

# **2019 Submission - Royal Commission into Victoria's Mental Health System**

## **Organisation Name**

N/A

## **Name**

Mr Tim Fraser

### **What are your suggestions to improve the Victorian community's understanding of mental illness and reduce stigma and discrimination?**

"A documentary series along the lines of Employable Me for mental health conditions, education throughout high schools on a diverse range of mental health conditions, more workplace initiatives that encourage open dialogue about mental health (something more in-depth and considered than RUOK day), and more discussion of alcohol & drug dependency that acknowledges that drug use is frequently non-harmful and potentially beneficial to mental health (to develop a more nuanced understanding of why problematic use develops i.e. self-medication for trauma, social/economic conditions, etc)."

### **What is already working well and what can be done better to prevent mental illness and to support people to get early treatment and support?**

"Public dialogue has sufficiently shifted and it is much easier to talk about mental health. Workplaces need to be much more open however, as mental health significantly impacts on workplace performance and seeking help can be complicated by work requirements and culture."

### **What is already working well and what can be done better to prevent suicide?**

Support lines and greater honesty about mental illness. What needs to improve is the provision of intensive support during acute periods of illness.

### **What makes it hard for people to experience good mental health and what can be done to improve this? This may include how people find, access and experience mental health treatment and support and how services link with each other.**

"Stigma, lack of understanding from health professionals, lack of dedicated resources to support mental illness (e.g. adequate funding for treatment) and a lack of efficacious treatments. The public conversation around mental health needs to continue and deepen. Health professionals, particularly GPs, need further training and mentorship, as well as an understanding of the range of treatments available beyond prescription medicine. Greater funding for therapeutic options and workplace support (i.e. EAPs). A willingness to explore, fund and recommend alternative treatments (i.e. CBT/talk therapy not the default recommendation from GPs)."

### **What are the drivers behind some communities in Victoria experiencing poorer mental health outcomes and what needs to be done to address this?**

Social justice issues that need to be acknowledged so that discussions of solutions broaden to a truly biopsychosocial model.

### **What are the needs of family members and carers and what can be done better to support them?**

N/A

**What can be done to attract, retain and better support the mental health workforce, including peer support workers?**

"More places for psychology training at universities. Further financial support for postgraduate mental health (i.e. psychology, social work, etc) students."

**What are the opportunities in the Victorian community for people living with mental illness to improve their social and economic participation, and what needs to be done to realise these opportunities?**

Supported employment through specialised social enterprises and not-for-profits. Community groups tailoring to their needs. Greater funding and organisational support for all of these.

**Thinking about what Victorias mental health system should ideally look like, tell us what areas and reform ideas you would like the Royal Commission to prioritise for change?**

"Funding research into alternative treatments, as current treatment models are insufficiently effective."

**What can be done now to prepare for changes to Victorias mental health system and support improvements to last?**

Funding. It's always going to be helped by more funding.

**Is there anything else you would like to share with the Royal Commission?**

"One way or another, I would very much like to see the Royal Commission recommend exploring alternative and promising emerging treatments, particularly the potential of using psychedelics to treat mental health conditions. Having spent years in the mental health care system and working, speaking and commiserating with many others who work or are a patient within it, I have come to the conclusion that talk therapy and antidepressants are highly ineffective for a large plurality - if not a majority - of people who engage with the mental health care system. Research from studies in the US, UK and elsewhere have indicated that psychedelics such as psilocybin, ayahuasca and MDMA may have immense potential in treating a range of mental health conditions, including mood, anxiety, and dependence disorders. Research is now beginning in Australia, with the St Vincent's trial of psilocybin for end of life anxiety+depression now underway and further research soon to be announced. The data from overseas trials is so promising that the Food and Drug Administration in the US has designated both psilocybin for anxiety+depression and MDMA for PTSD 'breakthrough therapy' status and trials are only a couple of years away from changing their scheduled status to legal medicines. Australia has some of the poorest mental health in the world, with 45% of Australians experiencing a mental illness in their lifetime. While I can understand the terms of reference for this inquiry may limit the commission's ability to recommend action in this area, I would implore that the commission considers the evidence included in my and others' submissions, as well as initiating its own research into the topic, so that it may best consider how it can use the power of its recommendations to influence change in this area. As an ongoing patient, a carer, a mental health support worker, and an advocate, I deeply hope you will consider this request and thank you for your efforts in doing so."



## Posttraumatic Stress Disorder (PTSD)

Our studies have shown that MDMA-assisted psychotherapy can help people overcome debilitating PTSD caused by sexual assault, war, violent crime, and other traumas.



## End-of-Life Anxiety

Our recently completed study of LSD-assisted psychotherapy in Switzerland was the first study of LSD in humans in over 35 years.



## Social Anxiety in Autistic Adults

We are conducting first-time research into MDMA-assisted therapy for the treatment of social anxiety in autistic adults.



## Drug Addiction Treatment

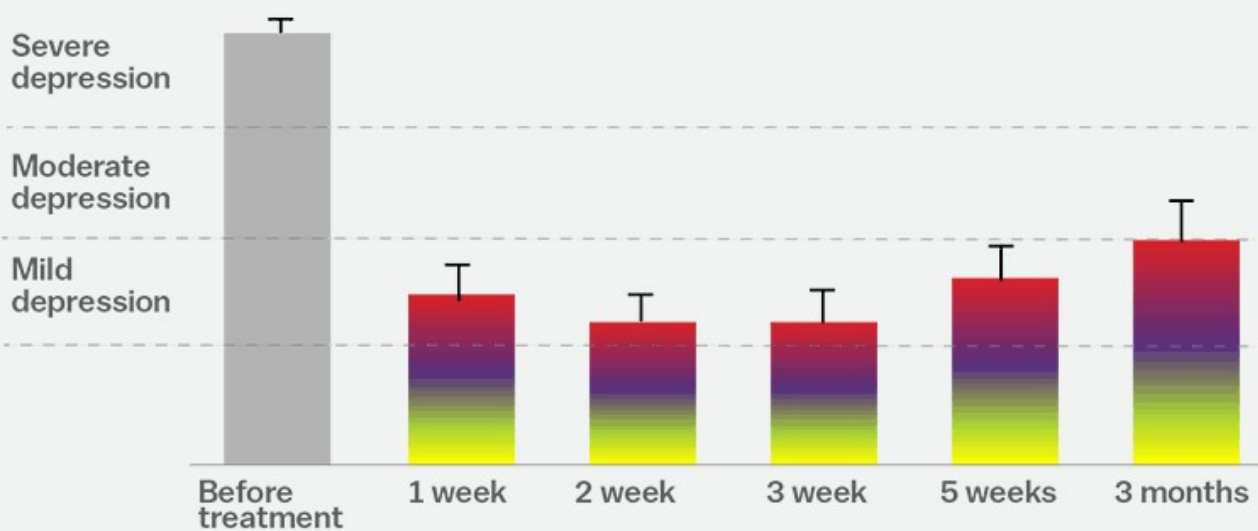
MAPS investigates treatments for opiate dependence using ibogaine, and supports research on ayahuasca-assisted therapy for substance abuse and dependence.



## Medical Marijuana

MAPS is the only organization working to demonstrate the safety and efficacy of whole-plant marijuana to develop it into an FDA-approved prescription medicine.

## Depression decreases after psilocybin treatment



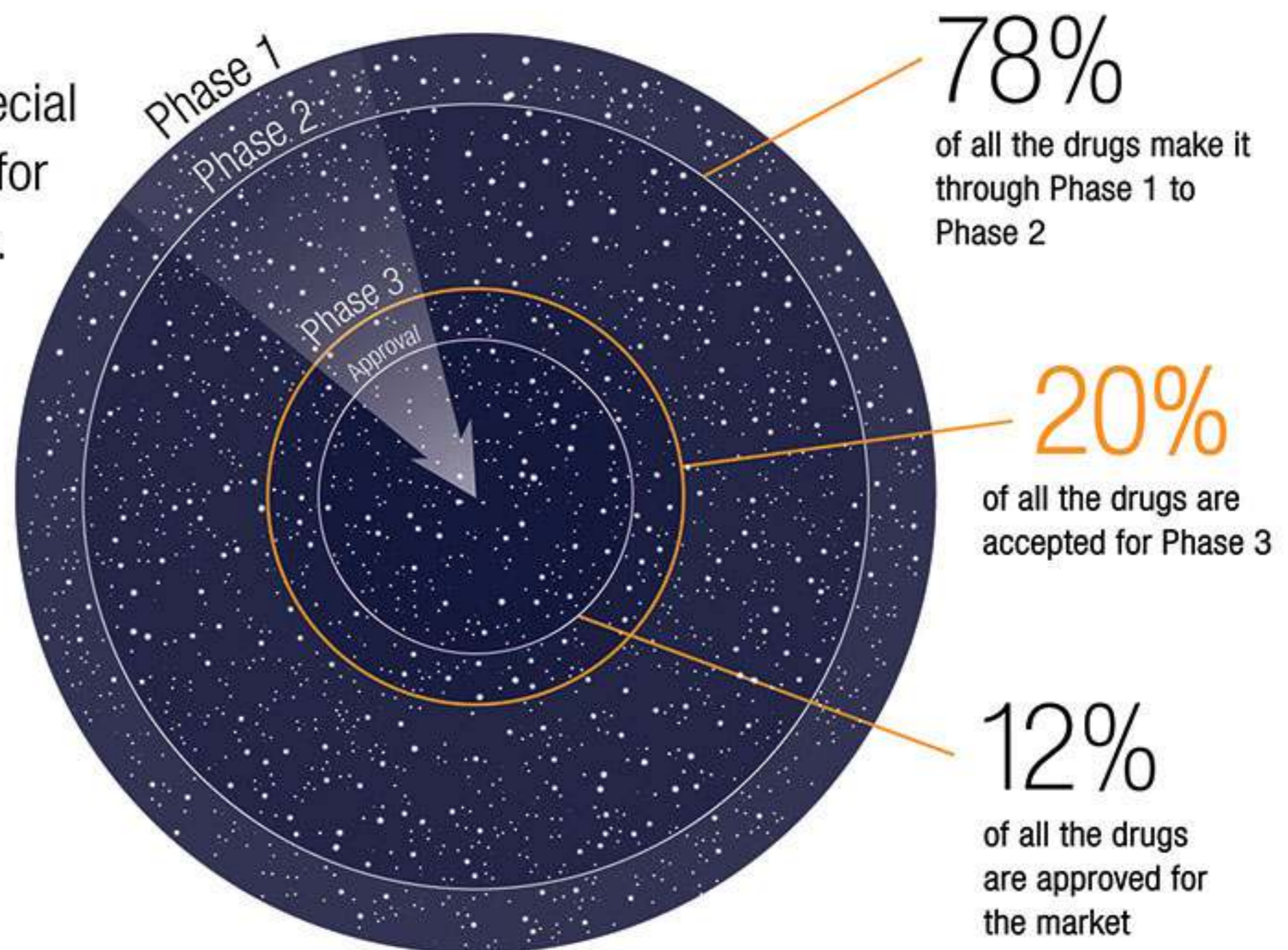
SOURCE: The Lancet

**Vox**

# The Universe of FDA Drug Approval

On July 28, 2017, MAPS and the FDA reached agreement on the Special Protocol Assessment for **Phase 3** clinical trials.

The chart depicts all studies that have entered the FDA drug approval process as represented by stars. Studies are placed according to how much of the approval process they completed. This means that all stars in the outer layer represent studies that did not advance after the Phase 1 trials. Stars in the inner layer represent drugs that have been approved by the FDA for the market.

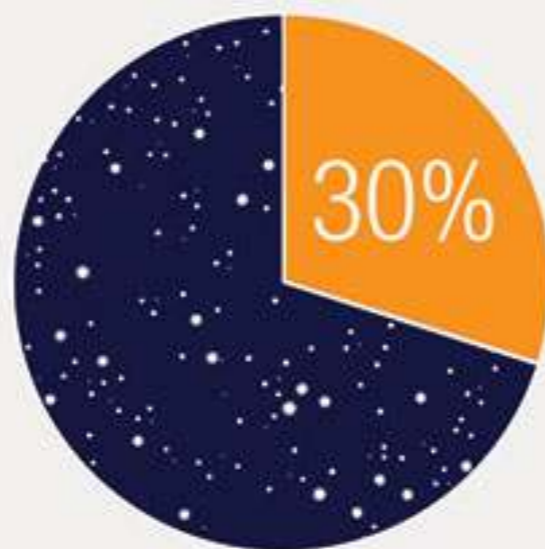


Source: Wong CH, Shaw K., Lo A. (2018) Estimation of clinical trial success rates and related parameters. Biostatistics (prepublished). Numbers from 2000 to 2015, with oncology excluded.

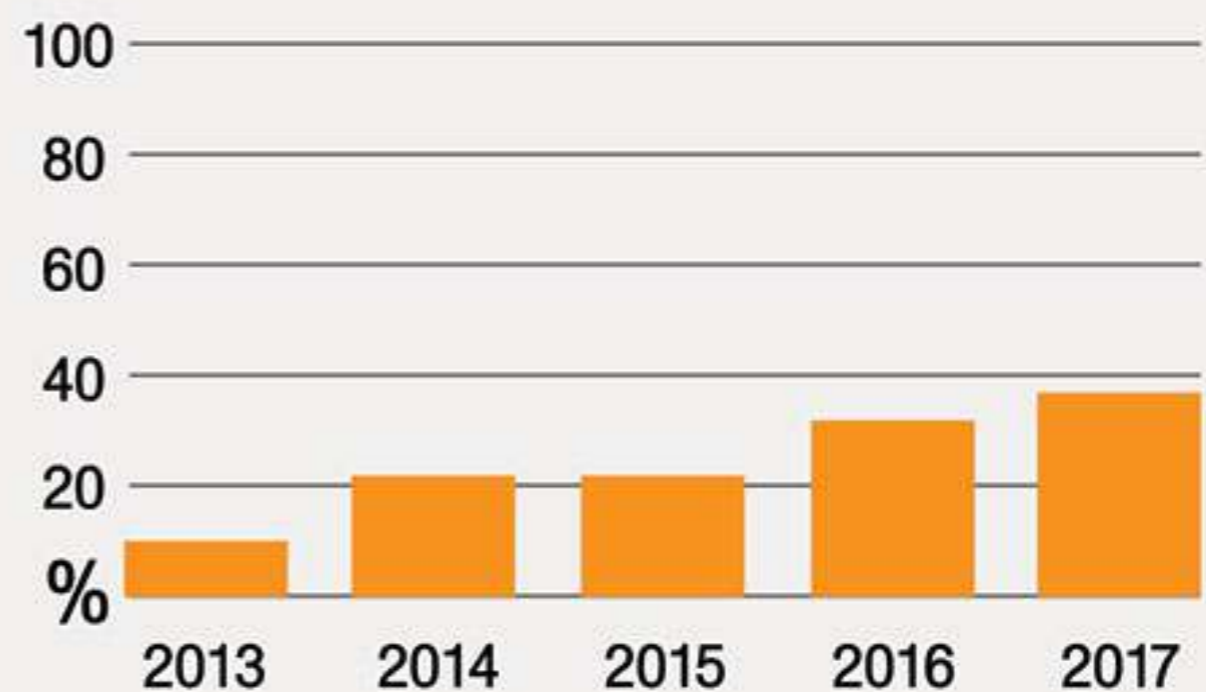
## BREAKTHROUGH THERAPY DESIGNATION (BTD)

On August 16, 2017, the FDA granted Breakthrough Therapy Designation to MDMA-assisted psychotherapy for PTSD.

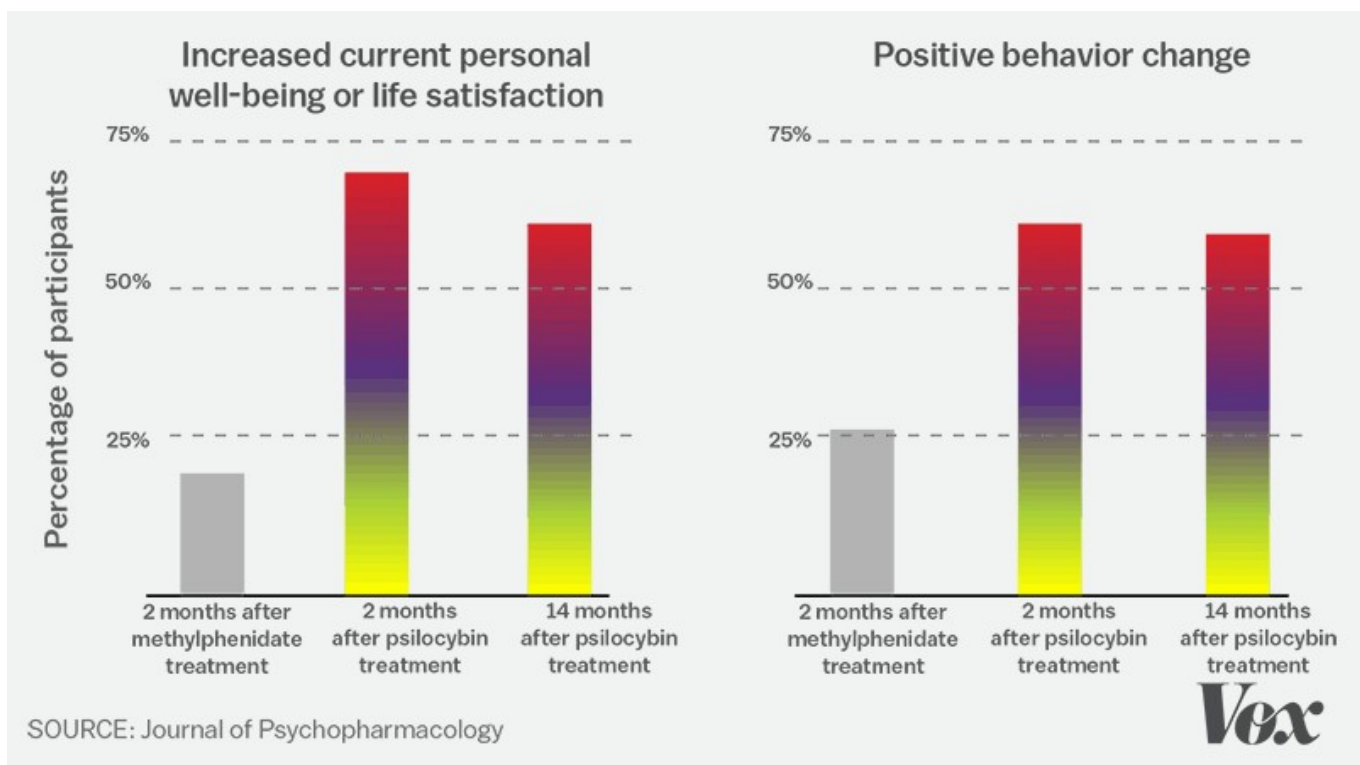
approximately 30% of the requests for BTD are granted by the FDA

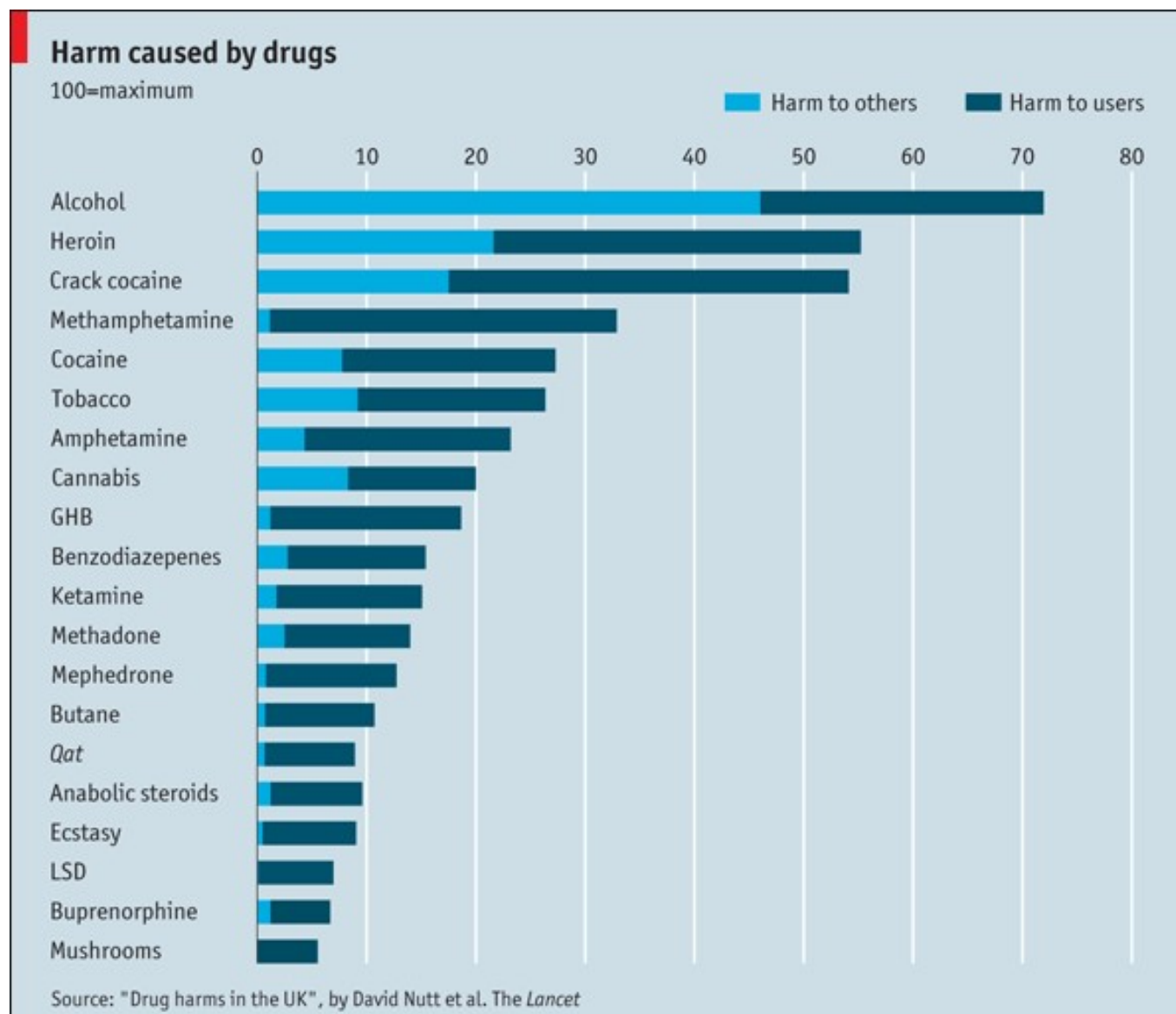


The BTD program was launched in 2012. The chart below shows the percentage of novel drugs designated as Breakthrough Therapies for each year.

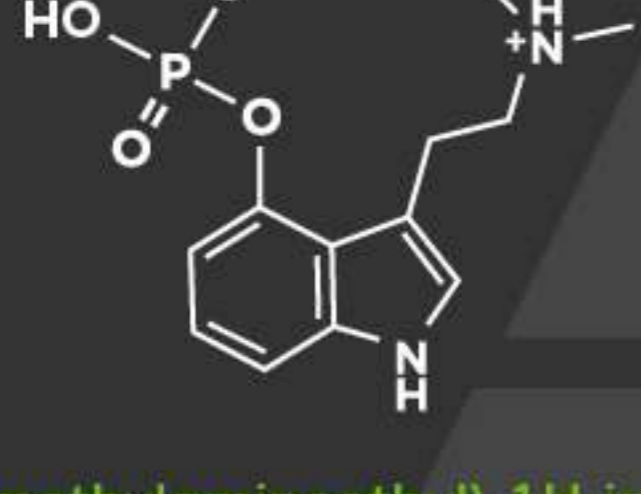


Source: FDA.gov novel drugs summaries for the years 2013-2017

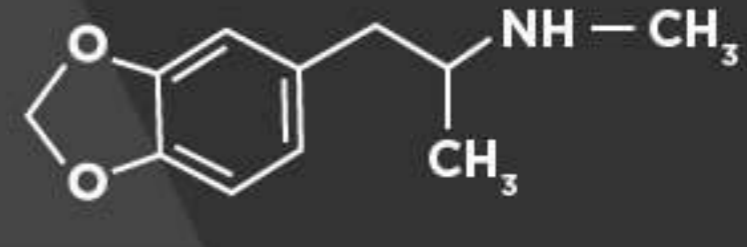
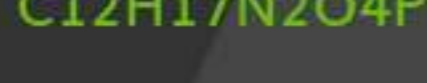




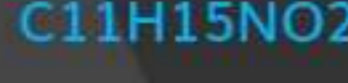
# PSILOCYBIN VS MDMA



[3-(2-Dimethylaminoethyl)-1H-indol-4-yl] dihydrogen phosphate



3,4-Methylenedioxymethamphetamine



**MDMA**, because of its uncanny ability to foster feelings of security and well-being combined with acute focus creates an ideal state for exploring traumatic events in the past. When the overarching feeling is 'safety', the mind is comfortable to explore, reprogram and heal trauma that may be quarantined in the deep recesses of the brain.

**Psilocybin** diverts cognitive priority from fear and survival based mechanisms to more conscious thought patterns, facilitating new ways to look at problems and reprogram mental disease. It can be an incredibly spiritual experience, often offering a different perspective on death and the nature of life itself.

## CANDIDATES

### 1 IN 5 MOOD DISORDERS

One in five of us will develop a mood disorder. By 2020, depression will rank second in morbidity among all illnesses worldwide. Tragically, suicide, often triggered by a mood disorder, takes roughly a million lives worldwide every year.

### 40 MILLION ADDICTION

Addiction is America's most neglected disease. According to a Columbia University study, "40 million Americans age 12 and over meet the clinical criteria for addiction involving nicotine, alcohol or other drugs." That's more Americans than those with heart disease, diabetes or cancer.

### 500,000 VETERANS AND FIRST RESPONDERS

who served in Iraq or Afghanistan suffer from PTSD

### 8.3 MILLION PSYCHOLOGICAL DISTRESS

American adults — about 3.4 percent of the U.S. population, suffer from serious psychological distress, an evaluation of federal health data concluded.

### 70% OF U.S. ADULTS TRAUMATIC EVENT

at least once in their lives. This equates to approximately

223.4 MILLION PEOPLE

## TRIAL RESULTS

### PSILOCYBIN-ASSISTED PSYCHOTHERAPY

### MDMA-ASSISTED PSYCHOTHERAPY

#### 1 SINGLE DOSE CURED

Flexible dose of .3-.4 mg per kg

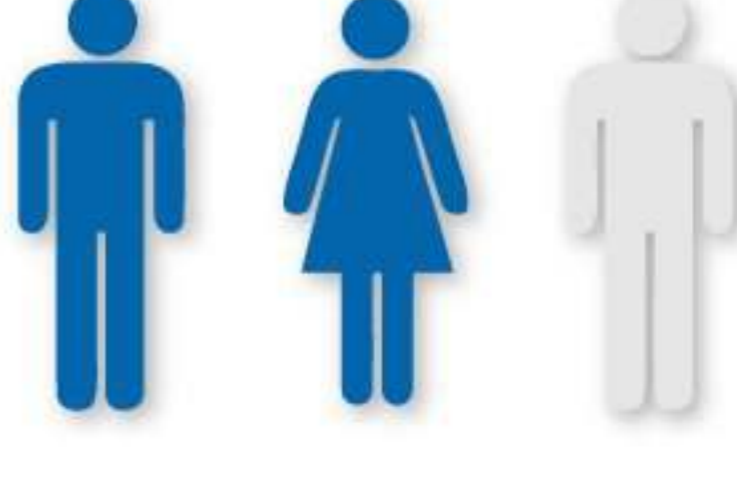


OF DEPRESSION AND ANXIETY IN THE PATIENTS STUDIED

n=92

#### 3 SESSIONS CURED PTSD

Flexible dose of 75-187.5 mg



AND CONTINUED TO REDUCE IT FOR YEARS LATER

n=107

#### PSILOCYBIN-FACILITATED SMOKING CESSATION

Flexible dose of .29mg-.43mg per kg



At six months, 80% of the participants were still abstinent.

n=15

#### SURVEYED 100 AUTISTIC ADULTS WHO HAD EXPERIENCED MDMA



72% of MDMA experienced individuals reported being "more comfortable in social settings".



12% indicated that these effects lasted for TWO OR MORE YEARS

n=150

## ECONOMIC IMPACT



ANXIETY DISORDERS ALONE HAVE AN ANNUAL COST OF

\$42.3 BILLION

PTSD IS THE MOST COSTLY

By enabling veterans to get off disability and return to work, this treatment could reduce the need for VA services, improve wait times, and reduce reliance on Social Security.

## WHAT DOES IT FEEL LIKE?

### THE SUBJECTIVE EFFECTS OF PSILOCYBIN

Psilocybin is a molecule that fits into the serotonin receptors in the brain, and diverts cognitive priority to areas associated with higher thought processes.

- New perspective on emotional experiences
- Increased introspection
- Synaesthesia (mixing sensory modalities)
- Altered sense of time
- Heightened feelings of connectedness

### THE SUBJECTIVE EFFECTS OF MDMA

MDMA affects the brain by increasing activity levels of three different neurotransmitters: dopamine, norepinephrine (noradrenaline), and serotonin.

- Increased empathy and compassion
- Enhanced communication and introspection
- Reduced feelings of fear
- Increased feelings of well-being
- Increased interpersonal trust
- Alert state of consciousness

### SUPPORTING PSYCHEDELIC MEDICINE IS SUPPORTING FULL LEGALIZATION

All of the current clinical trials are testing psychedelic medicine in controlled settings, with skilled practitioners present. Should psilocybin or MDMA become legal for medicinal use it will remain under these controlled conditions.

## MYTHS

### SHROOMS ARE POISONOUS

It's important to differentiate mushroom poisoning from non-hallucinogenic species and "intoxication" with hallucinogenic species. 'Magic' mushrooms and the active ingredient psilocybin is not toxic and cause no known major adverse effects.

### SHROOMS MAKE YOU GO INSANE

There is no conclusive evidence suggesting that latent mental health problems can be exacerbated by psychedelic use in a controlled setting. However people with mental health problems should refrain from recreational psychedelic use in the absence of a skilled medical practitioner.

### MDMA IS THE SAME AS "ECSTASY" OR "MOLLY."

Substances sold on the street under these names may contain MDMA, but frequently also contain unknown and/or dangerous adulterants. These adulterants and substitute chemicals can be dangerous and as such, recreational use of "MDMA" contains inherent risk.

### ECSTASY EATS AWAY AT YOUR BRAIN

There is no clinical evidence that moderate use of MDMA can cause damage to your brain. Frequent, high dose use can cause heart problems and memory problems. Early studies to the contrary have subsequently been retracted, as MDMA was accidentally mislabeled as the amphetamine tested.

M. Thompson, "Unlocking the secrets of PTSD," Time, vol. 185, no. 12, pp. 40-3, Apr. 2015.

National Center on Addiction and Substance Abuse at Columbia University, "Addiction: A Preventable and Treatable Disease," New York, New York, USA, 2013.

J. Weissman, D. Russell, M. Jay, J. M. Beasley, D. Malaspina, and C. Pegus, "Disparities In Health Care Utilization and Functional Limitations Among Adults With Serious Psychological Distress, 2006-2014," J. Psychiatr. Serv., p. appi.ps.2016002, 2017.

Stanford Mood Disorders Center, "Pioneering Solutions for Depression and Bipolar Disorder," 2017, [Online]. Available: <http://med.stanford.edu/mooddisorders.html>.

World Health Organization, "Suicide Data," 2017, [Online]. Available: [http://www.who.int/mental\\_health/prevention/suicide/suicideprevent/en/](http://www.who.int/mental_health/prevention/suicide/suicideprevent/en/).

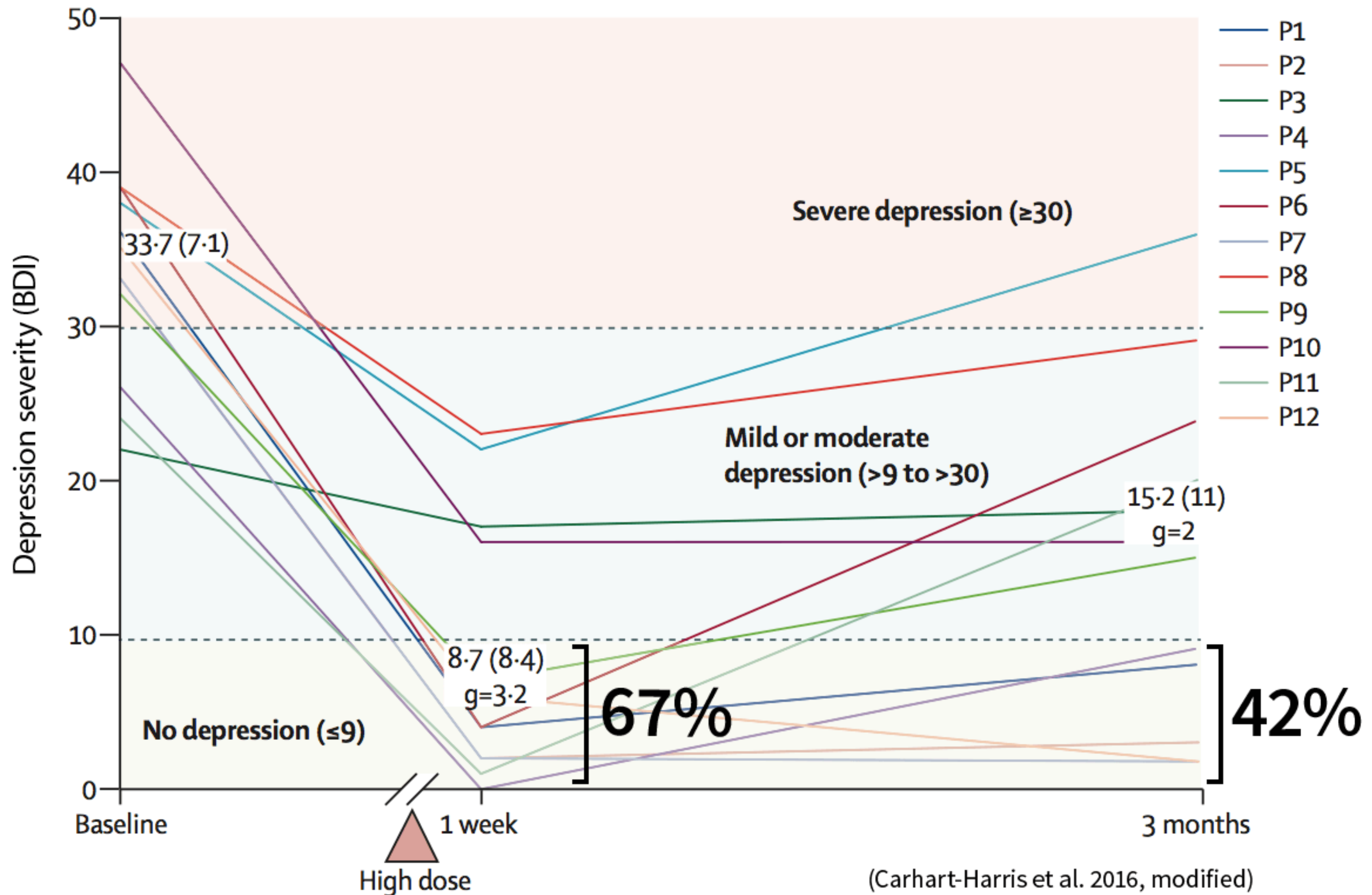
B. Burge, "PRESS RELEASE: FDA Grants Breakthrough Therapy Designation for MDMA-Assisted Psychotherapy for PTSD, Agrees on Special Protocol Assessment for Phase 3 Trials," Maps, 2017, [Online]. Available: <http://www.maps.org/news/media/6786-press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd,-agrees-on-special-protocol-assessment-for-phase-3-trials>.

A. Danforth, "Courage, Connection, And Clarity: A Mixed-Methods Collective-Case Study Of Mdma (Ecstasy) Experiences Of Autistic Adults," Sofia University, 2013.

R. R. Griffiths et al., "Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial," J. Psychopharmacol., vol. 30, no. 12, pp. 1181-1197, Dec. 2016

M. W. Johnson, A. Garcia-Romeu, M. P. Cosimano, and R. R. Griffiths, "Pilot study of the 5-HT 2A R agonist psilocybin in the treatment of tobacco addiction," J. Psychopharmacol., vol. 28, no.11, pp. 983-992, Nov. 2014.

PTSD United, "PTSD Statistics," 2013, [Online]. Available: <http://www.ptsdunited.org/ptsd-statistics-2/>.



# TREATING PTSD WITH MDMA-ASSISTED PSYCHOTHERAPY

Posttraumatic Stress Disorder (PTSD) is a widespread and devastating illness for which we urgently need more effective treatments. **Could non-profit research offer hope?** The controlled use of MDMA in a psychotherapeutic setting is an important step in the treatment of PTSD.

## What is PTSD?

Posttraumatic Stress Disorder (PTSD) can be a chronic, devastating illness that severely impacts quality of life. Sufferers often struggle to maintain healthy lives and relationships.



PTSD involves changes in the brain. Patients have decreased activity in the **hippocampus** and **prefrontal cortex** (areas associated with memory and learning) and increased activity in the **amygdala** (associated with fear).



**1 in 7** U.S. service members returning from Iraq and Afghanistan suffers from PTSD.

PTSD can be caused by:



war



sexual assault



childhood abuse



torture



accidents



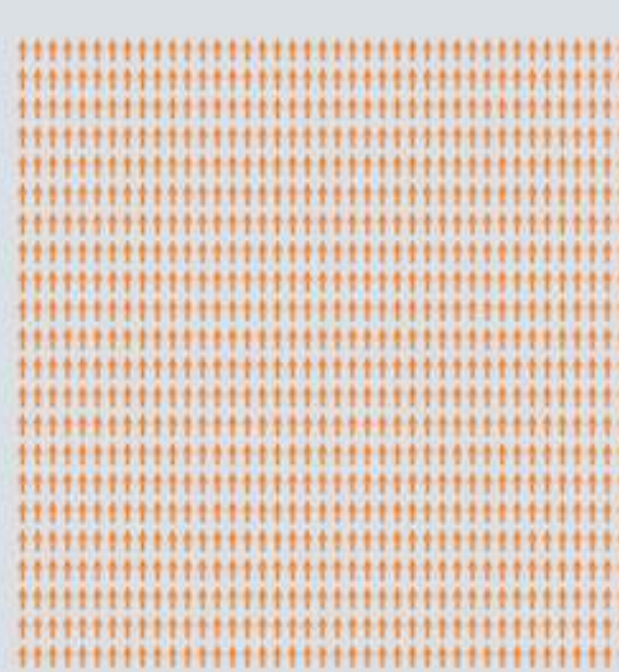
other stressful events

## What is MDMA-Assisted Psychotherapy?

A treatment that combines psychotherapy with the administration of MDMA, which catalyzes the therapeutic process.



**MDMA is not Ecstasy.** Substances sold illegally under the name "Ecstasy" often do not contain MDMA and sometimes contain harmful adulterants.



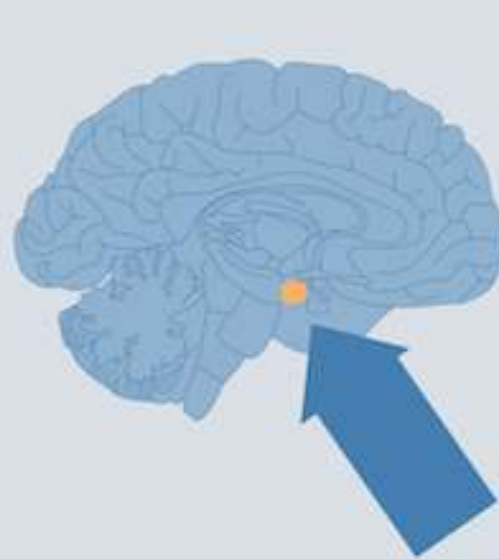
No drug is without risks. MDMA has been administered to over **780 human subjects in clinical studies** with only one serious adverse event.



MDMA is a synthetic compound that decreases **fear and defensiveness** while increasing **trust and empathy**, making it easier for patients to be comfortable between the extremes of fear and avoidance.



MDMA increases the release of **oxytocin and prolactin** (hormones associated with trust and bonding), allowing patients to discuss their memories openly.



MDMA significantly **decreases activity in the left amygdala**, associated with fear and traumatic memory. It may also **increase interpersonal trust** without inhibiting access to emotions or senses.



MDMA is not the therapy in itself, but a **tool for the therapist and patient**.

## How does MDMA-Assisted Psychotherapy work?

MDMA can make it easier for people with chronic, treatment-resistant PTSD to confront their traumatic memories.

Both FDA-approved PTSD treatments require patients to take drugs daily **for years or even the rest of their lives**. But **MDMA is only administered a few times**.

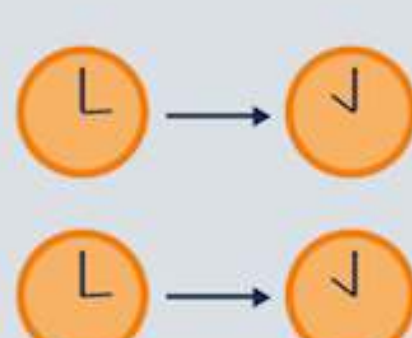


## Current Results

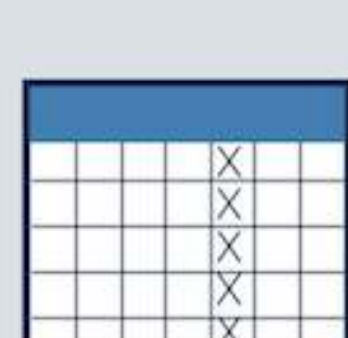
In a study of the efficacy of MDMA-assisted psychotherapy for treating PTSD:



subjects were given either **MDMA** or **placebo**



during 2 **8-hour sessions**, **3-5 weeks** apart



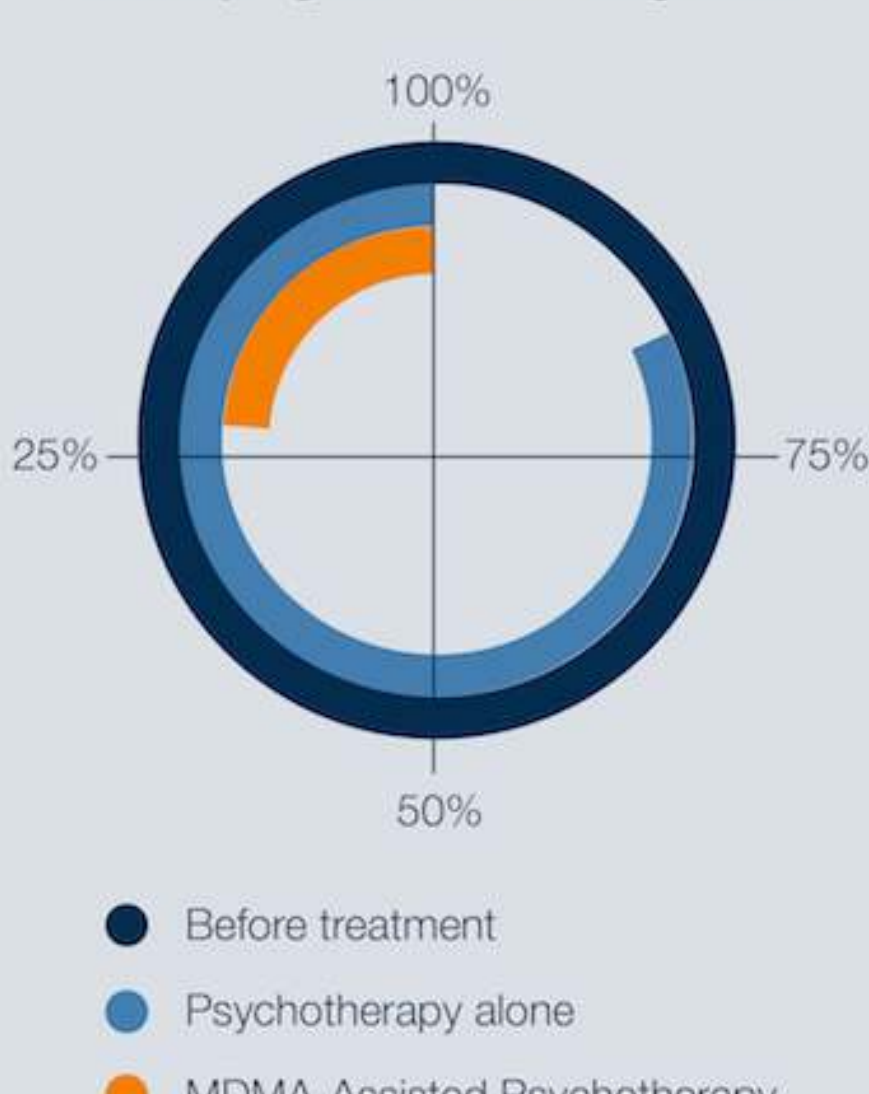
along with **weekly** non-drug psychotherapy sessions



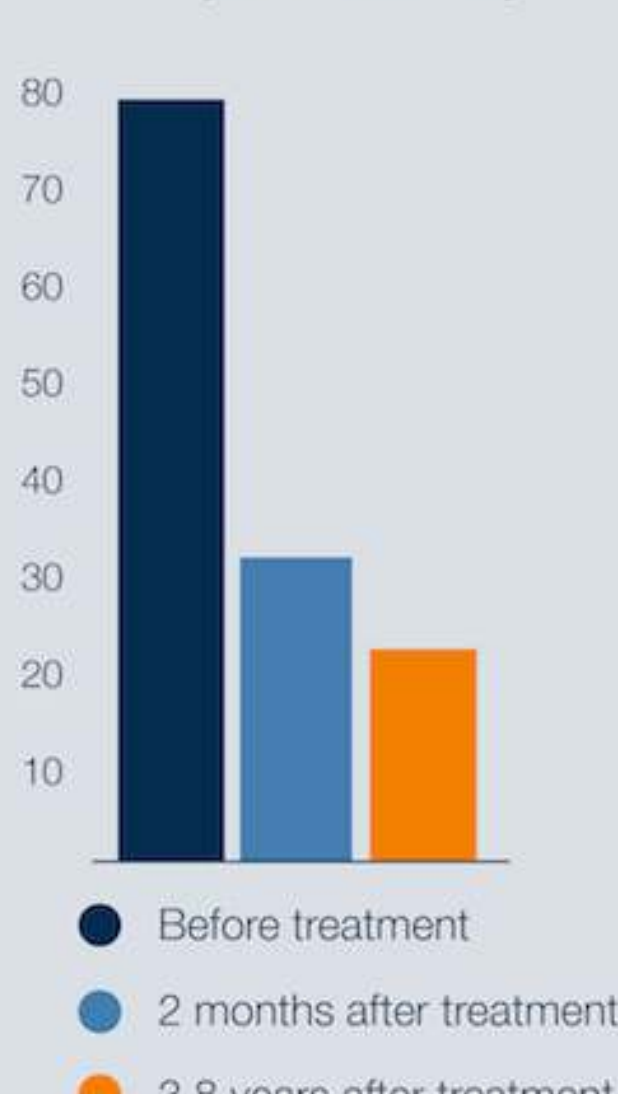
**83% of participants** were no longer diagnosed with PTSD at the 2-month follow-up.

Even more importantly, a long-term follow-up conducted a mean of 3.8 years later showed that the **benefits were (on average) maintained over time**.

Percent of Subjects Qualifying for PTSD Diagnosis



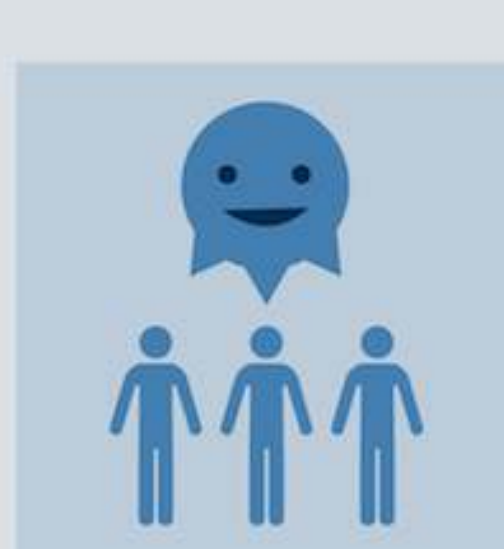
Severity of PTSD Symptoms (CAPS Score)



All subjects reported at least some persisting benefit from the study



Study found no negative effects on cognitive function associated with MDMA use



Many participants said the treatment gave them a new start on life

**The results show** long-lasting, clinically meaningful benefits and absence of harm from just a few MDMA-Assisted Psychotherapy sessions for PTSD.

Additional clinical trials are being planned or conducted around the world.

For more information and to help make this treatment available for people suffering from PTSD, visit:

# MDMAPTSD.ORG

The Multidisciplinary Association for Psychedelic Studies (MAPS) is a **501(c)(3) non-profit** research organization working to develop MDMA-Assisted Psychotherapy into an FDA-approved prescription treatment.