptoms, with results sometimes being felt within 0-72 hours, and sometimes lasting for days, weeks, or months. However, there is no way to predict how any single person will respond to KAP. Even if KAP results in an alleviation of psychological symptoms, this result may not be long-lasting. Your Provider does not guarantee any short-term or long-term improvement in your symptoms as a result of KAP treatment, and acknowledges that some people may experience a worsening of psychological symptoms as a result of KAP.

What are the risks of engaging in KAP?

The following side effects of ketamine use are relatively common:

- Hallucinations
- Nausea and vomiting
- Increased saliva production
- Dizziness
- Blurred vision
- Increased heart rate and/or blood pressure
- Change in motor skills

The following side effects are uncommon:

- Double vision
- Increased pressure in the eye(s)
- Jerky movements of arms and/or legs

The following side effects are rare, occurring in less than 0.1% percent of ketamine users:

- Allergic reaction
- Irregular or slow heart rate
- Arrhythmia
- Low blood pressure
- Cystitis of the bladder: inflammation, ulcers, and fibrosis

Other Risks:

- Ketamine can cause various symptoms including, but not limited to, flashbacks, hallucinations, feelings of unhappiness and/or restlessness, anxiety, insomnia, and disorientation.
- There is a potential risk of dosing error or unknown drug interaction that may require medical intervention including intubation (putting in a breathing tube) or hospitalization.
- Risk of other medications interacting with ketamine. For this reason, it is very important that, during your medical screening, you disclose all medications and other substances, including over-the-counter substances and illegal substances, that you are taking.
- Ketamine may not bring about any improvement in the condition for which you are seeking treatment.
- Ketamine is a mind-altering controlled substance, which can be abused. Cases of addiction to recreational use are known, although this has not been encountered or described in the clinical use literature.

The above list of common, uncommon, rare, and other risks is not exhaustive. In addition to the above risks, it should be noted that individual responses to ketamine are unpredictable and vary widely. During or after ketamine use, some patients may experience bliss, euphoria, or other positive emotions; some patients may experience terror, grief, or other negative emotions; some patients may experience both or neither.

It is the opinion of the Provider that even painful KAP experiences may be extremely useful for making psychospiritual progress. If you appear to be experiencing a medical emergency during a KAP session, your Provider will place a call to emergency medical professionals who will assist you further.

Will I be eligible for KAP treatment?

As part of the treatment process, your Provider and a medical professional will assess your psychological and medical condition in order to determine whether KAP is appropriate for you. Here is a non-exhaustive list of conditions that may, but will not necessarily, indicate that KAP is inappropriate:

- Pregnancy
- Untreated hypertension, i.e. high blood pressure
- History of heart disease
- Untreated hyperthyroidism
- Schizophrenia or another psychotic disorder
- An active/current substance abuse disorder

How does KAP work?

Currently, ketamine is understood as working as an NMDA antagonist, acting on the glutamate neurotransmitter system. This is a very different pathway than that of other psychiatric drugs such as SSRIs, SNRIs, mood stabilizers, antipsychotics, benzodiazepines, etc. It should be noted that, in addition to the subjective effects of ketamine, which last up to a few hours after dosing, ketamine metabolites may persist in the body for up to a week.

There is no single agreed-upon framework for understanding how KAP may improve mental health symptoms. However, one possible framework for understanding the process is outlined below.

Ketamine often induces a non-ordinary state of consciousness, or a trance state. Patients sometimes experience this trance state as a kind of waking dream. Just as in dreams, things experienced during the trance state may have significance for the patient's life, their internal world, their emotional difficulties, their important relationships, their traumatic experiences, their defensive structures, their repressed emotions and memories, and so forth. Accordingly, the trance state may be highly euphoric, highly unpleasant, both, or anywhere between.

Many patients experience short-term relief of psychological suffering as a result of KAP. However, in the form of KAP practiced by your Provider, it is believed that this short-term relief is not the main mechanism of change for the patient. Instead, change is believed to be brought about in two ways. First, the defense-lowering effects of the ketamine can sometimes provide both the patient and the Provider with greater access to unconscious and/or repressed psychological material. Second, it is believed that the trance experience itself can be the occasion of deep and lasting psychospiritual change, and that this change is best brought about by careful consideration and interpretation of the patient's subjective experience under the influence of ketamine. This is believed to be the case whether the trance state is euphoric or

unpleasant; indeed, both unpleasant and euphoric experiences can have a deep relationship to the suffering that the patient seeks to relieve via KAP.

In addition to the above, ketamine has been shown to create a short-term increase in neuroplasticity – that is, in the brain’s ability to form new neural pathways. This effects can last for a few hours to a few days. For this reason, your Provider recommends that you take good advantage of this “neuroplasticity window” by reserving ample time and space after your KAP session for journaling, conversations with important others, and quiet reflection.

Intention

During the preparation for the KAP session, your Provider will ask you to consider your intention – that is, the benefit that you hope to gain via the KAP experience. Intentions can range from general (“I want relief”) to specific (“I want to improve my relationship with my mother”). While there is no guarantee that the trance experience will feature anything related to the patient’s intention, or that the KAP experience will improve the things the patient hopes to improve, psychedelic medicines are often understood to be highly susceptible to the mindset of the patient who experiences them. As you prepare for KAP, you may wish to journal about your intention and/or to discuss it with your therapist or other people who are important to you.

Ritual and Spiritual Elements

If you have spiritual practices or beliefs that are important to you, you may wish to incorporate these things into your ketamine experience. One way to do this is to bring an object of spiritual and/or emotional significance with you to the KAP session. This object may relate in some way to your intention for the experience; for example, an object associated with a significant other or a parent, or an object that reminds you of a significant time in your life.

Another way to incorporate spirituality into the KAP experience is to begin the KAP session with a ritual invocation from your chosen spiritual tradition.

Ritual and/or spiritual elements of the KAP experience are, of course, strictly optional!

How should I prepare for my KAP session?

- You should abstain from the use of all intoxicating substances for a period of 48 hours, including alcohol, tobacco, cannabis, and any illicit substances. Since cannabis can sometimes mute the subjective effects of ketamine, you may wish to abstain for two or more weeks before your KAP session.
- You should not eat for 3-4 hours prior to the beginning of your KAP session. Since ketamine can cause temporary difficulties in mobility, you should also limit your water intake, to minimize the possibility that you will need to urinate during the KAP session.

- In consultation with your primary care physician and/or prescriber, you should hold (i.e. avoid taking on the day of the treatment) any medication that may raise blood pressure, e.g. stimulants. You may continue on anti-hypertension and/or diabetic medication, adjusting the dose as appropriate based on the adjustment to your dietary intake.
- You must arrange transportation for yourself; ideally, you should be driven home by a partner, friend, or family member. Since ketamine has temporary cognitive and motor effects, you agree not to drive after your KAP session for the remainder of the day.
- To the extent that it is possible, you should ensure that, after your KAP session, the rest of your day is free from undue demands or disturbances, and includes ample time for quiet reflection, journaling, and/or conversation with important others.

How is KAP treatment structured?

A single course of KAP treatment includes a psychological assessment, a medical assessment, a preparatory session, and one or more KAP sessions, each of which is followed by an integration session, ideally within 24 hours.

Psychological Screening - During this meeting, your Provider will assess your psychological readiness for KAP treatment. At the end of this meeting, your Provider may determine that they are unwilling to offer you KAP treatment; or they may provide you with a referral to a medical provider for a medical assessment.

Medical Assessment - During this meeting, a medical provider, in partnership with your KAP Provider, will assess your physical readiness for KAP treatment. At the end of this meeting, your medical provider may determine that they are unwilling to recommend you for KAP treatment; or they may provide you with a prescription for ketamine, at a dosage determined in collaboration with you and your KAP Provider. If the medical provider gives you a prescription, you will pick up the ketamine at the pharmacy, and will bring the ketamine to your KAP session.

Preparatory Session - During this meeting, your Provider will go over the logistics of the KAP session, discuss payment options, answer any questions you may have about the treatment, and will help you prepare psychologically for the KAP session.

KAP Session - During this session, you will bring your ketamine prescription to the Provider's office. While there, you will take the ketamine. Your Provider will remain present for the duration of the experience. When your Provider determines that it is safe to do so, you will leave the office and return home, via transportation that you have arranged ahead of time; you will not drive yourself home.

Integration Session - As soon as possible after the KAP session, ideally within 24 hours, you will meet with your Provider to discuss the experience you had during the KAP session.

Is KAP treatment covered by insurance?

Your insurance is unlikely to cover the cost of the ketamine itself. Your insurance may cover part of the course of treatment; for example, the psychological and/or medical assessment, the preparatory session, and the integration session. Since the KAP session itself is 3-4 hours long, your insurance will likely not cover this session.

What happens during the KAP session?

A standard KAP session lasts about 3-4 hours, and ends when your Provider determines that you are safely able to leave the office. These 3-4 hours are divided into preparation, dosing, trance, reflection, and recovery.

Preparation (15 minutes)

You will arrive at the office, bringing your ketamine prescription with you. The Provider will evaluate your mindset and ensure that you are ready for treatment. The Provider will address any lingering questions and anxieties you may have about the treatment. The Provider will confirm that you have transportation home from the session and will not be driving yourself. The Provider will ask you to commit to follow the Provider's instructions during the session, and not to leave the office until the Provider considers you safely able to do so. The Provider will invite you to reflect on your intention for the experience.

You may also discuss with the Provider whether you wish to be touched physically during the session. Any physical touch offered by the Provider will be non-sexual and non-genital; for example, the Provider may offer to place a hand on your shoulder or on your hand. Physical touch is strictly optional, and in all cases, your Provider will only touch you if you have explicitly given permission for them to do so before the experience.

Dosing (15 minutes)

The Provider will direct you to place the ketamine lozenge(s) in your mouth. During this time, the lozenge(s) will begin to dissolve, producing saliva. You should keep this saliva in your mouth **without swallowing it**; this will give the ketamine a chance to be absorbed through your oral mucosa, i.e. the tissue on the inside of your mouth.

While the ketamine is being absorbed, your Provider will play music and/or lead you in a guided meditation designed to help you relax and prepare for the trance state. When 15 minutes have elapsed, your Provider will direct you to spit out the saliva that has accumulated in your mouth. At this point, you will mostly likely have begun to experience the effects of the ketamine.

Trance State (30-90 minutes)

Your Provider will invite you to lie down on a couch (your sense of balance will likely be affected) and put on eye-shades, which will minimize distraction and help you to direct your attention inwards. During the first few minutes of the period, if you do not seem to be feeling the effects of the ketamine, your Provider may offer you an additional dose.

Your Provider will play music designed to evoke emotion and provide structure to the trance experience. While you are in the trance state, your Provider will be physically close to you, ready to offer any physical or emotional assistance you may need during the experience. Your Provider will also take notes on your reaction to the experience (e.g. things you may say out loud), in order to help you reflect on the experience later.

The trance state is generally (but not always) restful and is often non-verbal. You may experience heaviness in your body, possibly with the loss of sensation, followed by a separation from the usual state of cognitive processing, such that verbal expression may become limited and even absent.

Even during the trance state, it is generally possible to rouse patients to an alert and interactive state. If you appear distressed, the Provider may verbally check in with you to determine if there are any concerns. If you have explicitly given permission for them to do so, your Provider may offer reassuring physical contact, as described above. In the case of a medical emergency, your Provider may offer appropriate physical assistance. If you need to urinate, your Provider will assist you in reaching the bathroom.

During the trance state, you may undergo disconcerting or distressing experiences – e.g. vertigo, physical discomfort, nausea, the emergence of distressing psychological material, and so forth. Panic attacks can also occur on rare occasions.

Eventually, the trance state will subside. When the Provider observes that you are emerging from the trance state, they will invite you to remove your eyeshades and/or sit up, when you are ready to do so.

Reflection and Discussion (30-45 minutes)

To the extent that you wish to do so, you and the Provider will discuss your experience. Your Provider may share their observations about what you seemed to be experiencing, things you said while in the trance state, etc. You may prefer silence during this period; in this case, your Provider will simply offer their presence and any support you may want.

Recovery (5-120 minutes)

You will remain at the Provider's office until you are fully oriented to time, place, and person – that is, until you know who you are, who the Provider is, where you are, and what day and time it is. When the Provider determines that you can safely leave the office, you will leave via the

mode of transportation arranged beforehand; you will not drive yourself home and will not take public transportation, but you may use a ride share service or taxi/cab.

What should I do after the KAP session?

Once you arrive home, it is recommended that eat lightly and refrain from strenuous physical activity. You agree not to drive a motor vehicle or bicycle for the rest of the day of your KAP session. You may wish to spend time journaling, quietly reflecting, or discussing your experience with a trusted person.

You should report any unusual symptoms or side effects at once to your Provider. However, should any medical emergency arise after your KAP session, your Provider cannot provide medical assistance, and may not be able to respond immediately to texts, calls, emails, or other means of contact. Accordingly, you should arrange for a trusted person to be present for at least 4 hours after your KAP session, and in case of medical emergency, you should call 911.

You and your Provider will arrange to have an integration session as soon as possible after the day of the KAP session, ideally within 24 hours. It is also recommended that, if you are in ongoing therapy with another provider, you discuss your KAP experience with that provider, in order to continue to derive benefits from the experience.

Since KAP treatment can sometimes occasion a substantial but temporary shift in your perspective, it is recommended that you do not make any significant, irreversible life decisions for at least 48 hours after your KAP session.

Home Use

Depending on the treatment plan developed between you, your Provider, and your prescriber, you may be given lozenges to take home for designated evening ketamine sessions. Detailed instruction and additional consent will be provided if this treatment plan is to be recommended.

You may not take ketamine at home unless a specific treatment plan has been developed that includes this treatment. Taking ketamine at home without this treatment contract may result in termination from your Provider's practice. If you use lozenges at home, you must not drive for 4 hours after lozenge administration, and you must have another responsible and unimpaired adult present to support you.

Consent

You may ask your Provider any questions you may have concerning the procedure or effects of ketamine at any time. You may withdraw your consent to receive ketamine at any time, and you may discontinue your participation in KAP at any time up until the lozenge has been taken. Once you have taken the lozenge, you will be asked to remain in the Provider's office until the Provider determines that it is safe for you to leave.

If you wish to cancel any KAP or other session, you should let your provider know within 48 hours of the beginning of the session. Your Provider may, at their sole discretion, charge you the full session fee for any KAP or other session that is canceled with fewer than 48 hours' notice. In such cases, your Provider may be able to fill your spot with another client, or may offer you to reschedule the session, at their discretion. Even if your insurance has agreed to cover some or all of the KAP treatment, if you do not arrive for your scheduled appointment, or if you cancel the appointment with fewer than 48 hours' notice, your insurance will not reimburse you for the session fee; in these cases, you will be responsible for the full session fee.

As described above, you may choose to give consent for the Provider to touch you physically during the KAP session. Again, any physical touch offered by the Provider will be non-sexual and non-genital; as a rule, even if you have given consent for physical touch, the Provider will err on the side of not offering physical touch. You may withdraw your consent for physical touch at any time, even after administration of the lozenge.

During the KAP session, although it is recommended to lie on the couch with eyeshades on, these measures are strictly voluntary; at any point, you may choose to sit up and/or take your eyeshades off, with the understanding that this will likely lessen the effectiveness of the experience.

What are some limitations of, and alternatives to, KAP treatment?

Currently, ketamine is utilized as "off-label" treatment for various psychiatric conditions including depression, PTSD and other psychiatric diagnoses. Off-label prescribing is legal and occurs quite commonly; up to 20% of medication in the US is "off-label" by some measures; for example, the use of tricyclic antidepressants for pain, or the use of stimulants for depression. However, your Provider makes no guarantee that KAP treatment will offer any alleviation of the symptoms or difficulties for which you are seeking treatment.

The combination of medication and therapy is an effective treatment for many people. You may also wish to consider mindfulness and/or meditation courses and practices, therapy groups, or retreats. Ketamine use has been most studied when used intravenously, without psychotherapy, and for acute suicidal ideation and with addictions. At this point, there is very little data on the efficacy of KAP using the sublingual route of administration, which is the route offered by your Provider. While your Provider believes that KAP can enhance psychotherapy outcomes, your Provider makes no claim as to the superiority of their methods. You may also wish to consider an KAP treatment via the intravenous and/or intramuscular routes of administration from another provider.

Patient Agreement and Consent

By signing this document, you agree to the following statements.

1. I understand that KAP is not an FDA-approved treatment for depression, anxiety, addiction, bipolar disorder, or PTSD.
2. It is my choice to take part in KAP.
3. I understand that I may decide not to take part or to withdraw from KAP at any time, except directly after the administration of the ketamine, as detailed above. Directly after administration of the ketamine, I agree to remain at the Provider's office until the Provider determines that it is safe for me to leave.
4. I understand that the provider may discontinue the treatment without my consent.
5. I understand that KAP may not provide any relief of the symptoms and/or difficulties for which I am seeking treatment, and that any relief KAP does provide may not be long-lasting.
6. I have had a chance to ask my prescriber questions about this treatment.
7. My prescriber has answered to my satisfaction all the questions that I asked them about the treatment.
8. The nature and possible risks of ketamine use have been fully explained to me.
9. Possible alternative methods of treatment, the risks involved, and the possibility of complications have been fully explained to me.
10. No guarantees or assurances have been made or given to me about the results that may be obtained from this treatment.
11. I understand that the only physical contact to be expected throughout the session is for the purpose of maintaining my physical safety, unless another form of therapeutic touch is explicitly requested and agreed upon prior to the administration of the ketamine. There will be no sexual or genital touch during any part of the treatment.