

Assessment of Ketamine Treatment Practices for Patients with Post-Traumatic Stress Disorder (PTSD) in the United States

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Background

- Ketamine, a dissociative drug, has been approved by FDA for nearly 50 years for use as an anesthetic. Due to recent interest in new applications as well as the successful development of esketamine (Spravato®) for treatment-resistant depression, ketamine is now being offered off-label at a lower dosage for the treatment of mental health conditions such as PTSD in clinics across the US, in absence of demonstrated clinical benefit to patients.
- Ketamine treatment may pose additional risks for patients with PTSD, as dissociation may bring up distressing memories or thoughts related to trauma and impact a patient's sense of self. Psychotherapy is the standard of care for PTSD given the role processing of trauma plays in fostering coping skills and improving symptoms.
- Psychotherapy, guidance from a trained monitor, and a controlled environment are all critical for patients with PTSD to ensure safety during the ketamine treatment experience. However, psychotherapy services and/or supports may not always be provided for those receiving ketamine off-label.

Objective

- Identify current practices in ketamine clinics that offer treatment for PTSD, including treatment parameters, session monitor standards, and environmental factors.
- Consider associated ethical challenges related to off-label ketamine treatment for patients with PTSD and recommend policy solutions.

Methods

- A literature review of available research on ketamine treatment practices for mental health conditions, including PTSD, was performed.
- The top ten most highly visited websites for each of two clinic types offering ketamine treatment to individuals with PTSD were identified. Practices among selected clinics for content analysis were characterized.
- Ethical challenges arising from existing practices were identified.

Literature Review

- Most assessments of ketamine clinics and recommendations for practices focus on conditions other than PTSD, notably major depressive disorder.
- While only a small percentage of patients seeking care through ketamine clinics have PTSD, PTSD care requirements differ in important ways from the other conditions being treated.
- Special considerations around care needs for individuals with PTSD, such as risk of re-traumatization, warrant additional practices to ensure safety.

Clinic Characteristics

Clinic Type	Online Only (n= 10)	In-person (n= 10)
Clinic Examples	Mindbloom, My Ketamine Home	Field Trip, Revitalist
Administration Method	Oral administration	IV infusion, occasionally oral administration
Cost	\$1,100-\$1,400 per month of service (all inclusive)	\$400-800 per session, may exclude medication, other services
Number of Treatments	6 included	1 included
Integration Sessions	Typically offered, included in pricing	Not typically offered, additional fee
Monitor Standards	Highly variable	Highly variable

Selected References

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Ethical Challenges

Vulnerable Population

- Patients with PTSD, especially treatment-resistant PTSD, may be particularly vulnerable to predatory practices given limited effective treatment options.
- Pricing structure may encourage volume purchasing or foregoing essential supportive services. Patients may not have adequate information to determine what level of service is appropriate for presenting condition.

Consent

- Research on efficacy of ketamine for treatment of PTSD is very limited; there is a lack of evidence to support current treatment regimens offered by clinics.
- Clinics are rarely transparent about relevant evidence of safety, clinical benefit.
- Under these conditions, patients with PTSD may not be able to meaningfully consent to ketamine treatment.

Identity, Sense of Self

- Trauma leading to PTSD may result in enduring impacts to sense of self.
- Clinics that do not adequately monitor patients place patients with PTSD at risk of further injury to personal identity or sense of self while undergoing treatment due to ketamine-induced dissociation and reprocessing of trauma.

Policy Solutions

Advertisement Oversight

- Additional regulator scrutiny of advertising practices and medical claims made by ketamine clinics may help encourage more transparency around available evidence of efficacy for mental health conditions, including PTSD.

Monitor Standards

- Improved monitor standards across the industry will help ensure evidence-based supportive care is adequately incorporated to promote patient safety.

Adverse Event Reporting

- Establishing requirements for adverse event reporting and compulsory participation in patient registries can help fill safety, efficacy information gap.

Conclusion

- Interest in alternative therapies such as ketamine will likely continue to increase due to the growing mental health crisis in the US, including increasing incidence of PTSD, making establishment of new policies and practices to promote patient safety even more urgent.
- Solutions must balance need for novel treatments for serious unmet medical needs with existing patient safety concerns around off-label use of ketamine.