Psychedelic-Assisted Therapy: Breakthrough Treatments for Complex Mental Health Disorders

Peter H Addy, PhD
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What are psychedelics?

The five categories of psychedelic and psychedelic-adjacent medicines

1. "Classic" psychedelics
2. Empathogens
3. Dissociatives
4. Complex psychedelics
5. Atypical psychedelics

1: "Classic" psychedelics

Psilocybin

- Legal status: Schedule III
- Spores openly sold, not prohibited

LSD

Mescaline/Peyote

DMT

Classic Psychedelics

Lysergic acid diethylamide (LSD) is a semi-synthetic tryptamine derived from the naturally occurring ergot alkaloid ergotamine (Nichols, 2004). LSD acts primarily as a serotonergic agonist, but also shows action at dopaminergic and adrenergic receptor sites (Halberstadt, 2014; Nichols, 2004).

Psilocybin (4-phosphoryloxy-N,N-dimethyltryptamine) is most accurately characterized as a prodrug, and is dephosphorylated by hepatic first pass metabolism into the 5-HT2A, 1A and 2C receptor agonist psilocin (Presti & Nichols, 2004).It is the active ingredient in "magic mushrooms".

Mescaline (3,4,5-trimethoxy-β-phenethylamine) is a naturally occurring psychedelic derived from the amino acid phenylalanine.

DMT displays affinity and agonist activity at serotonin 2A, 2C, and 1A, sigma-1, and trace amine associated receptors, among others (Bunzow et al., 2001; Fontanilla et al., 2009).

Classic Psychedelics - Timeline

1896, Mescaline isolated

1938, LSD first synthesized

1943, First LSD trip

1958, Psilocybin isolated

1963, Good Friday experiment

1970, President Nixon signs Controlled Substances Act

Classic Psychedelics - Risks

LSD has not been found to produce physiological toxicity, and there have been no documented human deaths from LSD overdose (Passie et al., 2008). However, drug effects can result in disorientation, anxiety, fear of insanity, and feelings that one is dying, which have been characterized colloquially as a "bad trip."

2: Empathogens

MDMA

- Legal status: Schedule I

MDA

MDEA

Empathogens

MDMA possesses properties of both methamphetamine and mescaline. Like methamphetamine, MDMA is a potent releaser of catecholamine neurotransmitters (i.e., epinephrine, norepinephrine, and dopamine) via action at presynaptic reuptake sites. MDMA is also a potent releaser and reuptake inhibitorof pre-synaptic serotonin (De la Torre et al., 2004; Nichols & Oberlender 1989; 1990; Nichols, 1994).

Most psychedelics were outlawed in the United States in 1970. MDMA was not!

Empathogens - Timeline

- 1912, MDMA is first synthesized for use as an intermediary in the production of other chemicals.
- 1958, MDA patented and tested as appetite suppressant. Project abandoned due to psychoactive properties.
- Late 1960s, Therapists experiment with MDA-assisted psychotherapy (Shulgin & Sargent, 1967)
- 1970, MDA made illegal
- 1976, Dr. Shulgin first synthesizes and takes MDMA.
- 1977, Dr. Shulgin introduced MDMA to Dr. Leo Zeff, who trains 4,000 therapists in early MDMA-assisted psychotherapy.
- 1986, DEA judge recommends Schedule III. DEA administrator ignores this. MDMA is classified as a Schedule I controlled substance during an emergency session of the DEA.

Empathogens - Risks

MDMA: increased heart rate, increased systolic and diastolic blood pressure, accelerated breathing, jaw clenching, thirst and increases in core body temperature (Dumont & Verkes, 2006; Freedman et al., 2005; Kirkpatrick et al., 2014a; Liechti et al., 2001).

Ecstasy: cognitive deficits, including memory deficits (Laws & Kokkalis 2007; Nulsen et al., 2010; Rogers et al., 2009).

3: Dissociatives

Ketamine

- Legal status: Schedule I, but can be prescribed in clinics

Dextromethorphan (DXM)

Nitrous Oxide

Phencyclidine (PCP)

Dissociatives

A group of glutamatergic NMDA antagonists that are either unscheduled (DXM and N2O), or restricted but available for use as anesthetics (ketamine).

Ketamine is a schedule III controlled substance and is available by prescription.

DXM is a non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor (Zhou & Musacchio, 1991), which also acts upon the serotonin transporter (SERT), sigma-1 receptors (Werling et al., 2007), and α3β4 nicotinic acetylcholine receptors (Hernandez et al. 2000).

Dissociatives - Timeline

1874, William James describes nitrous oxide-facilitated mystical experience

1962, Ketamine first synthesized

1970, DXM specifically excluded from Controlled Substances Act

1973, Ketamine-assisted psychotherapy

1999, Ketamine Classified as a Schedule III drug

Dissociatives - Risks

Chronic ketamine street use is known to cause serious toxicity to both the gastrointestinal and urinary tract with ulcerative cystitis, hepatic dysfunction and abdominal cramps among the most common medical problems associated with chronic use (Bokor & Anderson 2014). Street ketamine use has also been linked to persisting cognitive deficits (Morgan et al., 2004; Morgan et al., 2010),

Withdrawal symptoms among chronic users are less extensively studied, however, craving, sweating, shaking and palpitations have been documented among a small sample of chronic users (Morgan & Curran, 2012).

To date controlled administration of ketamine in medical and research settings has not been linked to lasting complications such as ketamine abuse or cognitive impairment (e.g., Krupitsky et al., 2002).

4: Complex psychedelics

Ayahuasca

- Legal status: Contains DMT, schedule III

Ibogaine/Iboga

Complex Psychedelics

Ayahuasca = Psychotria viridis leaves (DMT) + Banisteriopsis caapi bark (β-carbolines)

DMT is rapidly metabolized by monoamine oxidase (MAO) in the gut following oral administration, however, the β-carboline alkaloids harmine, tetrahydroharmine and harmaline are potent MAO inhibitors (MAOIs), preventing the first-pass oxidative deamination of DMT (Callaway et al., 1999; McKenna & Towers, 1984).

Ibogaine acts as a serotonin 2A agonist, MOR agonist, KOR antagonist, and NMDA antagonist (Alper et al., 1999; Schenberg et al., 2014). Ibogaine is one of several indole alkaloids found in the root and root cortex of the African shrub Tabernathe iboga, native to West Central Africa including Gabon, the Democratic Republic of the Congo, and Angola (Rätsch, 2006).

Complex Psychedelics - Risks

The most controversial aspect of clinical ibogaine use is concerns of both neurotoxicity and cardiac toxicity. Concerns over possible cardiac toxicity have come from reports of human fatalities associated with the ingestion of ibogaine (Hoelen et al., 2009).

5: Atypical psychedelics

Cannabis

- Legal status: Adult use legal as of 2018

Amanita mushrooms

Salvia divinorum

Atypical Psychedelics

Both in vivo and in vitro studies suggest SA acts selectively as an agonist at the kappa opioid receptor (KOR) (Roth et al., 2002). Acute KOR activation by SA leads to decreased synaptic dopamine within the nucleus accumbens and caudate-putamen (Ebner et al., 2010).

Finally, cannabis is sometimes attributed hallucinogenic properties (Keeler et al., 1971), and will therefore be discussed briefly.

Psilocybe vs Amanita

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Recent clinical research

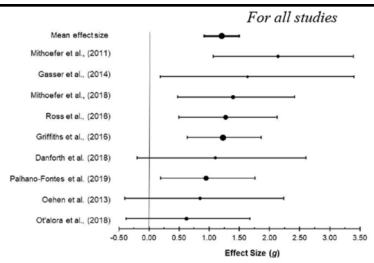
1. Psilocybin
2. MDMA
3. Ketamine

Psychedelic-assisted psychotherapy

Most studies involve:

- Medical and psychiatric screening to ensure safety
- Preparation sessions: discuss expectations, intentions, build rapport
- 1-3 therapy sessions including the medicine and therapist dyad
- 2-4 integration sessions after each medicine session

Set and Setting



The analysis of the pooled effect of psychedelic-assisted therapy in these nine studies resulted in a mean between-groups effect of **Hedges g = 1.21** J Psychoactive Drugs. 2020 Sep-Oct; 52(4): 289–299.

Psilocybin

Recent clinical research

- Alcohol dependence (Bogenschutz et al., 2015)
- Anxiety associated with advanced cancer (Grob et al., 2011)
- Depression (Carhart-Harris et al., 2016)
- Obsessive compulsive disorder (Moreno et al., 2006)
- Tobacco dependence (Johnson et al., 2014)

Psilocybin-Assisted Psychotherapy

Week	Treatment	
-4 to -1		
-1 to 0		
0	META Session	(1 hour)
1	META Session	(1 hour)
2	Preparation Session	(2 hours)
3	Preparation Session	(2 hours)
4	Medication session (Double-Blind)	(8.5 hours)
4.1	Debriefing Session	(2 hours)
5	META Session	(1 hour)
6	META Session	(1 hour)
7	Preparation Session	(1 hour)
8	Medication session (Double-Blind)	(8.5 hours)
8.1	Debriefing Session	(2 hours)
9	META Session	(1 hour)
10	META Session	(1 hour)
12	META Session	(1 hour)

The proposed mechanism of action for psilocybin-assisted psychotherapy is having a mystical experience

What is a Mystical Experience?

(Maclean et al. 2012)

1. **Factor One: Mystical**
   a. Internal unity (i.e., undifferentiated awareness, unitary consciousness);
   b. External unity (i.e., a sense of unity with the surrounding environment);
   c. Inner subjectivity (i.e., a sense of life or living presence in all things);
   d. Objectivity and reality (i.e., noetic quality, a sense that the experience was a source of objective truth);
   e. Sacredness (i.e., worthy of reverence, divine, or holy);
1. **Factor Two: Positive Mood**
   a. Deeply felt peace and joy;
1. **Factor Three: Time/Space**
   a. Nontemporal and nonspatial quality (i.e., feelings of infinite time and limitless space, transcending usual time and space boundaries);
1. **Factor Four: Ineffability**
   a. Ineffability (i.e., difficulty of communicating or describing the experience to others).

Recent clinical research

MDMA-assisted psychotherapy

- Posttraumatic stress disorder
- Social anxiety

Study Design Overview

Phase III Clinical Trials for MDMA-Assisted Psychotherapy for PTSD

- ~ 46.5 hours total
- 24 hours with MDMA

Screening	Preparation	Treatment 1	Treatment 2	Treatment 3	Termination
		MDMA Session 1	MDMA Session 2	MDMA Session 3	
Screening 1	Preparatory Session 1	Integration Session 1.1	Integration Session 2.1	Integration Session 3.1	Study Termination
Screening 2	Preparatory Session 2	Integration Session 1.2	Integration Session 2.2	Integration Session 3.2	
Enrollment	Preparatory Session 3	Integration Session 1.3	Integration Session 2.3	Integration Session 3.3	

MDMA-assisted psychotherapy for PTSD

Six Phase 2 studies: 107 participants enrolled, 100 completers

Significant and meaningful reduction in PTSD and depression symptoms

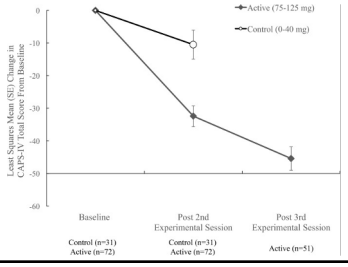
At primary endpoint

- 82% symptom improvement
- 56% no longer met PTSD criteria

At long-term follow-up

- 67% no longer met PTSD criteria

MDMA-assisted psychotherapy for PTSD



CAPS-IV total score least squared mean estimates at endpoints. The change in scores from baseline to post two experimental sessions were significantly different between MDMA and control groups (***P < 0.0001). After the third MDMA session, the active dose group showed further improvement compared to post two MDMA sessions (***P < 0.0001)

(Mithoefer et al., 2019)

The Doctors (2014)

Part 1

https://www.youtube.com/watch?v=6e0jlepgNLI

Part 2

https://www.youtube.com/watch?v=Rhhi9H8fNdc

Timeline

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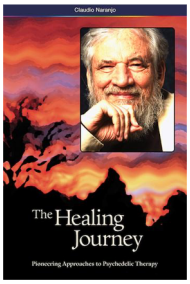
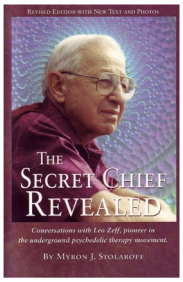




Pharmacology

How MDMA Works in the Brain and Body

Pharmacology

MDMA is a potent releaser of pre-synaptic serotonin

The subjective effects of MDMA are attenuated by the 5-HT2AR antagonist ketanserin

MDMA is a potent releaser of catecholamine neurotransmitters (i.e., epinephrine, norepinephrine, and dopamine) via action at presynaptic reuptake sites

MDMA has been shown to have dramatic effects on plasma levels of oxytocin, cortisol, and prolactin

Garcia-Romeu et al., 2016

Acute positive affective state

MDMA has been shown to increase subjective ratings in healthy volunteers in the laboratory:

- emotional excitability,
- extroversion,
- friendliness,
- loving,
- playfulness,
- thoughtfulness-contemplativeness, and
- well-being (38, 39).

Emotional impact of painful memory recall

MDMA reduces negative emotions associated with recalling least favorite autobiographical memories

Favorite memories were positive, vivid, and emotional

Worst memories were less negative, equally vivid and emotional

Positively biases cognitive empathy

MDMA reduced recognition of negative emotion faces

attenuated amygdala response to angry faces and enhanced ventral striatum response to happy faces

Increases sociability

MDMA increases prosocial feelings, fairness, and desire for social contact while decreasing sensitivity to rejection.

MDMA

Recently Completed Research

PTSD

Social Anxiety in Autistic Adults

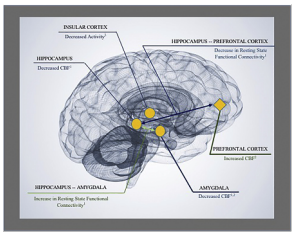
How MDMA May Assist Psychotherapy

Neuropharmacological Perspective

1. MDMA increases BDNF and excitatory neurotransmitters (acetylcholine and glutamate, enhancing **synaptic plasticity**
2. MDMA increases cortisol and (nor)epinephrine release, enhancing **memory reconsolidation and fear extinction**
3. MDMA enhances oxytocin release, promoting **prosocial behavior and empathy**

Feduccia & Mithoefer, 2018

Memory reconsolidation and fear extinction



MDMA modulates brain regions involved in learning, memory, emotion, and attention. In neuroimaging studies of healthy individuals, MDMA reduced cerebral blood flow (CBF) to amygdala and hippocampus; decreased resting state connectivity between the medial prefrontal cortex (mPFC) and hippocampus; decreased activity in the insular cortex; and increased CBF in the ventromedial prefrontal cortex.

(from Feduccia & Mithoefer, 2018)

How MDMA May Assist Psychotherapy

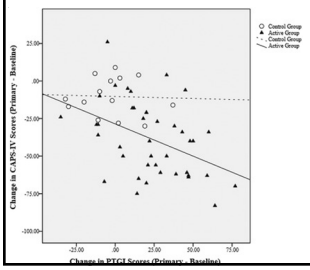
Posttraumatic Growth (PTG)

Positive psychological change experienced as a result of the struggle with highly challenging life circumstances. Five factors:

1. Relating to others
2. New possibilities
3. Personal strengths
4. Spiritual change
5. Appreciation of life

Gorman et al., 2020

Posttraumatic Growth



After two sessions, active doses of MDMA combined with psychotherapy resulted in decreased PTSD symptom severity and increased PTG (n=41; r = −.42, p = .006).

The results at long-term follow-up suggest these clinical improvements are durable, lasting at least 1 year.

(from Gorman et al., 2020)

How MDMA May Assist Psychotherapy

Perceived benefits from qualitative analysis (n=19)

Participants interviewed during long-term follow-up session one year after the end of the trial.

- 16 military veterans, 2 firefighters, 1 police officer
- 88% White, 6% Native American, 6% White and Native
- 13 men, 6 women
- 24 - 56 years old at time of interview

(Barone et al., 2019)

Perceived Benefits

Lasting Benefits Mentioned	% participants
Reduction in PTSD Symptoms	100
Enhanced Quality of Life	100
Engagement in New Activities	100
Improved Self-Awareness	100
Openness to Further Therapy	74
Reduced Problem Substance Use	68
Improved Family Relationships	63
Improved Friendships	58

I think that the MDMA gave me the ability to feel as though I was capable and safe of tackling the issues. Whereas before I feared those thoughts and I tried to avoid them at all times, and avoid things that reminded me of those thoughts, I think it allowed me to feel safe in my space. I felt like I had the ability and tools, whereas before I was unarmed, unarmored, and had no support. And this type of environment, with [the therapists], the catalyst drug, and everything else, it felt as though I had backup. Now it was safe and I had my tools and weapons to be able to tackle the obstacles that I never had before.

(Barone et al., 2019)

Phase 2 Protocol

Screening

Preparation

Treatment

Integration

Posttraumatic Stress Disorder

Six Phase 2 studies: 107 participants enrolled, 100 completers

Significant and meaningful reduction in PTSD and depression symptoms

At primary endpoint

- 82% symptom improvement
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At long-term follow-up

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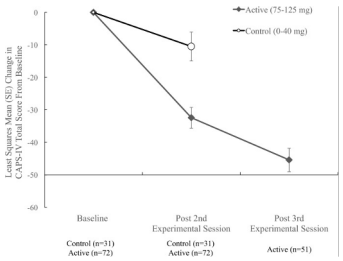

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(Mithoefer et al., 2019)

Social Anxiety in Autistic Adults

One double-blind placebo-controlled, randomized pilot study (n=11)

2 sessions with 75-125 mg MDMA (n=7) or placebo (n=4)

Significant and meaningful reduction in social anxiety at primary endpoint and 6-month follow-up

(Danforth et al., 2018)

Other MDMA-Assisted Psychotherapy Studies

Ongoing

- Therapist Training Program
- Eating Disorders
- Moderate Hepatic Impairment
- Startle Response

Completed

- Cognitive-Behavioral Conjoint Therapy (CBCT) in Dyads

Discontinued

- Anxiety Associated With a Life-threatening Illness

Study Design Overview

Phase III Clinical Trials for MDMA-Assisted Psychotherapy for PTSD

- ~ 46.5 hours total
- 24 hours with MDMA
- 0 hours with ecstasy!

Screening	Preparation	Treatment 1	Treatment 2	Treatment 3	Termination
		MDMA Session 1	**MDMA Session 2**	**MDMA Session 3**	
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Ketamine

Recent clinical research

Ketamine therapy

Ketamine-assisted psychotherapy

Recent clinical research

Ketamine-assisted psychotherapy

- Depression
- Posttraumatic stress disorder
- Suicidality

Ketamine-assisted psychotherapy

- Anxiety and depression
- Posttraumatic stress disorder
- Substance use disorder

Ketamine therapy

Intravenous (IV)

Intramuscular (IM)

Intranasal (IN)

Sublingual (SL)

oral

Ketamine-assisted psychotherapy

"ketamine promotes a time-out from ordinary, usual mind, relief from negativity, and an openness to the expansiveness of mind with access to self in the larger sense" (Dore et al., 2019)

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Mechanisms of action

Why is this therapeutic?

1. Psychedelic
2. Empathogen
3. Entheogen
4. Psychoplastogen

Mechanisms of action

Psychedelic
Empathogen
Entheogen
Psychoplastigen

To manifest the mind or to reveal the soul (Osmond, 1957)

Mechanisms of action

Psychedelic
Empathogen
Entheogen
Psychoplastigen

To generate or evoke the divine within (Ruck et al., 1979)

> "Psilocybin can occasion mystical-type experiences having substantial and sustained personal meaning and spiritual significance" (Griffiths et al., 2006)

Mechanisms of action

Psychedelic
Empathogen
Entheogen
Psychoplastigen

To generate or evoke empathy (Nichols, 1986)

- MDMA enhances oxytocin release, promoting prosocial behavior and empathy
- MDMA induces a positive shift in cognitive and affective empathy

Mechanisms of action

Psychedelic
Empathogen
Entheogen
Psychoplastigen

Capable of rapidly promoting structural and functional neural plasticity (Olson, 2018)

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Risks Associated with MDMA in Research Settings

Cardiovascular and Cerebrovascular Risks

MDMA is known to transiently increase heart rate and blood pressure

Psychological Risks

Mild anxiety and depressed mood are occasionally reported 1 to 3 days after MDMA administration

Common Adverse Events with MDMA-Assisted Psychotherapy Clinical Trials

During Experimental Sessions:

- muscle tightness in the jaw
- lack of appetite
- dizziness
- nausea

During the week following treatment:

- lack of appetite
- muscle tightness in the jaw
- restlessness
- weakness
- dry mouth
- thirst
- impaired gait/balance
- sensitivity to cold

MDMA-Medication Interactions

SSRIs and SNRIs decrease physiological and subjective effects of MDMA

Buproprion (DNRI) increases MDMA effects, may increase seizure risk

Reboxetine (SNRI) increases plasma concentrations of MDMA, may increase risk of overdose

Moclobemide and phenelzine (MAOIs) may cause serotonin syndrome, including death

Methylphenidate increases cardiovascular effects

Exclusion Criteria

1. Are not able to give adequate informed consent
2. Have used Ecstasy (material represented as containing MDMA) within 3 months of the first Experimental Session; or have previously participated in a MAPS-sponsored MDMA clinical trial
3. Have any current problem which, in the opinion of the investigator or Medical Monitor, might interfere with participation
4. In the investigator's opinion, lack a stable living situation or supportive family/network
5. Have received Electroconvulsive Therapy (ECT) within 12 weeks of enrollment
6. Have evidence or history of significant medical and psychiatric disorders
7. Any patient presenting current serious suicide risk
8. Would present a serious risk to others as established through clinical interview and contact with treating psychiatrist
9. Require ongoing concomitant therapy with a psychiatric medication
10. Have evidence or history of significant hematological, endocrine, cerebrovascular, cardiovascular, coronary, pulmonary, renal, gastrointestinal, immunocompromising, or neurological disease, including seizure disorder, or any other medical disorder judged by the investigator to significantly increase the risk of MDMA
11. **Have a history of ventricular arrhythmia, other than occasional PVCs in the absence of ischemic heart disease, at any time or with a history of supraventricular arrhythmia within the past year**
12. **Have uncontrolled hypertension using the standard criteria of the American Heart Association (values of 140/90 milligrams of Mercury [mmHg] or higher assessed on three separate occasions)**
13. **Have a marked baseline prolongation of QT/QTc interval (e.g., repeated demonstration of a QTc interval >450 milliseconds [ms] corrected by Bazett's formula)**
14. **Have a history of additional risk factors for Torsade de pointes (e.g., heart failure, hypokalemia, family history of Long QT Syndrome)**
15. **Require use of concomitant medications that prolong the QT/QTc interval during Experimental Sessions**
16. Have symptomatic liver disease or have significant liver enzyme elevation
17. Have a history of HCV that has not been evaluated and treated successfully if treatment is indicated
18. Have history of hyponatremia or hyperthermia
19. Are pregnant or able to bear children and are not practicing an effective means of birth control
20. Are breastfeeding (unless willing to dispose of breastmilk from dosing through 84 hours after each Experimental Session)

Generalizability?

11% of phase 2 participants were people of color

Unknown % LGBTQ or gender nonconforming participants

Ethical Concerns

Access and Equity

Sexual Trauma

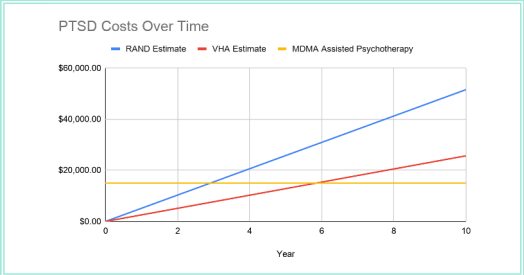
Costs

MAPS estimates a 3-month course of MDMA-assisted psychotherapy might cost about **$15,000 per person** (around $250-350/hour).

RAND estimated total societal costs of veterans with PTSD, which included not only direct treatment but also indirect societal costs such as unemployment and suicide. The researchers found that the costs of PTSD ranged from $5,900 to $10,300 **for two years** (in 2005 dollars; **$7,745 to $13,521** in 2020 dollars).

A VHA study found the average cost of VHA treatment for veterans with PTSD **over four years** was $12,500, compared to the average cost of treatment for veterans without PTSD over four years was $3,500 (difference of $9,000 in 2011 dollars, or **$10,258** in 2020 dollars).

CBO. 2010. The Veterans Health Administration's Treatment of PTSD and Traumatic Brain Injury Among Recent Combat Veterans.



Research Limitations

Original Papers

Psychopharmacology

Human hallucinogen research: guidelines for safety

MW Johnson, WA Richards, RR Griffiths

Abstract

Introduction

Guidelines for safety

- Selection of volunteers
- Study personnel
- Physical environment
- Preparation of volunteers
- Conduct of hallucinogen administration sessions
- Post-session procedures

Generalizability of the research?

18 Psychedelic-assisted psychotherapy studies (total n=282)

- 82% White
- 5% Indigenous
- 5% Mixed
- 3% Black
- 2% Latinx
- 2% Asian
- 2% "Other"

Gender identity and sexual orientation representation:

?

Sexual Trauma and Power

Research has found that more than 90 percent of people have more sexual desire on MDMA, with many women experiencing enhanced vaginal lubrication, said Matthew Johnson, professor of psychiatry and behavioral sciences at the Johns Hopkins University School of Medicine.

https://www.vice.com/en_us/article/939xma/why-mdma-sex-feels-so-good

Though extremely rare, there have been incidents in which a psychiatrist delivering psychedelic psychotherapy sexually abused several patients. The loving and trusting feelings that can be induced by MDMA can make patients more vulnerable to sexual pressure.

Rick Doblin, 2000

Power and Abuse

People who seek MDMA-assisted psychotherapy are vulnerable

People who provide MDMA-assisted psychotherapy have power

At least two MDMA-assisted psychotherapy researchers have committed sexual ethical violations,

MAPS uses two therapists of different genders for each client session. This is specifcally to reduce the likelihood ot sexual abuse by a therapist.