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Nordic Reform Conference – Oslo, Norway
20th September 2019

Using
MDMA-Assisted
Psychotherapy
to treat
Alcohol
Addiction

DID YOU KNOW?



#EndTheDrugWar

THERE IS A STRONGER LINK BETWEEN CHILDHOOD TRAUMA AND ADDICTION, THEN THERE IS BETWEEN OBESITY AND DIABETES. TWO THIRDS OF ADDICTS REPORT BEING ABUSED AS CHILDREN. THAT MEANS THAT THE WAR ON DRUGS IS A WAR ON TRAUMATIZED PEOPLE THAT JUST NEED HELP.

Child Abuse, Trauma and Psychosocial Stressors

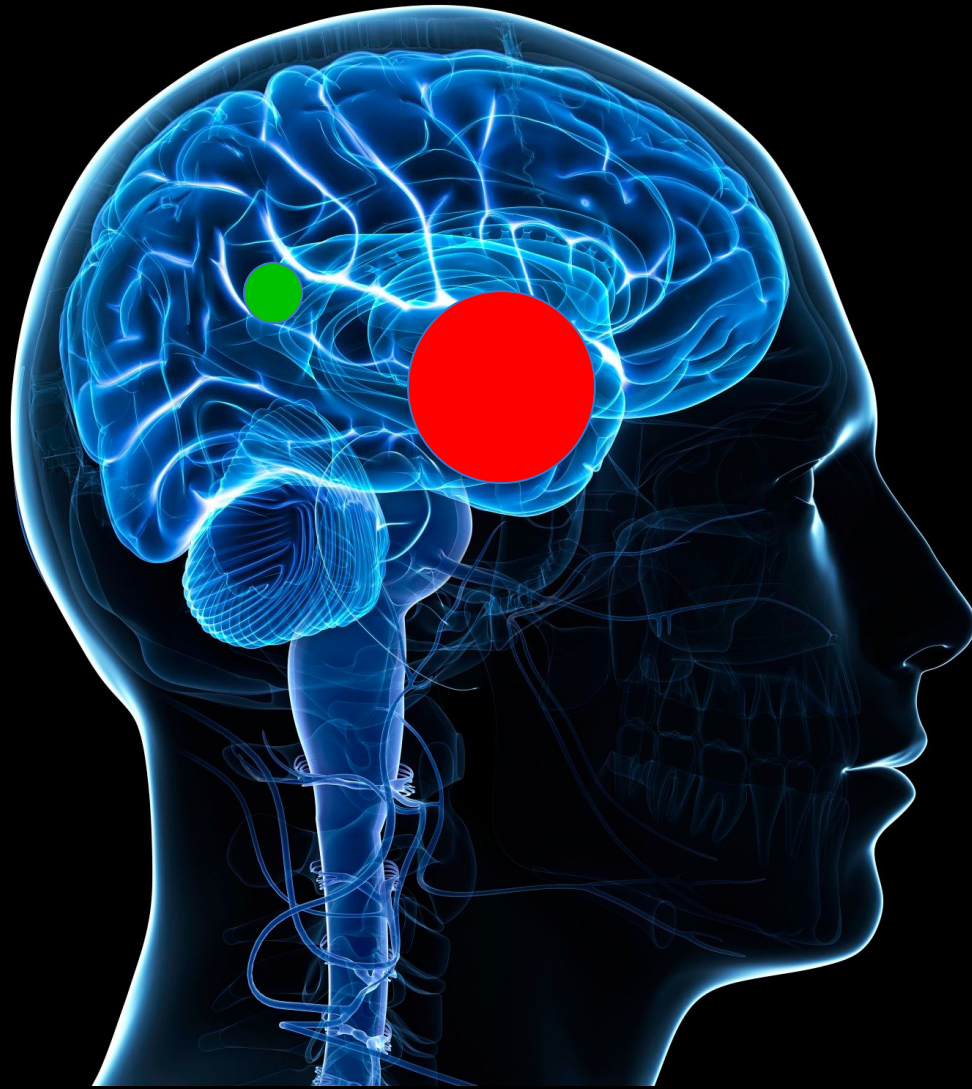


- Parental criminality
- Parental mental illness
- Domestic Violence
- Parental Substance Misuse
- Unemployment
- Poor housing
- Race and social exclusion
- Poor education



Fear, Trauma and the Developing Brain:

The Prefrontal Cortex versus **The Amygdala**



Childhood
Trauma

Identity Formation

INSECURE
Attachment

```
graph TD; A[INSECURE Attachment] --> B[Self Narrative]; A --> C[World Narrative];
```

Self Narrative:

“I’m a bad person”
“I cannot achieve”
“I am unlovable”

World Narrative:

“Trust no one”
“The world is dangerous”
“People will hurt me”

Identity Formation

INSECURE

Attachment

Block out the world with
sedating substances

The Burden of Childhood Trauma



- Polypharmacy
- Poly-psychotherapies
- High rates of self-harm and suicide
- **50% treatment resistance**
- **High rates of substance misuse and addiction**

The Clinical, Social and Financial Burden of Alcohol Dependence

- **One quarter** of adults consume alcohol harmfully.
- 6% of men and 2% of women are **dependent**.
- Self-medication for **Undiagnosed PTSD**.
- Costs around £20 billion a year in England alone.
- **'The UK's drinks industry is the US's N.R.A.'**



How well is modern psychiatry doing to manage alcohol use disorder?

How well is modern psychiatry doing to manage alcohol use disorder?

Roughly 90% of people will relapse within 4 years after completing treatment.

□ National Institute on Alcohol Abuse and Alcoholism. (1989). *Relapse and Craving*.

The Bristol Alcohol Treatments **OUTCOMES STUDY:** Eleven patients

Screen before detox



Detox



Treatment as usual

(Rehab, Group Therapy, Individual Therapy, AA, SMART
Groups etc.)



Outcomes Follow-Up at:

3-months

6-months

9-months

PARTICIPANT NUMBER:	RELAPSE OF ALCOHOL USE DIORDER AT NINE-MONTHS POST DETOX
T01	No
T02	Yes
T03	Yes
T04	Yes
T05	No
T06	Yes
T07	Yes
T08	No
T09	Yes
T10	Yes
T11	Yes

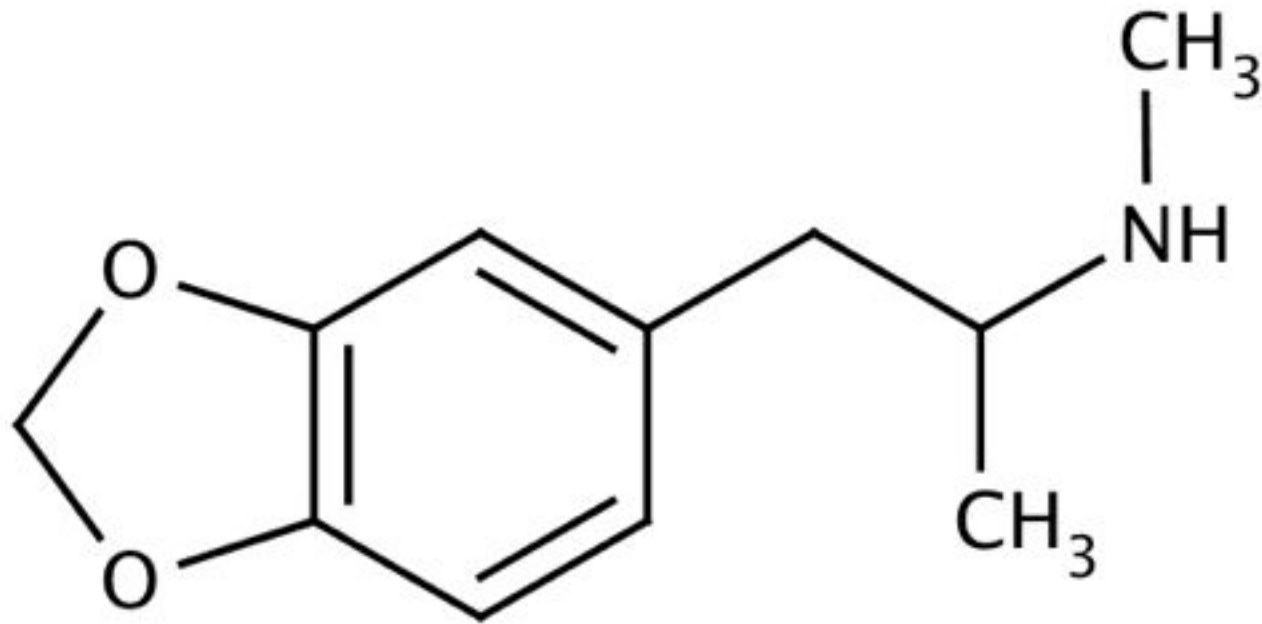


After 100 years
of modern
Psychiatry

**This is not
good enough!**

**So where are
we going
wrong?**

MDMA



Could MDMA Treat Alcohol Dependence?



- Non-specific adjunct / to enhance the psychotherapeutic relationship?
- Peak experience / personality change?
- Spiritual Experience?
- Trauma
- Empathy

3,4 Methylendioxyamphetamine (MDMA)

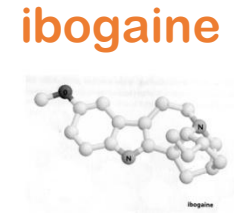
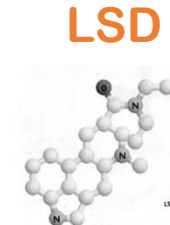
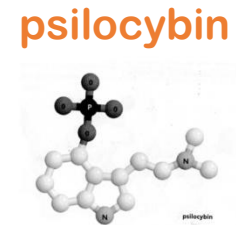
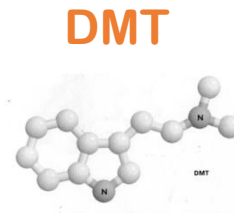
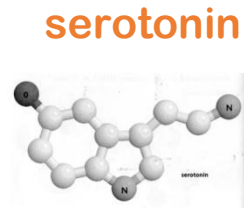
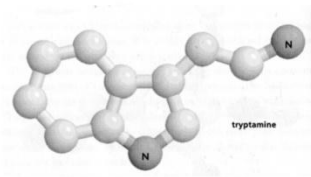
The 'Perfect Tool' for Trauma Psychotherapy

- Short acting
- Less perceptually disturbing than classical psychedelics
- Almost always pleasurable
- Safe in therapeutic applications
- Access to painful traumatic memories
- **Enhances empathy**

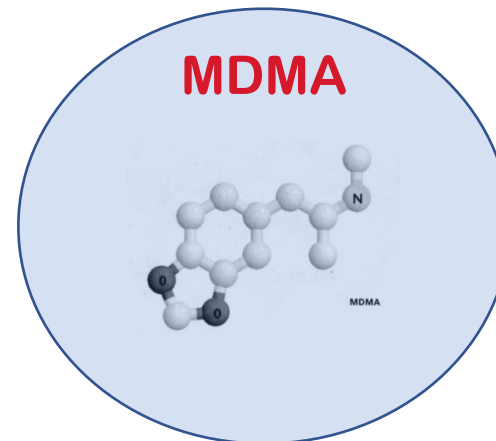
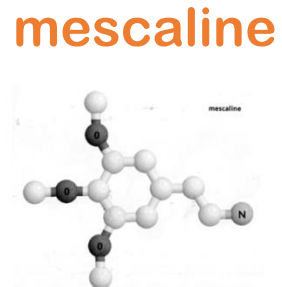
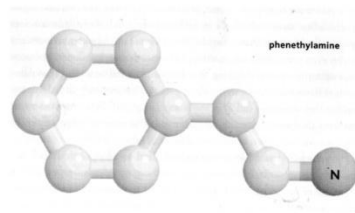


What sort of psychedelic drug is MDMA?

Tryptamines



Phenethylamines



What sort of psychedelic drug is MDMA?

Classical psychedelics (5-HT_{2A} receptor partial agonists)

LSD, Psilocybin, DMT, Mescaline

Entactogens (Serotonin receptor agonists)

MDMA, MDA, MMDA, 2C-series etc

Dissociative anaesthetics (NMDA-antagonists)

Ketamine, PCP, NO₂

THC (Cannabinoid receptor agonist)

Ibogaine (Nicotinic receptor antagonist)

Salvia Divinorum (Kappa-Opioid receptor agonist)

How can MDMA assist trauma-focused Psychotherapy?

Action in the brain:		Effects
Increased Serotonin: (POSITIVE MOOD + CREATIVE THINKING)	5-HT _{1A} 5-HT _{1B}	<ul style="list-style-type: none"> • ↓ depression • ↓ anxiety • ↓ fear (at the amygdala) • ↓ aggression and defensiveness • ↑ self-confidence
	5-HT _{2A}	<ul style="list-style-type: none"> • Alterations in perception of meaning
Increased Dopamine and Noradrenaline (STIMULATION)		<ul style="list-style-type: none"> • ↑ level of alertness • ↑ arousal • ↑ conscious registration of external stimuli
Increased alpha-2 activity (RELAXATION)		<ul style="list-style-type: none"> • ↑ calmness and relaxation
At the hypothalamus (EMPATHY / BONDING)		<ul style="list-style-type: none"> • Release of oxytocin

Fear, Trauma and the Developing Brain:

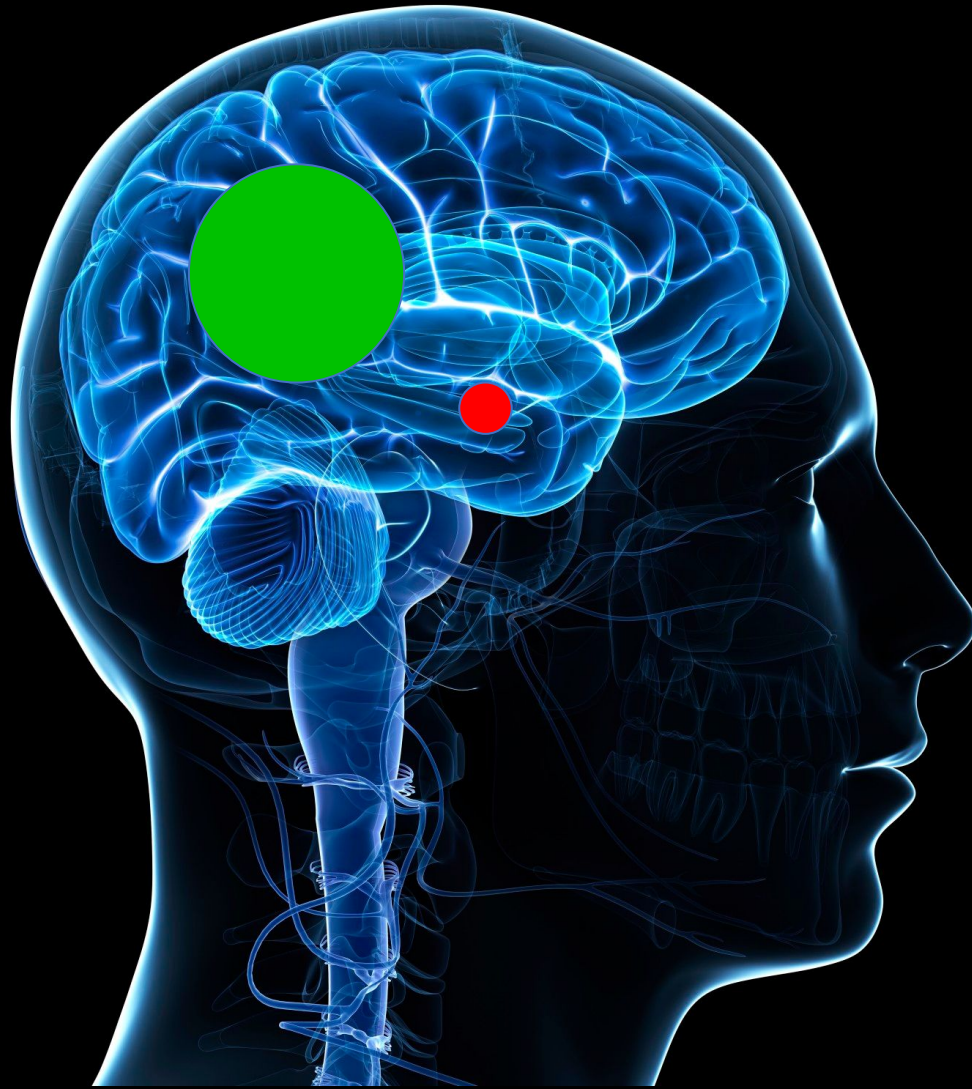
The Prefrontal Cortex versus **The Amygdala**



Trauma

Fear, Trauma and the Developing Brain:

The Prefrontal Cortex versus **The Amygdala**



MDMA

How Does Clinical MDMA Work?

**POSITIVE MOOD &
CREATIVE THINKING**

STIMULATION

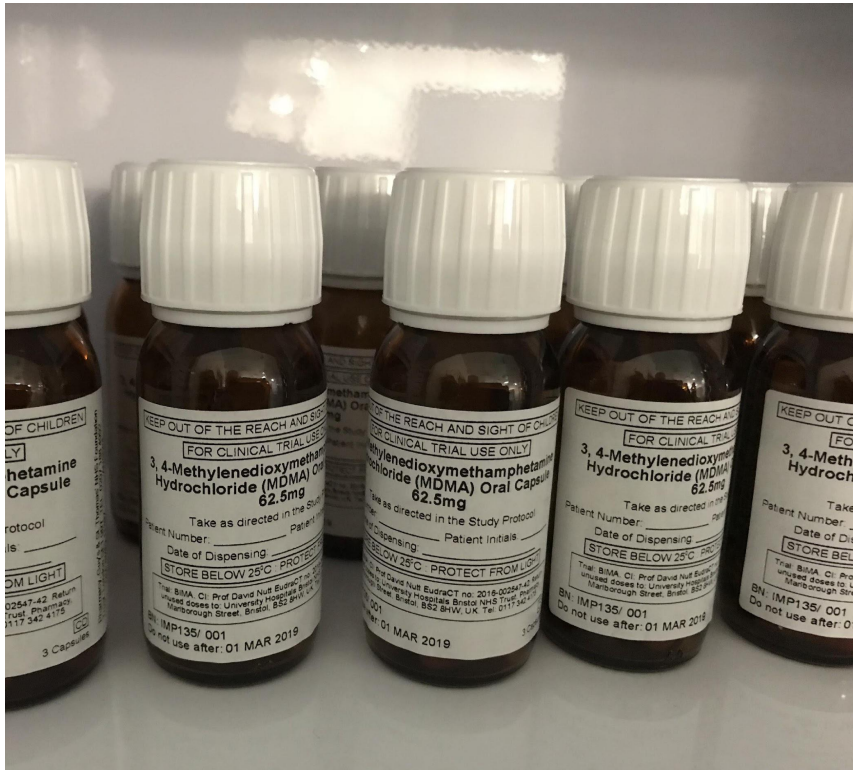
RELAXATION

**EMPATHY /
BONDING**



**SELECTIVELY
INHIBITS THE FEAR
RESPONSE WHILST
LEAVING THE
OTHER FACULTIES
INTACT.**

The Bristol MDMA-Alcoholism Project 'BIMA'



- **Open-Label** Safety and Tolerability
- 8-week course of psychotherapy
- Male-Female co-therapist pair
- Two MDMA Sessions
- 125mg + 62.5mg MDMA
- Overnight stay

Ben Sessa, Laurie Higbed, Sue Wilson, Tim Williams, Claire Durant, Chloe Sakal, Steve O'Brien and David Nutt
Imperial College London and Bristol University

The Bristol MDMA-Alcoholism Project 'BIMA'

2-weeks pre-detox	Screening, consent and eligibility interview	
Alcohol Detox	Seven to Ten Days, carried out by local Community Alcohol Detox Team. Followed by baseline assessments.	
1 week post detox	Session 1	60-minute therapy session.
2 weeks post detox	Session 2	60-minute therapy session
3 weeks post detox	Session 3	MDMA-assisted therapy session 1 (~6-8 hours)
	Session 4	Next day follow-up session (60 min) then daily phone calls 6 days.
4 weeks post detox	Session 5	60-minute therapy session
5 weeks post detox	Session 6	60-minute therapy session
6 weeks post detox	Session 7	MDMA-assisted therapy session 1 (~6-8hours)
	Session 8	Next day follow-up session (60 min) then daily phone calls 6 days.
7 weeks post detox	Session 9	60-minute therapy session
8 weeks post detox	Session 10	60-minute therapy session
3 months post detox	Face-to-face Follow-up interview	
6 months post detox	Face-to-face Follow-up interview	
9 months post detox	Face-to-face Follow-up interview	

Safety Profile of MDMA

- Very low rates of morbidity and mortality.
- Risks easily controlled in clinical setting.

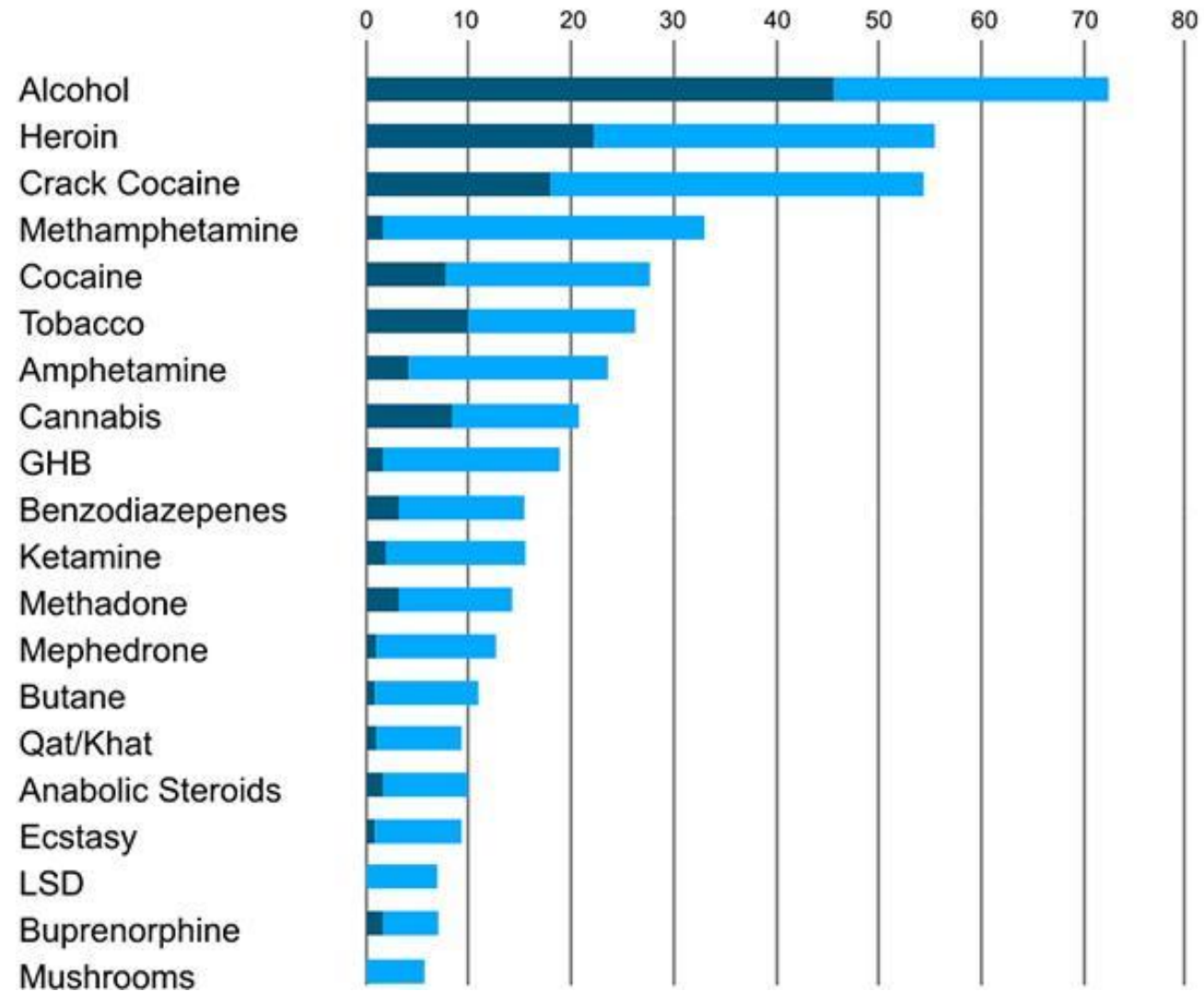
• Clinical MDMA is not recreational ecstasy.



Harm Caused by Drugs

■ Harm to others
■ Harm to users

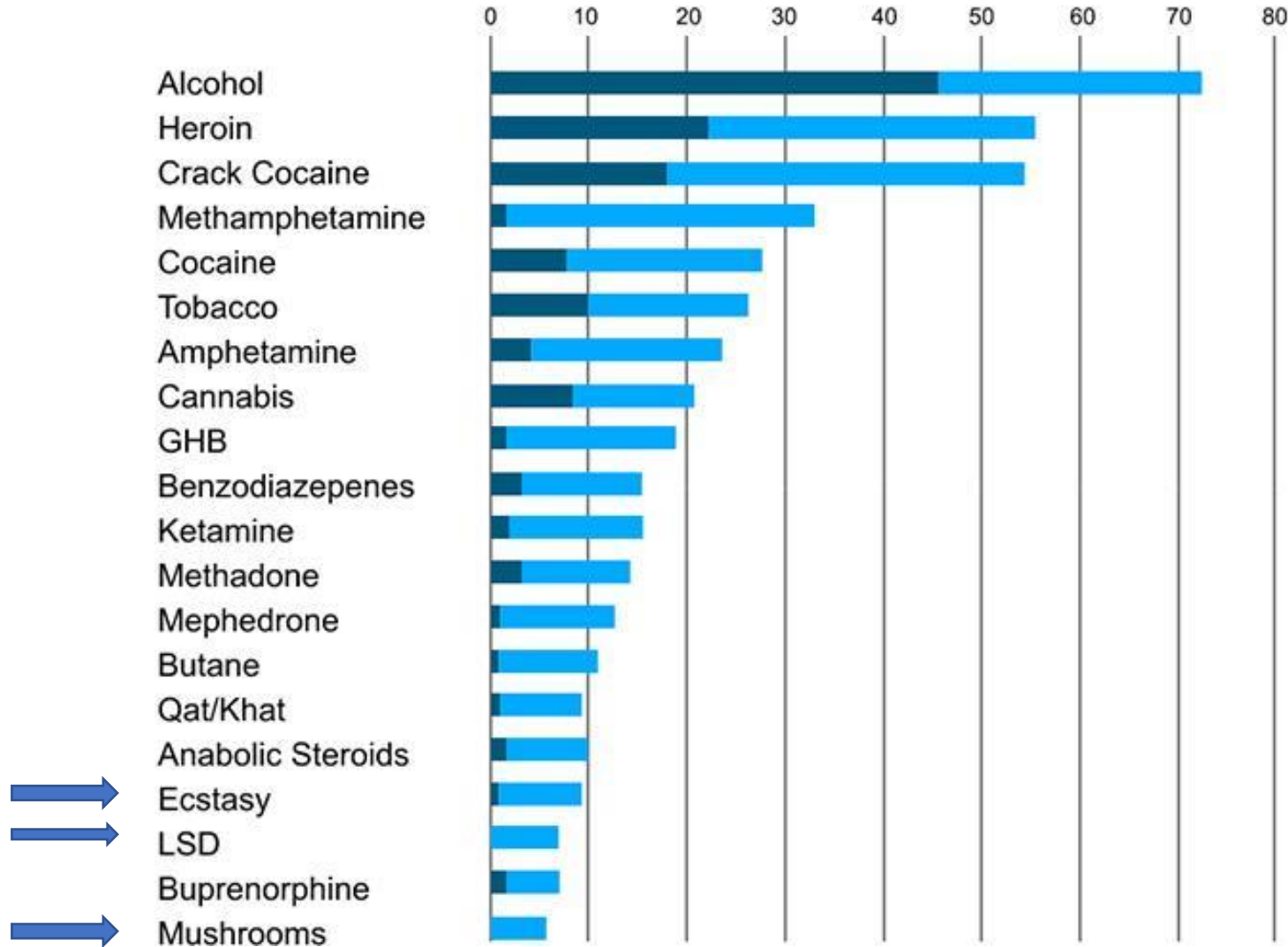
*With a maximum possible harm rating of 100



Harm Caused by Drugs

■ Harm to others
■ Harm to users

*With a maximum possible harm rating of 100



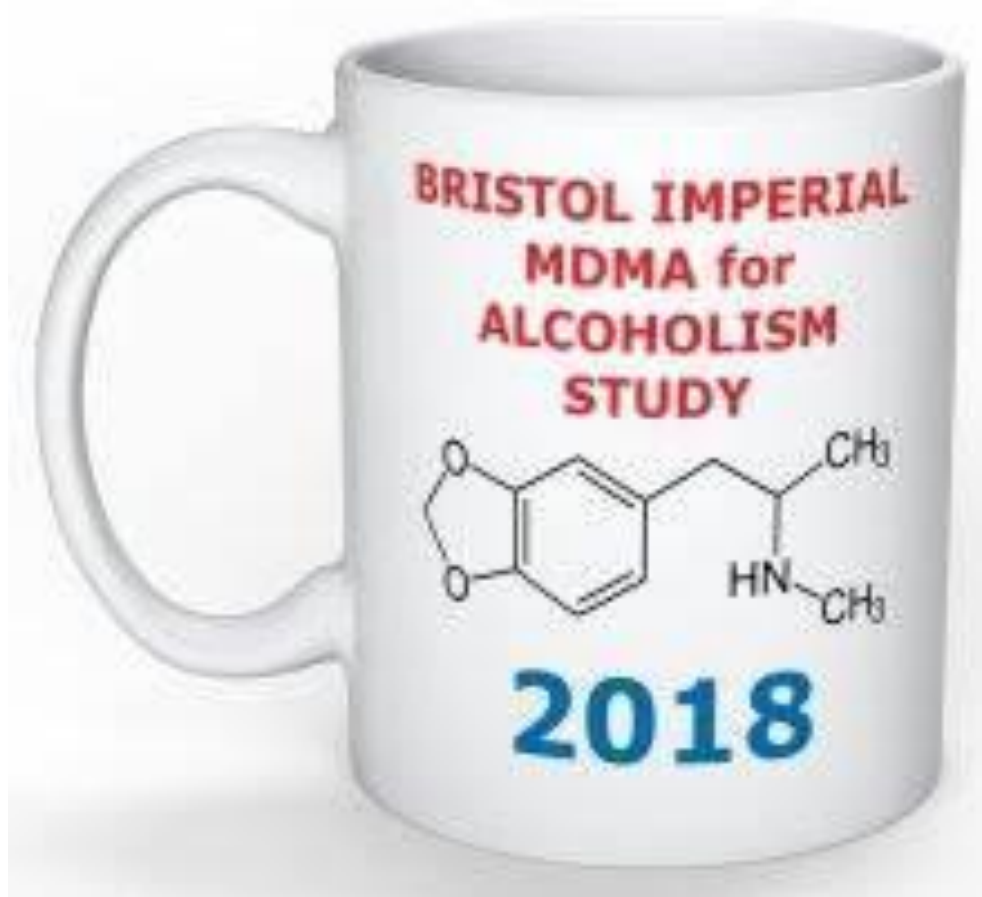
Class	Possession	Supply and production
A	Up to 7 years in prison, an unlimited fine or both	Up to life in prison, an unlimited fine or both
B	Up to 5 years in prison, an unlimited fine or both	Up to 14 years in prison, an unlimited fine or both
C	Up to 2 years in prison, an unlimited fine or both (except anabolic steroids - it's not an offence to possess them for personal use)	Up to 4 years in prison, an unlimited fine or both
Temporary class drugs	None, but police can take away a suspected temporary class drug	Up to 14 years in prison, an unlimited fine or both

Table 2. Drug Scheduling.

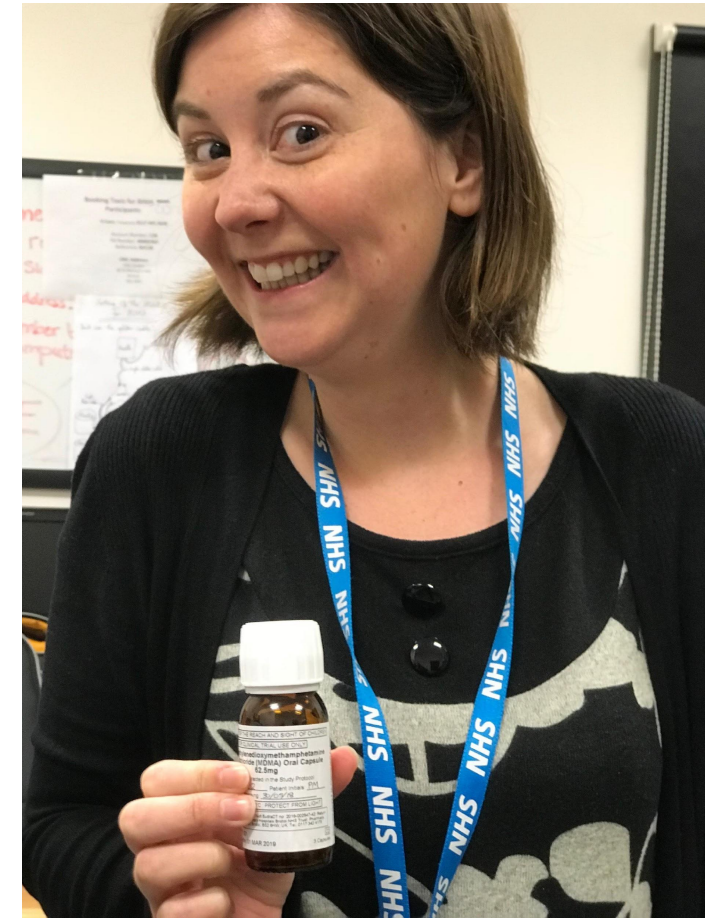
Schedule	Characteristics	Examples
I	High potential for abuse, with no currently accepted medical use in the United States. Considered dangerous when used without medical supervision.	MDMA, ecstasy, marijuana, LSD, GHB, heroin
II	High potential for abuse, but with some accepted medical uses in the United States. Abuse leads to physical and/or psychological dependence and is considered dangerous.	Morphine, cocaine, PCP, opium
III	Potential for abuse, but lower than prior categories. There are accepted medical uses for these, and abuse can lead to mild or moderate physical dependence or great psychological dependence.	Ketamine, codeine combination products, lysergic acid (LSD precursor), anabolic steroids
IV	Drugs with relatively low potential for abuse. Have accepted medical uses in the US. Abuse leads to limited physical and psychological dependence.	Benzodiazepines, phenobarbital
V	Low potential for abuse, with accepted medical uses in the US. Abuse may lead to limited physical or psychological dependence.	Opioid preparations of antidiarrheal and antitussive medications

Pseudo-science!

Starting the world's first clinical MDMA addictions study...in Bristol



Starting the world's first clinical MDMA addictions study...in Bristol



Progress so far:



"In the past I've isolated from people, been too judgemental. But the MDMA helps you see things more clearly, see things how they really are."

"MDMA helps you see everything you do negatively, and you realize you don't have to own that."

"It's only a drug, but it releases part of you, and you can tap into that and better appreciate things. It kicks away all the fears. It heightens, strengthens and enlightens."



"My drinking has isolated me; stopped me from connecting with other people. I'd totally disconnected, been put into solitary...but MDMA has opened the door. All those fears, you can see them on MDMA, they're not the real me. ...the MDMA has triggered a process to help me see the fears...it took me to a deeper level, and now it feels more natural. I now know what to do."

Progress so far:

“MDMA Therapy is far more effective for me than my previous attempts at tackling my drinking.”

“For the first time in my life I can see clearly why I have been drinking and what I need to do to stop.”

“I have no intention of ever returning to alcohol again.”

“MDMA has shown me that I am a good and worthy person.”

“MDMA has shown me that the abuse I suffered as a child, which led me to drinking, was not my fault. Now I can hold my head up high and go on and achieve what I am capable of in life.”

“MDMA Therapy has changed my life.”



Published this month

BMJ Case Reports

Novel treatment (new drug/intervention; established drug/procedure in new situation)

CASE REPORT

First study of safety and tolerability of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy in patients with alcohol use disorder: preliminary data on the first four participants

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²Department of Medicine, Avon and Wiltshire Mental Health Partnership NHS Trust, Bath, UK

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SUMMARY

We present the preliminary data in an ongoing open-label safety and tolerability proof of concept study exploring the potential role for 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy in treating patients with alcohol use disorder. At this stage, seven participants have completed the full 8-week MDMA-assisted psychotherapy course, including two therapy sessions each with MDMA. This paper focuses on the safety and tolerability of the therapeutic course for the first four participants to complete treatment. Longer-term outcomes of drinking behaviour will be presented later when the full project data are published. Results show all four participants have successfully tolerated the treatment. There have been no serious adverse events related to MDMA, no unexpected physiological responses to the MDMA sessions or changes to blood results or electrocardiograms, measured before and after the 8-week course. We conclude that the treatment is well-tolerated and are making plans to expand the project into a randomised placebo-controlled study.

Physiologically tolerated

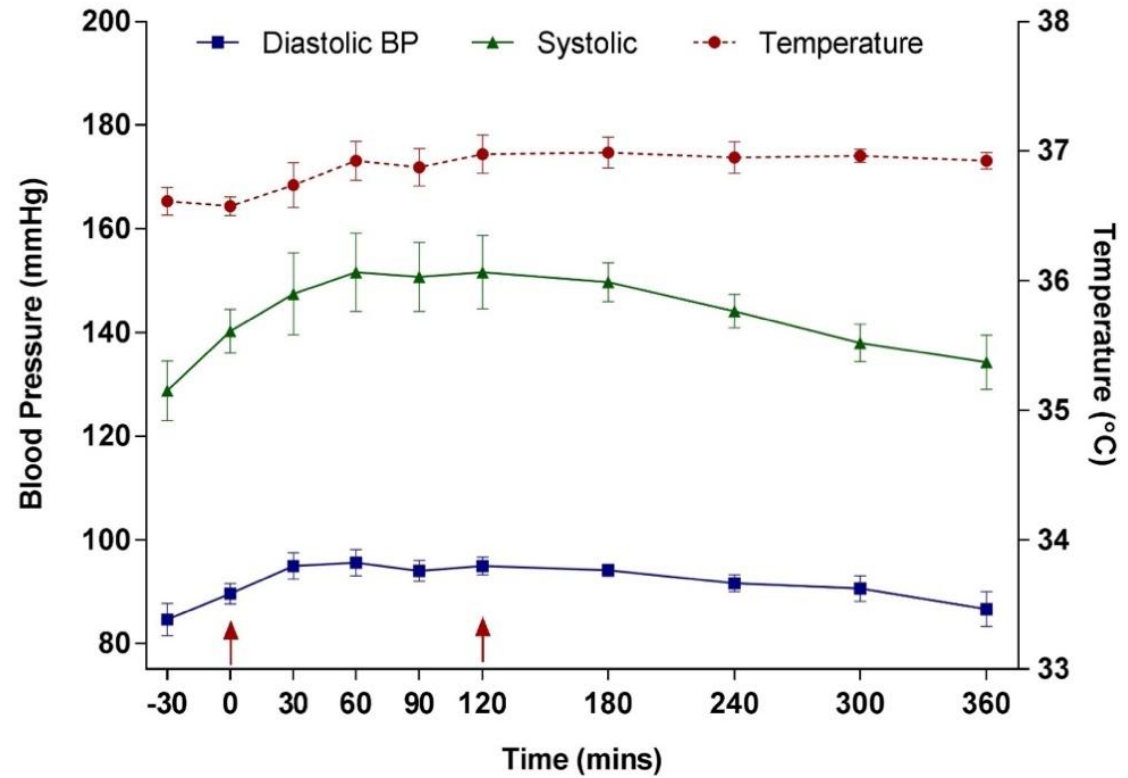


Figure 1: Blood pressure and temperature following MDMA at T=0, 125mg (arrow) and T=120, 62.5mg (arrow), n=4. Mean data combined for both MDMA therapy sessions, error bars +/- SEM

Is Blue Monday /
Black Tuesday
merely a raver's
artefact?

If anything, we are
seeing an afterglow
effect.

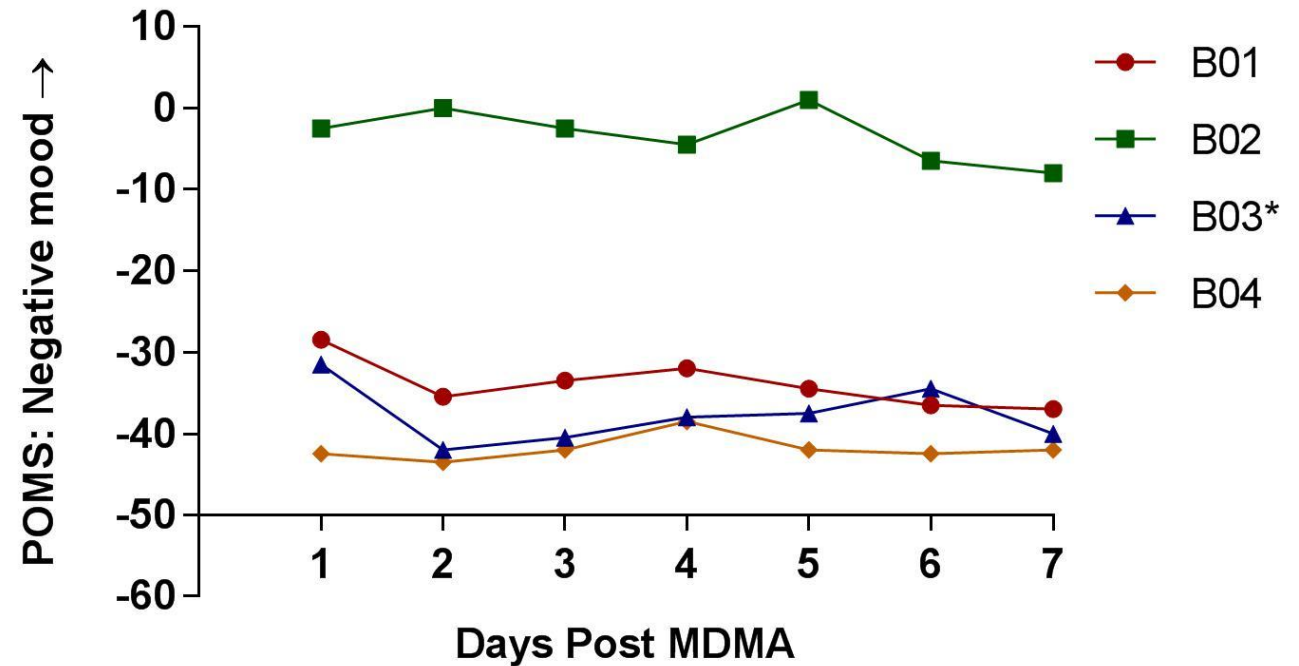


Figure 2: Individual POMS composite scores (n=4) for 7 days following MDMA assisted therapy (day 0). Data are mean of the 2 MDMA sessions . *On day 4 B03 scored very negatively due to an argument, this was discussed during the daily phone call and the score removed as the event was unrelated to the study.

Other
Measures
looked at
with BIMA
study

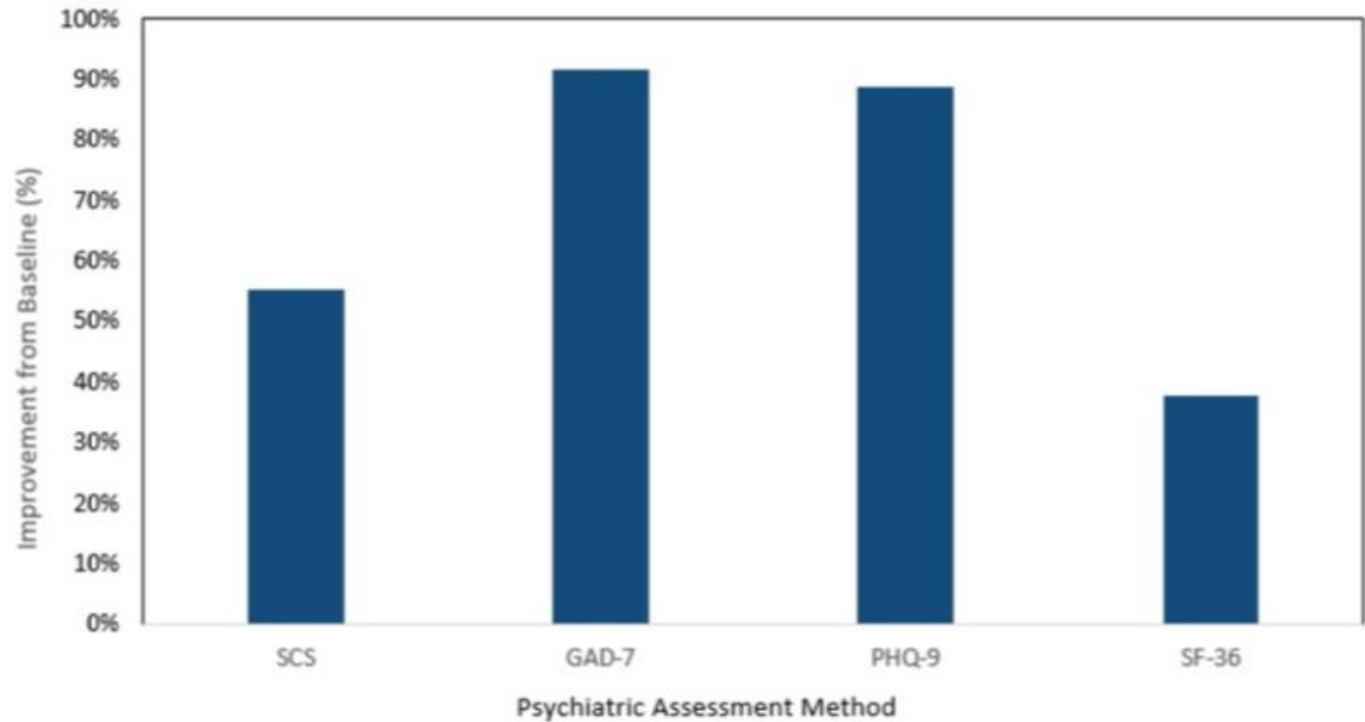


Figure 3 Self Compassion Scale (SCS), Generalised Health Questionnaire-7 (GAD-7), Patient Health Questionnaire-9 (PHQ-9) and Short Form Health Survey (SF-36) % improvement between baseline session and session 10, after completion of the 8-week psychotherapy course. Bars are mean data n=4.

Contemporary Clinical Psychedelic Research

MDMA Therapy for PTSD: Pilot study and LTFU (Mithoefer 2010 and 2013)

MDMA Therapy for PTSD in War Veterans, USA

MDMA Therapy for PTSD for Boulder, USA

MDMA Therapy for PTSD Israel

MDMA Therapy for PTSD Canada

MDMA Therapy for Social Anxiety in Autism (Danforth et al 2015)

Psilocybin Therapy for Obsessive Compulsive Disorder (Moreno et al 2006)

Psilocybin Therapy for Anxiety in end-stage cancer (Grob et al 2010)

Psilocybin Therapy for Anxiety in end-stage cancer (Ross et al 2015)

Psilocybin Therapy for Smoking Cessation (Johnson et al 2015)

Psilocybin Therapy for Alcohol Dependence (Bogenschutz 2015)

Psilocybin Therapy for Depression (Carhart-Harris 2019)

LSD Therapy for Anxiety in end-stage cancer (Gasser 2010)

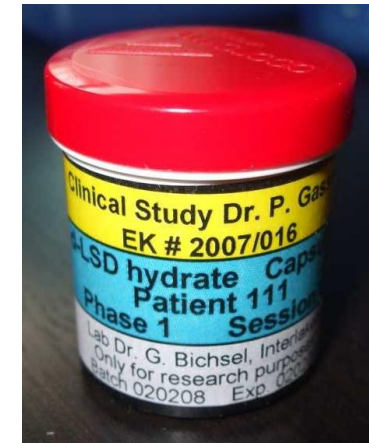
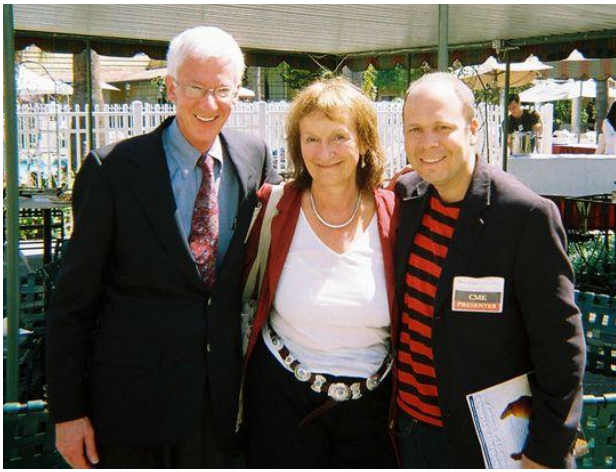
Ketamine Therapy for Opiate addiction (Krupitsky et al 2007)

Ketamine Therapy for Depression (McShane 2016)

Ibogaine Therapy as a treatment for Opiate Addiction (Brown 2017)

Ibogaine Therapy as a treatment for Opiate Addiction (Knoller 2017)

Ayahuasca Therapy for Depression (de Arujo – IN PRINT)



Ten Years of UK Psychedel ic



Bristol Psilocybin Pilot
Study Group 2009



European MAPS Training MDMA
Academic Group 2014



Eleusis LSD Creativity
Group 2015



Beckley-Imperial
Psilocybin MEG-fMRI
Study Group 2013



Beckley-Imperial
LSD Group 2014



Cardiff University MDMA
Study Group 2015



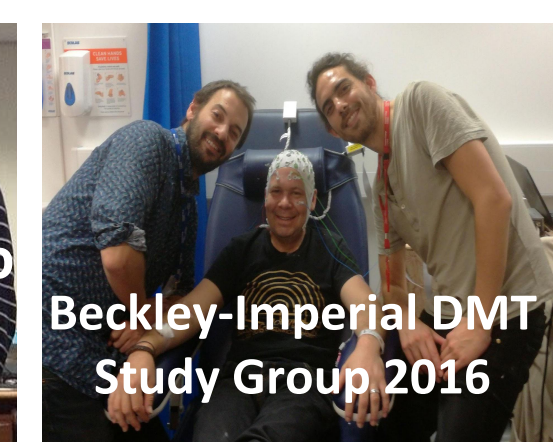
Bristol-Imperial MDMA
Study Group 2015



UK/International DMT
Study Group 2015



Beckley-Imperial-Psilo
cybin-Study Team
2014



Beckley-Imperial DMT
Study Group 2016

'Career Suicide'



...Not according to these institutions and publications!

HARVARD
UNIVERSITY

South London and Maudsley
NHS Foundation Trust



University of
BRISTOL



nature
International weekly journal of science



CARDIFF
UNIVERSITY
PRIFYSGOL
CAERDYDD



UNIVERSITY OF
CAMBRIDGE



Imperial College
London

BAP
British Association for
Psychopharmacology



Yale University



THE
LANCET

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#EndTheDrugWar

Thanks

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