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Ketamine Assisted Psychotherapy (KAP) Informed Consent

Ketamine is an “off-label” treatment for various chronic mental conditions that have been resistant to other forms of treatment. Ketamine is a Schedule 3 medication that has long been used safely as an anesthetic and analgesic agent. It is now being used effectively for treatment of depression, alcoholism, substance dependencies, PTSD and other psychiatric diagnoses as well as for existential, psychological and spiritual crises and growth.

How does it work? The current, most probable understanding of ketamine’s mode of action is as an NMDA antagonist working through the glutamate neurotransmitter system. This is a different pathway than that of other psychiatric drugs such as the SSRIs, SNRIs, lamotrigine, anti-psychotics and benzodiazepines.

At the dosage we will administer for therapy, you will most likely experience mild anesthetic, anti-anxiety, anti-depressant and potentially psychedelic effects. You are likely to experience a relaxation from ordinary concerns while maintaining conscious awareness of the flow of mind. This tends to lead to a disruption of negative feelings and obsessional preoccupations. This relief and the exploration and experience of other possible states of consciousness augment the capacity to do therapy from a different psychological vantage point under the careful watch and facilitation of your therapist.

We will use a sublingual form of administration, lozenges or tablets infused with 50-200mg of ketamine placed under the tongue as they dissolve. We will meet for 1-3 preparation sessions (or more if necessary) and plan to follow the medicine session with integrative psychotherapy sessions. You will meet with a physician/psychiatrist who will conduct a physical and medical review and prescribe the medication for you to pick up at the compounding pharmacy. The day of the medicine session you will be given instructions to follow.

You may experience important positive changes in personality, mood and cognition during treatment. Some experiences may be temporarily disturbing to you. The ketamine experience is designed to enable your own healing wisdom to be accessed for your benefit. The psychotherapy support you receive will aid you in making your experiences valuable and understandable.

Please raise any questions that arise at any point during the treatment process and know that you may withdraw from the treatment at any time.

Your experience will be unique to you and if you have multiple sessions, each will be different. The number of sessions varies based on personal needs and treatment responses. KAP journeys are adventures that cannot be pre-programmed. They evolve from your own inner world and vary in intensity.

While it is best to form an intention for your journey, you may or may not be able to hold onto that. Indeed, **not** holding on and following the path that unfolds while relaxing into it is best. Holding on is the main source of anxiety in this treatment.

A ketamine session can be light, dark, or both. There will be concepts, visions encounters and you may well deal with your own death, mortality and immortality. Some experiences are enjoyable and filled with awe and some are difficult, but everyone grows from their experience.

Eligibility for ketamine treatment

Before participating in ketamine assisted psychotherapy you will be carefully interviewed to determine if you are eligible for the therapy. Assessment will include a medical history, physical exam if necessary, review of your medical/psychiatric records, psychiatric history and possibly administration of brief psychological tests.

Pregnant women and nursing mothers are not eligible because of potential effects on the fetus or nursing child. The effects of ketamine on pregnancy and the fetus are undetermined and therefore it is advisable to protect against pregnancy while exposing yourself to ketamine or in the immediate aftermath of its use.

Untreated hypertension is a contraindication to ketamine use as the medicine causes a rise in blood pressure. Similarly, a history of heart disease may make you ineligible to participate.

Information on ketamine's interaction with other medicines will be assessed to determine your eligibility.

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

Overview of Ketamine Therapy— KAP

During the ketamine administration session you will be asked to make two agreements with the therapist(s) to ensure your safety and well-being:

1. You agree to follow any instructions given to you by your therapist until it is determined that the session is over

2. You agree to remain at the location of the session until your therapist decides you are ready to leave.

The length of ketamine sessions varies from person to person and from experience to experience. You will be mostly internally focused for the first 45 minutes to 1.5 hours. You will continue to remain under ketamine's influence at a lesser level for one hour more.

You will receive a lower dose during the initial session. It is always better to start with a lower dose to reduce anxiety and become familiar with how the medicine affects you. There is always an opportunity to make a choice for a larger dose at a future date. It is more difficult to correct a bad experience because of too high an initial dose and the anxiety it may engender. Individuals experienced with psychedelics may receive a higher initial dose.

Administration will be through one or more sublingual lozenges each containing 50-100mg of ketamine. It will dissolve slowly and we ask you not to swallow your saliva for around 12 minutes. Ketamine will penetrate the oral mucosa~ lining of your mouth~ and will be absorbed rapidly in that manner. This will give us a measure of your sensitivity to ketamine. The therapist will watch the time and let you know when to spit or swallow.

You will be listening to gentle non-lyric containing music and wear eye shades for the most inward part of your experience. You and the therapist are creating a state of mind (set) in a safe setting conducive to transformation.

Potential Risks of Ketamine therapy

You will be asked to lie down during the ketamine administration because your sense of balance and coordination will be adversely affected until the drug's effect has worn off. It is possible you may fall asleep. Other possibilities for adverse effects include blurred and uncomfortable vision (you are advised to keep your eyes closed until the main effects have worn off), 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, anxiety, nausea and vomiting. Visual, tactile and auditory processing are affected by the drug. Synesthesia, or mingling of the senses, may occur. Ordinary sense of time will be altered.

Because of the risk of nausea and vomiting please refrain from eating and drinking for at least 4 hours preceding the session and eat lightly when you do. Hydrate well the night before. If you are prone to nausea you may be offered a prescription for an anti-nausea medication~ ondansetron~ in pill or oral dissolving tablet forms.

Ketamine generally causes a significant increase in blood pressure but usually not pulse rate. If blood pressure monitoring reveals that your blood pressure is too high you may be offered clonidine to remedy this.

Agitation may occur during the course of a ketamine session. Your therapist will help you work through the sensations. If agitation is severe, you may be offered lorazepam orally to help you relax.

The administration of ketamine may also cause the following adverse reactions: Tachycardia (elevated pulse), double vision, nystagmus (rapid eye movements), feeling of pressure in the

eyes and loss of appetite. The above reactions were noted in the literature after rapid or high doses of ketamine (5 mg/kg used for surgical anesthesia). The dose to be used in this sub-anesthetic ketamine therapy is much lower (2 mg/kg or less).

Driving an automobile or engaging in hazardous activities should not be undertaken until all effects have stopped. You will be assessed for safety prior to leaving the office.

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.

During the experience some people have reported frightening or unusual experiences. These frightening experiences may be of paramount value to your process of recovery from the suffering that brought you to your KAP work. They will stop. You will receive psychotherapeutic help and ongoing guidance from your therapist.

Potential for ketamine abuse and physical dependence

Ketamine belongs to the same group of chemicals as Phencyclidine (Sernyl, PCP, “angel dust”). This group of chemical compounds is known chemically as Arylcyclohexylamines and is classified as a Hallucinogen. Ketamine is a controlled substance and is subject to Schedule 3 rules under the Controlled Substance Act of 1970. Medical evidence 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 a history of heavy use of psychedelic drugs. In addition, ketamine can have effects of mood, cognition and perception that may make some people want to use it repeatedly. Therefore, ketamine should never be used except under the supervision of a licensed physician or therapist.

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 occur within the framework of our treatment.

You will be provided just the amount of lozenges necessary for your treatment. They have no street value.

Alternative Procedures

No other procedure is available in medicine that produces ketamine’s effects. Major Depression, PTSD and Bipolar Disorders are usually treated with anti-depressant medications, tranquilizers, mood stabilizers and psychotherapy, Electroconvulsive Therapy (ECT) and the recently introduced Transcranial Magnetic Stimulation (TMS) are also in use for treatment resistant depression. Ketamine has also been used in the treatment of addictions and alcoholism as part of comprehensive and usually residential treatment programs, primarily abroad.

Confidentiality

Your therapy records will be kept confidential. To allow others access to your records, you will have to provide a signed release form. The results of this ketamine therapy may be published in clinical literature. Published report will not include your name or any other information that would identify you.

Background

This consent form contains information about the use of sub-anesthetic dosages of ketamine for psychiatric purposes including depression and PTSD. Ketamine was approved by the FDA for use as an anesthetic agent several decades ago. 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. The only official indication for use of ketamine is anesthesia. Its use in psychiatric treatment is not yet a mainstream treatment, though there are now many studies that demonstrate that it may be an effective treatment.

Psychiatric use of ketamine has become relatively wide-spread 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 has been administered by intravenous, intramuscular (IM), sublingual, oral and intra-nasal routes. Often it has been used after other treatment approaches have been unsuccessful. There is an expanding array of ketamine clinics across the country primarily administering ketamine intravenously and usually without a therapy component, in other words, solely for the physiological effect. That therapeutic 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. If your depressive symptoms respond to KAP you may still elect to be treated with medications and ongoing psychotherapy to try to reduce the possibility of relapse over time. You may also need additional ketamine treatments or other therapies to maintain your remission.

Once you indicate that you have understood the benefits and risks of this treatment, you will be asked to sign this form in order to participate in this treatment. You will be given 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 and that you give your consent. Withdrawal from KAP is always your option. Even after agreeing to undertake ketamine assisted psychotherapy you may decide to withdraw from treatment at any time up until ingestion of the lozenges.

I understand that I need to have someone drive me home from the session and not engage in any driving or hazardous activity for at least 4 hours or more depending on the continued presence of effects after my session has concluded.

By signing this form I agree that:

1. I have fully read this informed consent form describing ketamine assisted psychotherapy and agree to its terms. I agree to hold harmless the practitioners involved, waiving, releasing and discharging all claims rights and causes of action which may arise out of, or in connection with, my participation in KAP. No oral or written statements, representations or inducements have been made to cause me to enter into this agreement.
2. I have had the opportunity to raise questions and have received satisfactory answers.
3. I fully understand that the ketamine session can result in a profound change in mental state and may result in unusual psychological and physiological effects.
4. I give my consent to the use of lorazepam if deemed necessary for agitation, ondansetron for nausea, and clonidine for high blood pressure.
5. I have been given a signed copy of this informed consent which is mine to keep.
6. I understand the risks and benefits and freely give my consent to participate in KAP as outlined in this form and under the conditions indicated in it.
7. I understand that I may withdraw from KAP at any time, up until the actual lozenge has been given.

I voluntarily sign my name evidencing acceptance of this agreement.

Signature _____ Date _____

Printed name _____

Physician/therapist statement

I have carefully explained the nature of KAP 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.

KAP Therapist

Date