

The Bristol Imperial MDMA for Alcoholism (BIMA) Study

The World's First Addictions Study with MDMA-Assisted Psychotherapy

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Psychedelics in Psychiatry and Psychotherapy (ISPPP)

24th September 2020

Unstable Attachments....

Unstable Psychological and Social Environments....

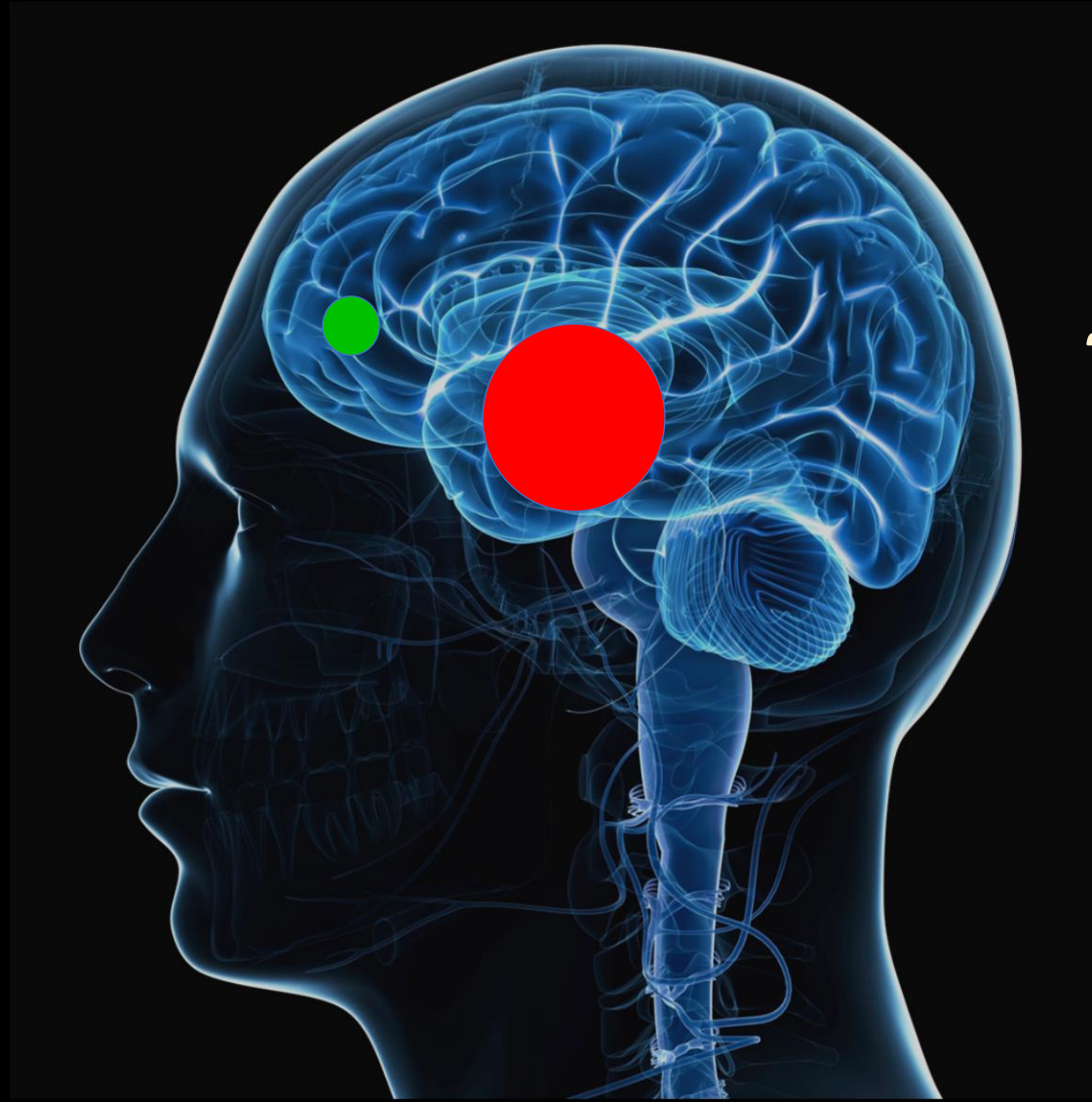


- Physical, Sexual, Emotional abuse and neglect in childhood
- Feeling unloved, unsafe and unlovable
- Parental criminality
- Parental mental illness
- Domestic Violence
- Parental Substance Misuse
- Unemployment
- Poor housing
- Race and social exclusion
- Poor education



Fear, Trauma and the Developing Brain:

The Prefrontal Cortex versus **The Amygdala**



Trauma

Identity Formation

Secure
Attachment

```
graph TD; A[Secure Attachment] --> B[Self Narrative: "I'm a good person", "I can achieve", "I'm loved & lovable"]; A --> C[World Narrative: "People can be trusted", "The world is a safe place", "People will help me"];
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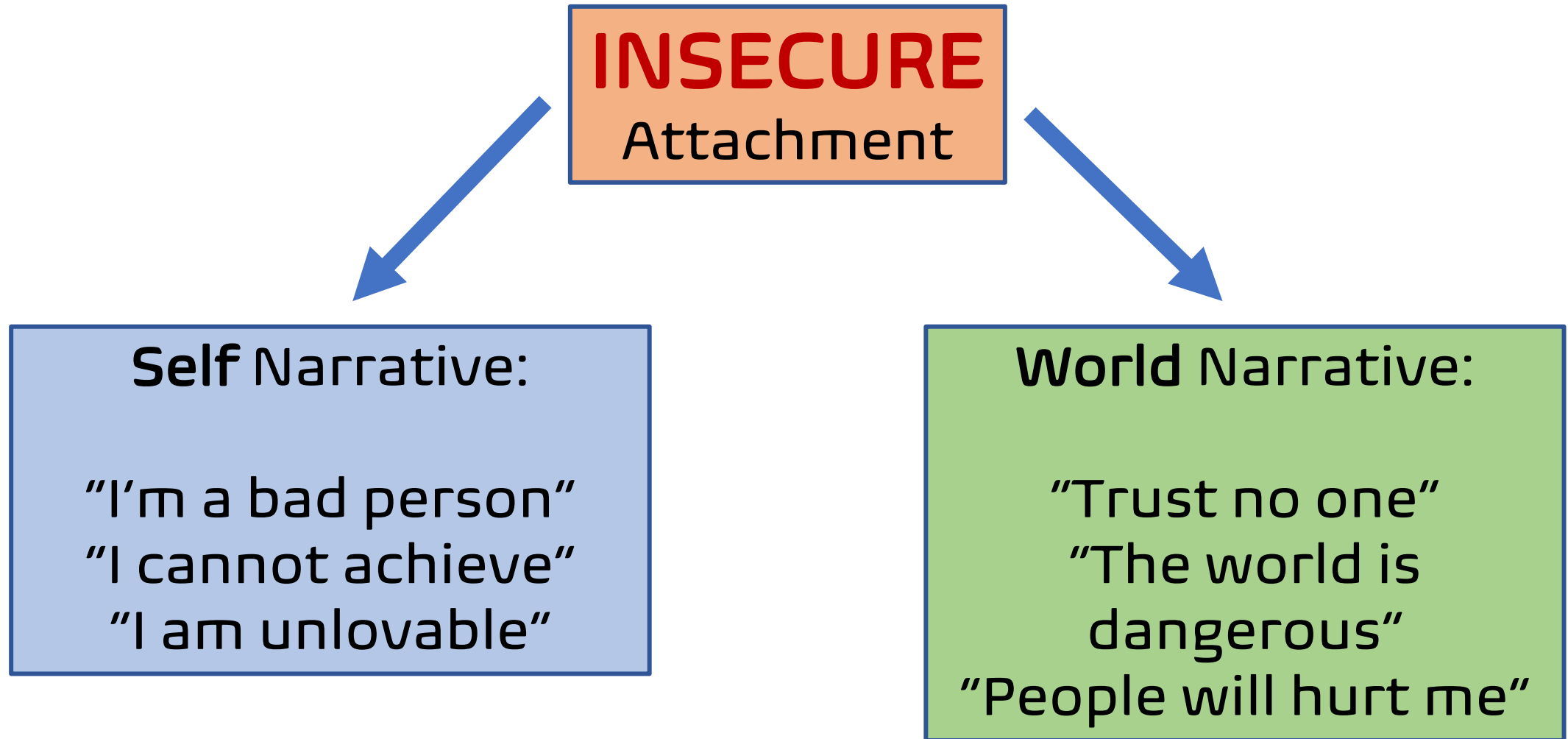
Self Narrative:

"I'm a good person"
"I can achieve"
"I'm loved & lovable"

World Narrative:

"People can be
trusted"
"The world is a safe
place"
"People will help me"

Identity Formation



Identity Formation

Insecure
Attachment

**Numb myself and
block out the world
with sedating
substances**

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"



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.'

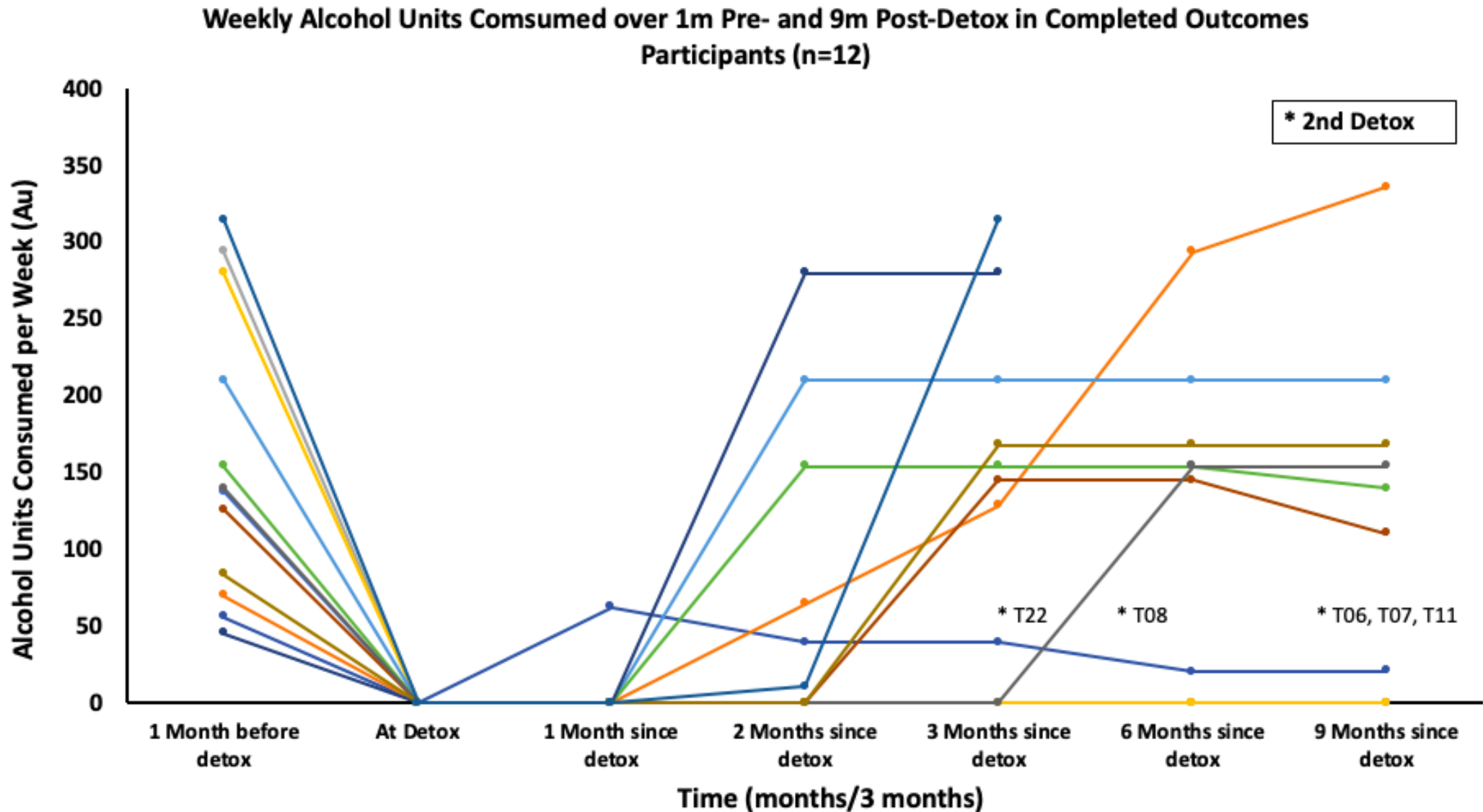
How well is modern psychiatry doing
to manage alcohol use disorder?

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

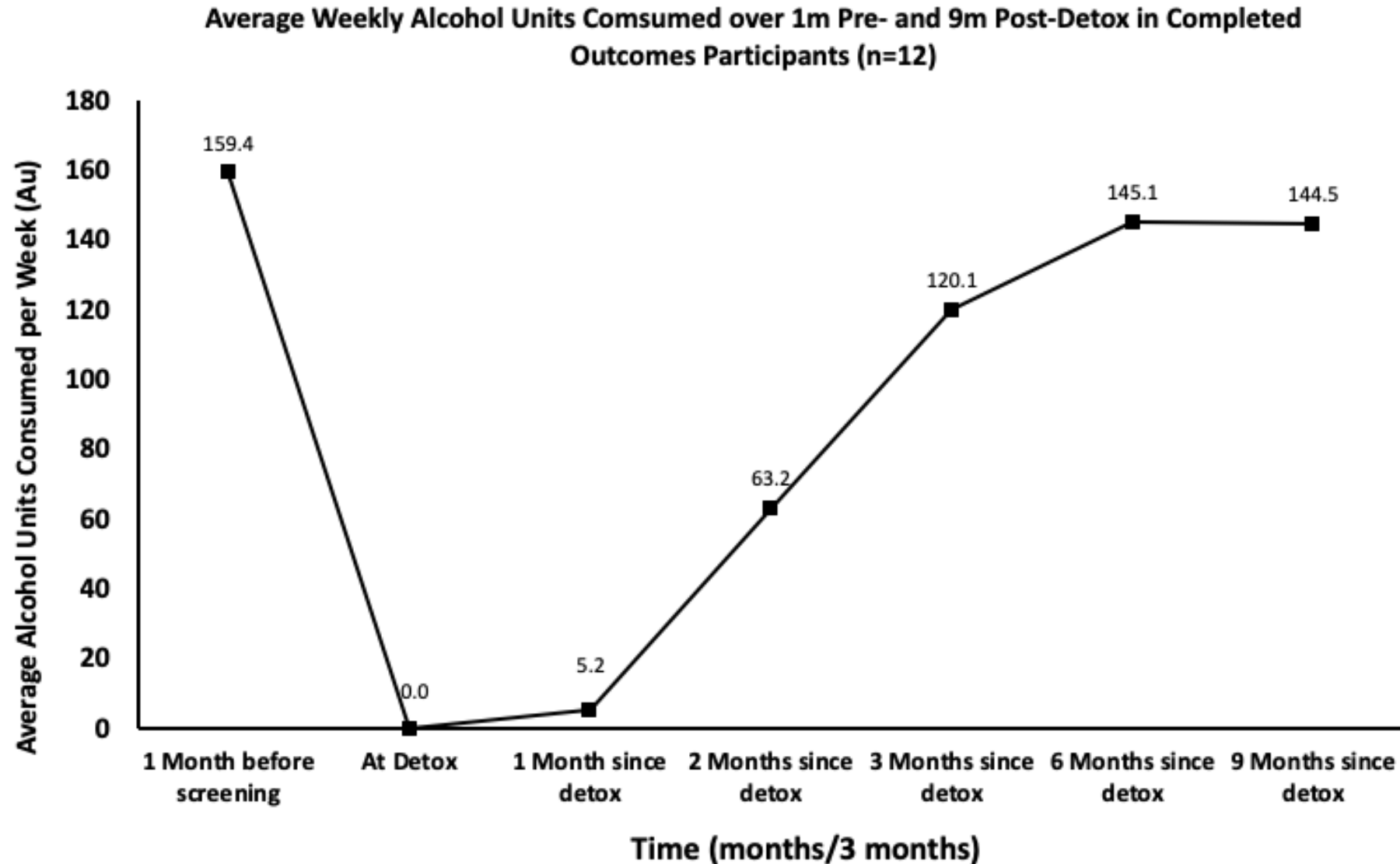
Roughly 90% of people will relapse within 4 years after completing treatment.

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

The OUTCOMES (Observational) Study:

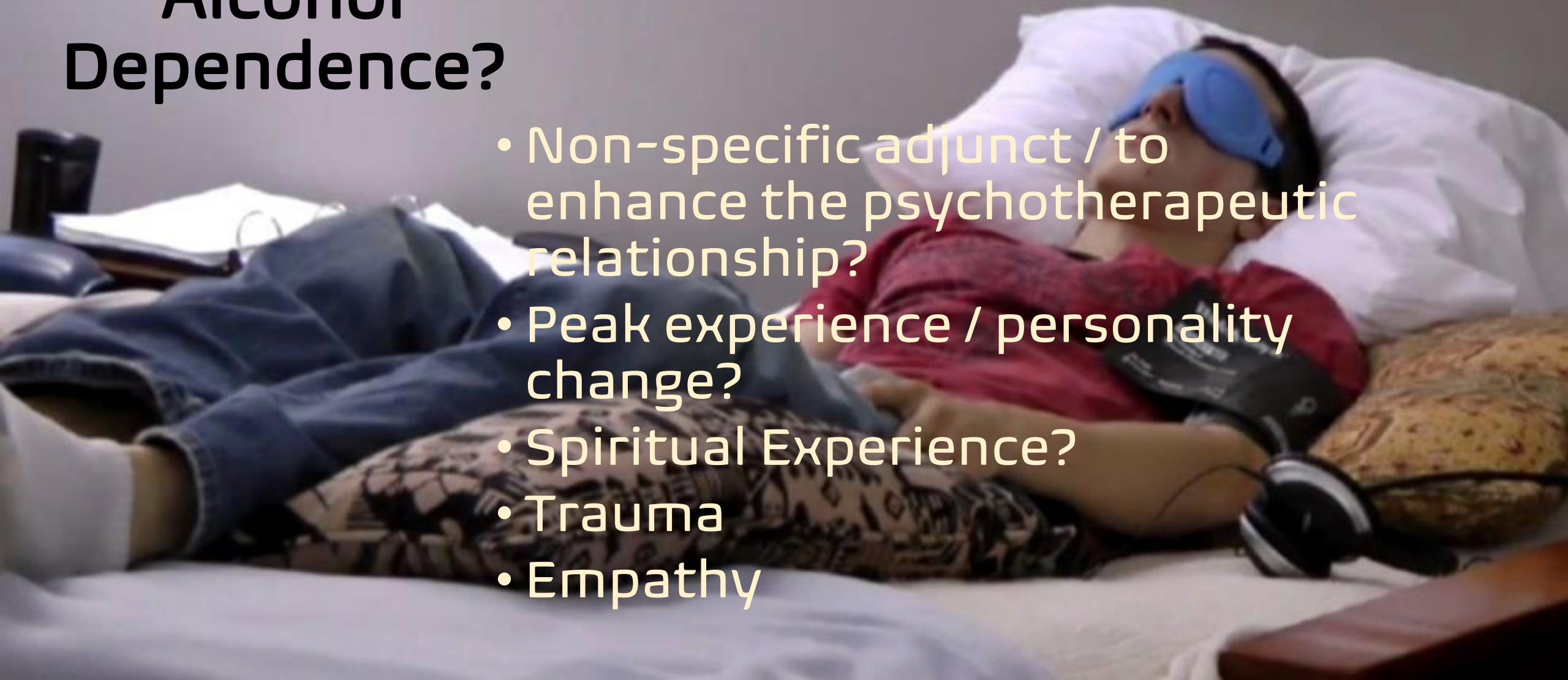


The OUTCOMES (Observational) Study:



But Could MDMA Treat Alcohol Dependence?

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



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

How Does Clinical MDMA Work?

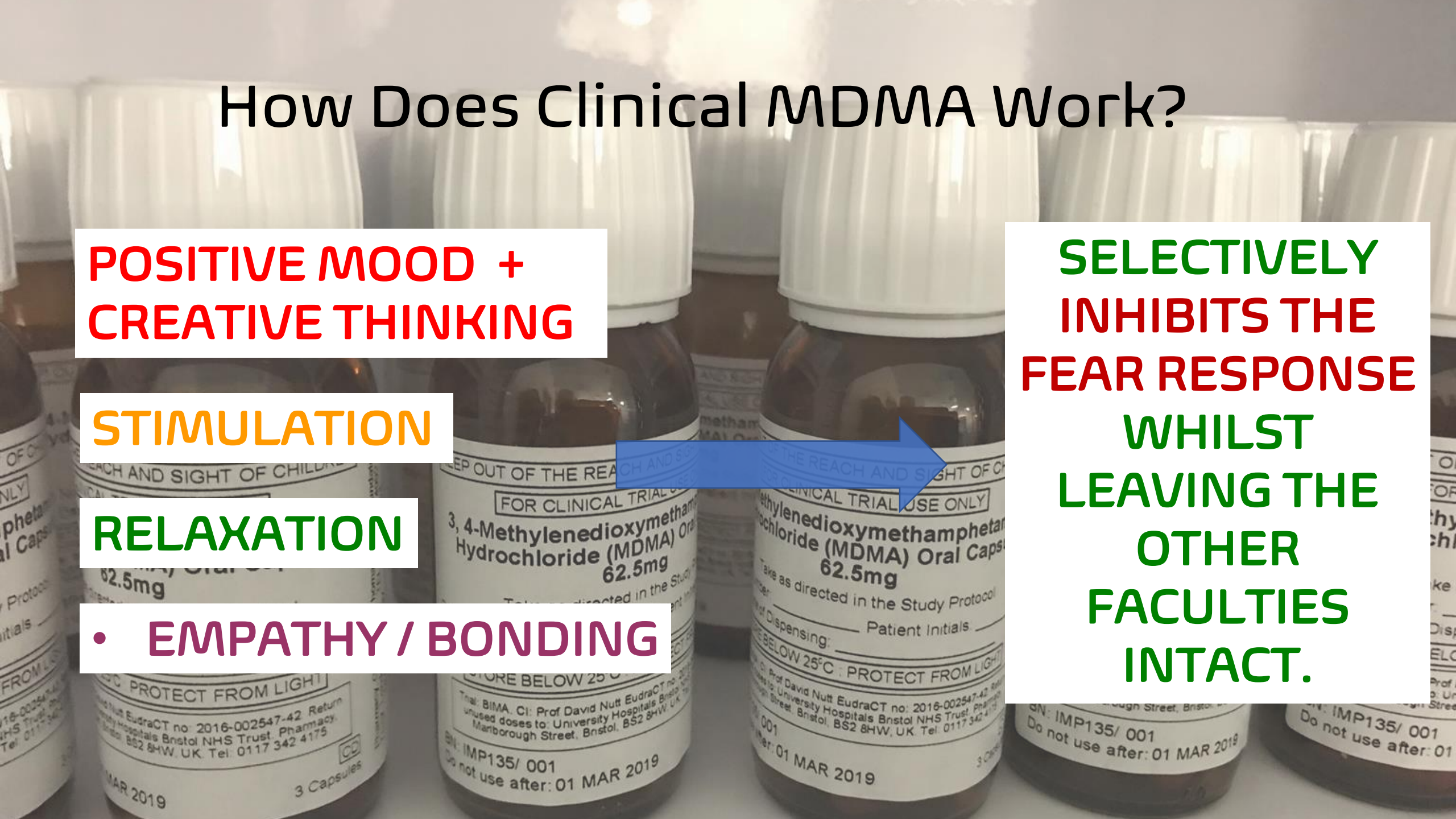
**POSITIVE MOOD +
CREATIVE THINKING**

STIMULATION

RELAXATION

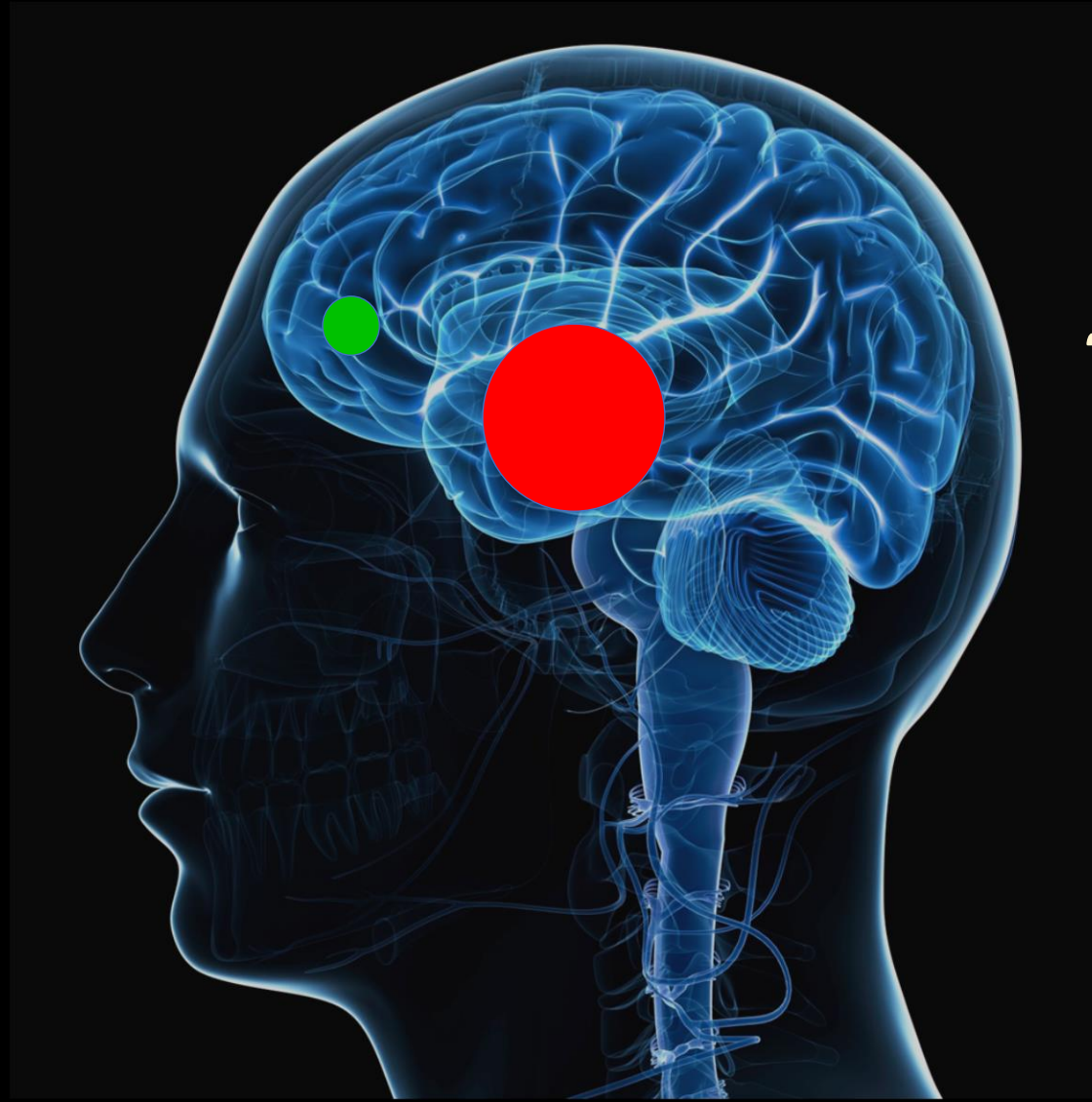
- EMPATHY / BONDING**

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



Fear, Trauma and the Developing Brain:

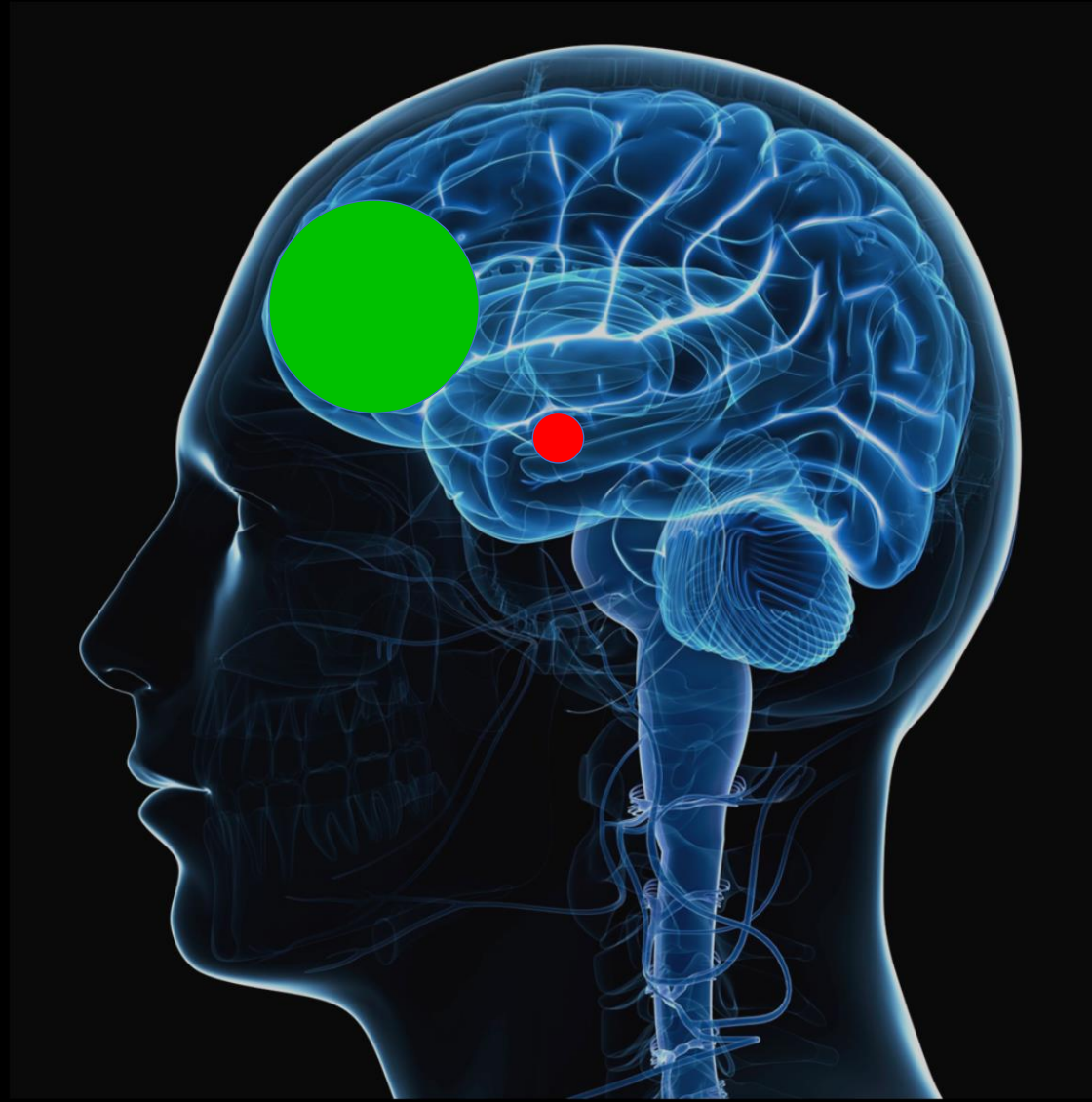
The Prefrontal Cortex versus The Amygdala



Trauma

Fear, Trauma and the Developing Brain:

The Prefrontal Cortex versus **The Amygdala**



MDMA

The Bristol-Imperial MDMA-Alcoholism (‘BIMA’) Study

- 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, Tim Williams,
Claire Durant, Steve O’Brien, Chloe Sakal
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 4 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 4 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	

Demographics:

- Participants **recruited** from local addictions service.
- **Thirty-six** participants were screened.
- **Fourteen** people were eligible; of which six were females.
- Average age **48 years**.
- All were **white-UK race**.
- **Four** were **employed**, **nine unemployed** and **one retired**.
- **Alcohol characteristics:**
 - The average age the participants **first used alcohol** was **13 years old**.
 - The average age when alcohol use became **daily** was **34 years old**.
 - **64%** of participants reported a **history of blackouts**
 - **14%** of participants had experienced **alcohol withdrawal-induced seizures**.
 - **86%** of participants reported **risky or vulnerable incidences** due to alcohol.
 - **75%** of participants had a history of **offending behaviour** due to their alcohol use.
- **Physiological parameters at baseline:**
 - The average BP (mmHg) was **131/85**, the average Heart Rate was **75bpm**.



BIMA: Safety and Tolerability data (N=14)

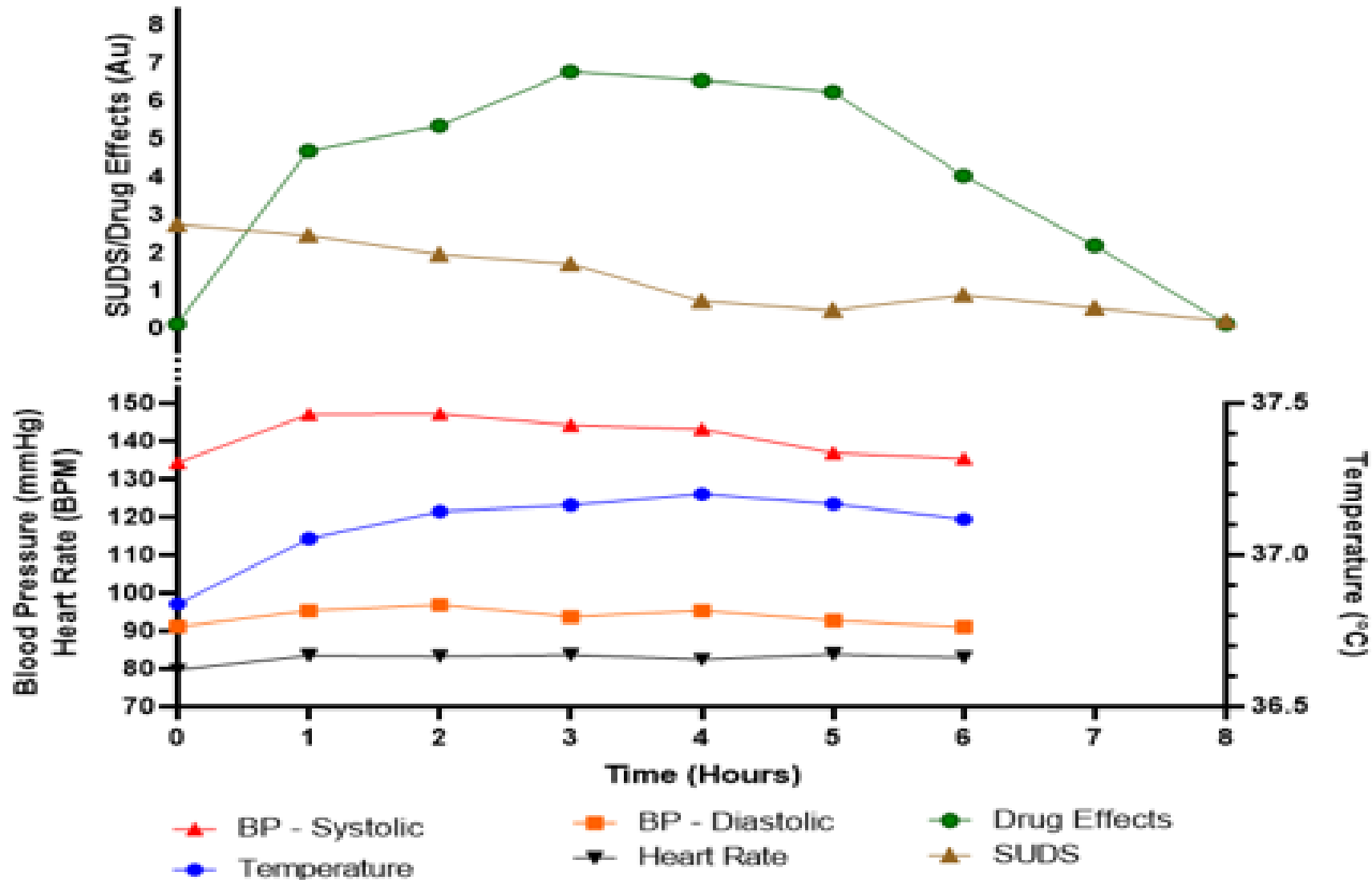
PARTICIPANT NUMBER:	ABNNORMAL PHYSIOLOGICAL CHANGES IN MDMA SESSIONS OBSERVED:	SERIOUS ADVERSE EVENTS RECORDED:	POST-MDMA AFFECT DROP IN THE WEEK AFTER THE SESSION	SUICIDE RISK (AS MEASURED BY C-SSRS):	SUBJECTIVE REPORT OF PARTICIPANTS' TOLERABILITY OF MDMA THERAPY COURSE:	ABNORMAL CHANGES IN BLOOD TEST RESULTS AND ECG BETWEEN BASELINE AND THE END OF THE MDMA COURSE:
B01	None	None	None	Nil	Positive	Nil
B02	None	None	None	Nil	Positive	Nil
B04	None	None	None	Nil	Positive	Nil
B05	None	None	None	Nil	Positive	Nil
B09	None	None	None	Nil	Positive	Nil
B11	None	None	None	Nil	Positive	Nil
B15	None	None	None	Nil	Positive	Nil
B16	None	None	None	Nil	Positive	Nil
B17	None	None	None	Nil	Positive	Nil
B20	None	None	None	Nil	Positive	Nil
B21	None	None	None	Nil	Positive	Nil
B25	None	None	None	Nil	Positive	Nil
B26	None	None	None	Nil	Positive	Nil
B28	None	None	None	Nil	Positive	Nil

BIMA: Safety and Tolerability data (N=14)

PARTICIPANT NUMBER:	ABNORMAL PHYSIOLOGICAL CHANGES IN MDMA SESSIONS OBSERVED:	SERIOUS ADVERSE EVENTS RECORDED:	POST-MDMA AFFECT DROP IN THE WEEK AFTER THE SESSION	SUICIDE RISK (AS MEASURED BY C-SSRS):	SUBJECTIVE REPORT OF PARTICIPANTS' TOLERABILITY OF MDMA THERAPY COURSE:	ABNORMAL CHANGES IN BLOOD TEST RESULTS AND ECG BETWEEN BASELINE AND THE END OF THE MDMA COURSE:
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B11	None	None	None	Nil	Positive	Nil
B15	None	None	None	Nil	Positive	Nil
B16	None	None	None	Nil	Positive	Nil
B17	None	None	None	Nil	Positive	Nil
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B21	None	None	None	Nil	Positive	Nil
B25	None	None	None	Nil	Positive	Nil
B26	None	None	None	Nil	Positive	Nil
B28	None	None	None	Nil	Positive	Nil

Was MDMA Tolerated by Patients with AUD?

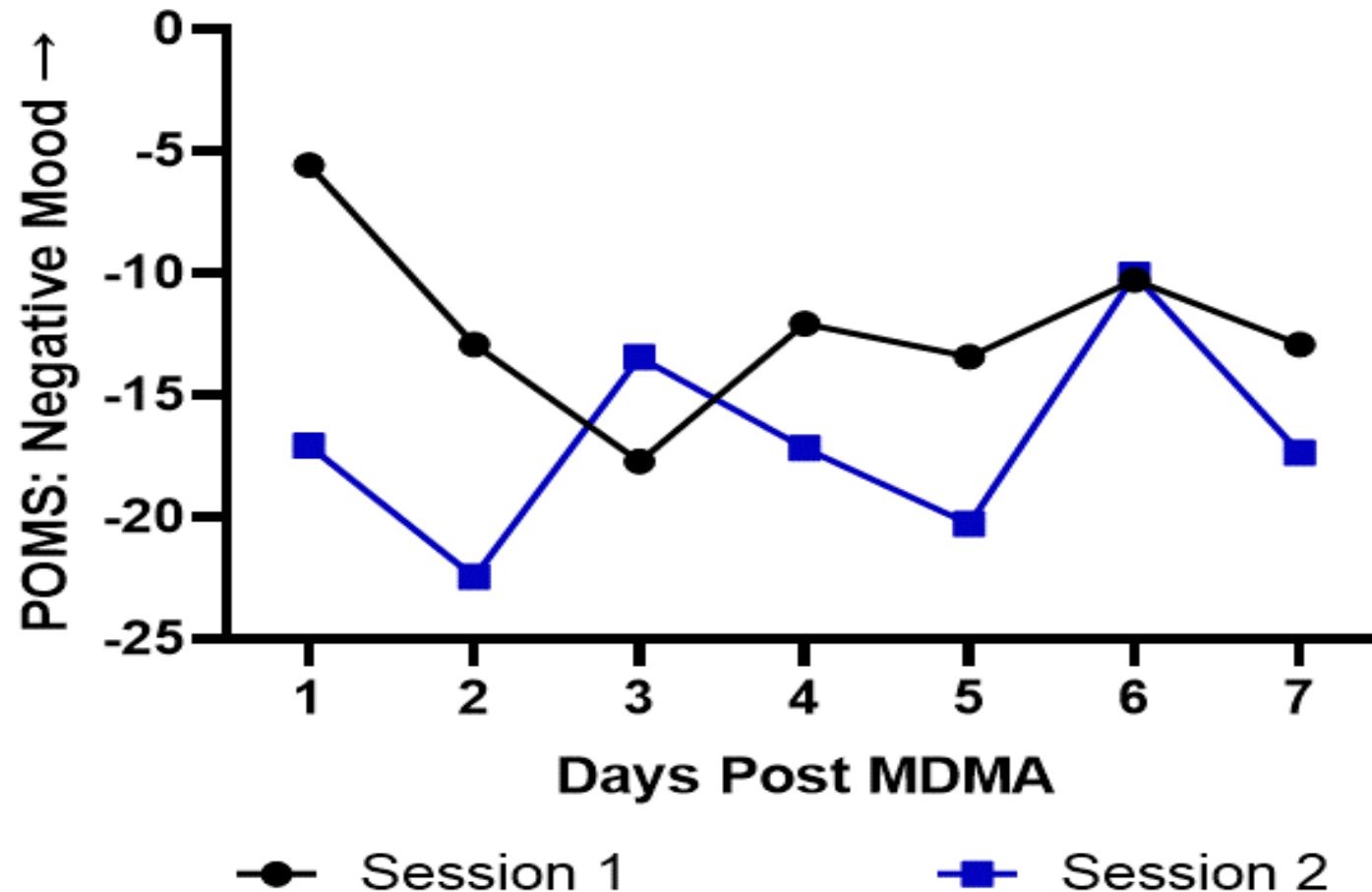
(Average scores across all 26 MDMA sessions)



What about 'Come Downs',
Blue Monday, Black Tuesday and
Suicide Wednesday?



Profile of Mood States (POMS) carried out by daily telephone calls for 7-days after each MDMA session (Average scores across 26 MDMA sessions)





Safety Profile of MDMA

Very low rates of morbidity and mortality.

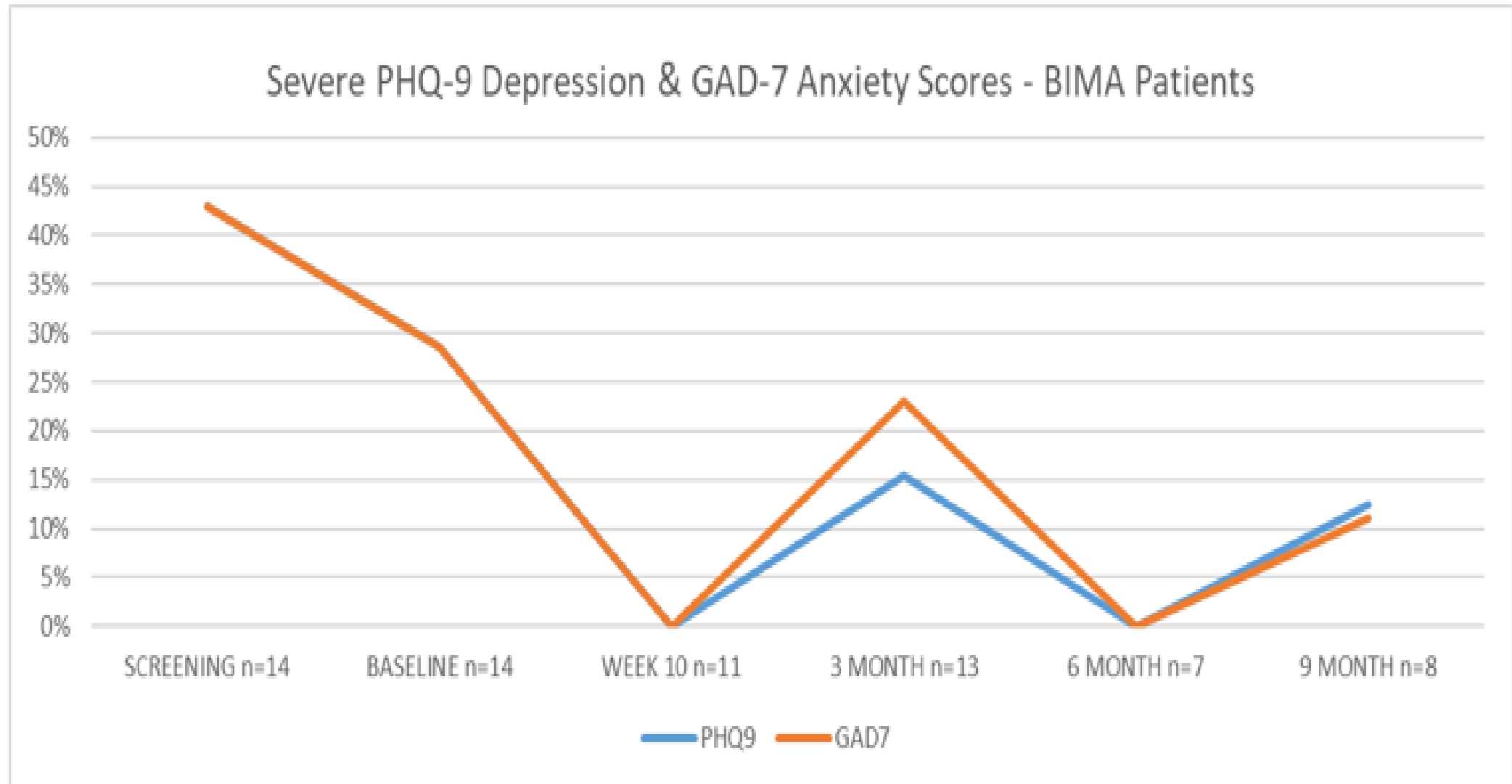
Risks easily controlled in clinical setting.

Clinical MDMA is not recreational ecstasy.

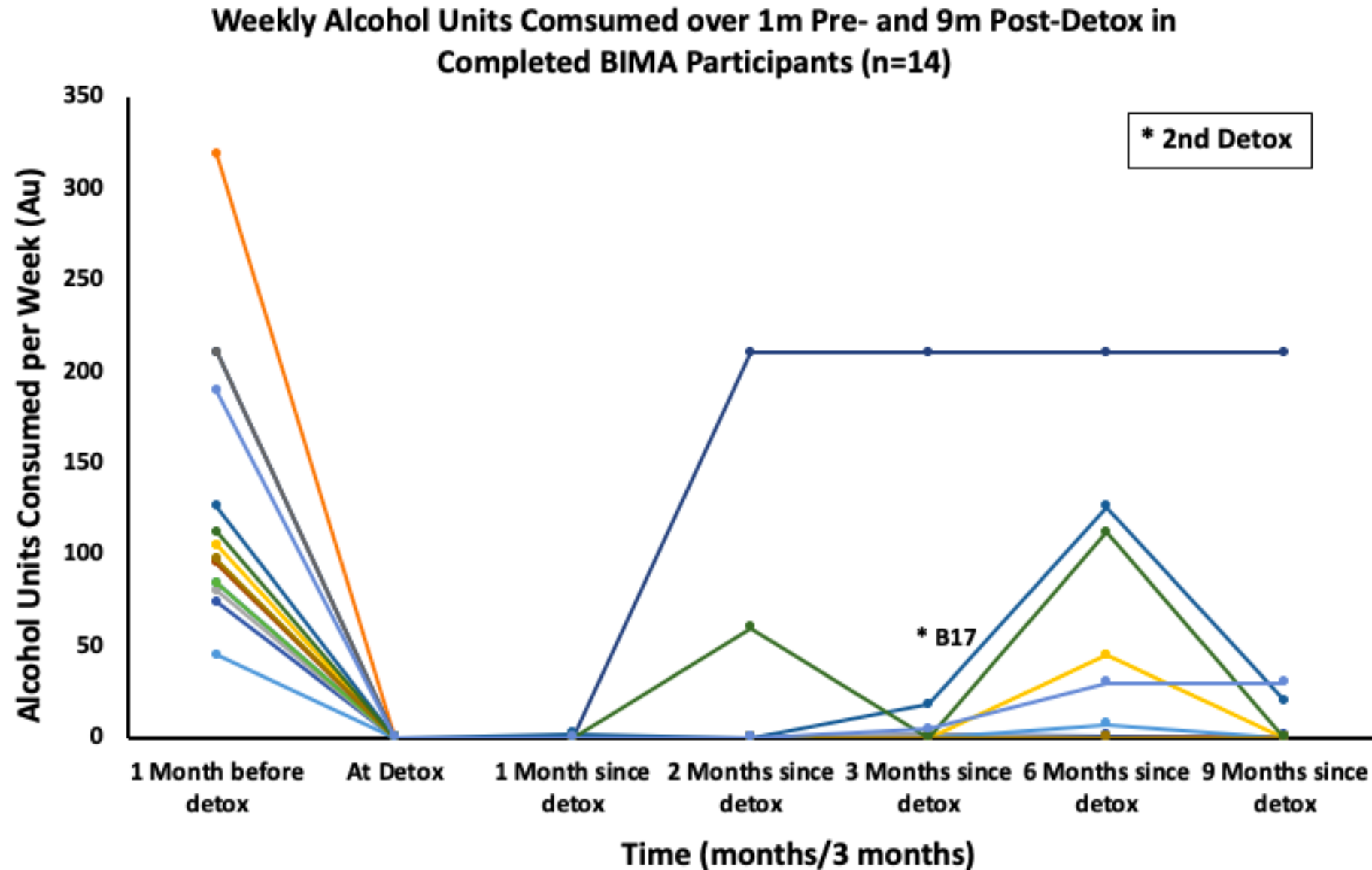
Doblin R1, Greer G, Holland J, Jerome L, Mithoefer MC, Sessa B. (2014) A reconsideration and response to Parrott AC (2013) "Human psychobiology of MDMA or 'Ecstasy': an overview of 25 years of empirical research". Hum Psychopharmacol. 2014 Mar;29(2):105-8. doi: 10.1002/hup.2389.

Other measures: Global Depression and Anxiety

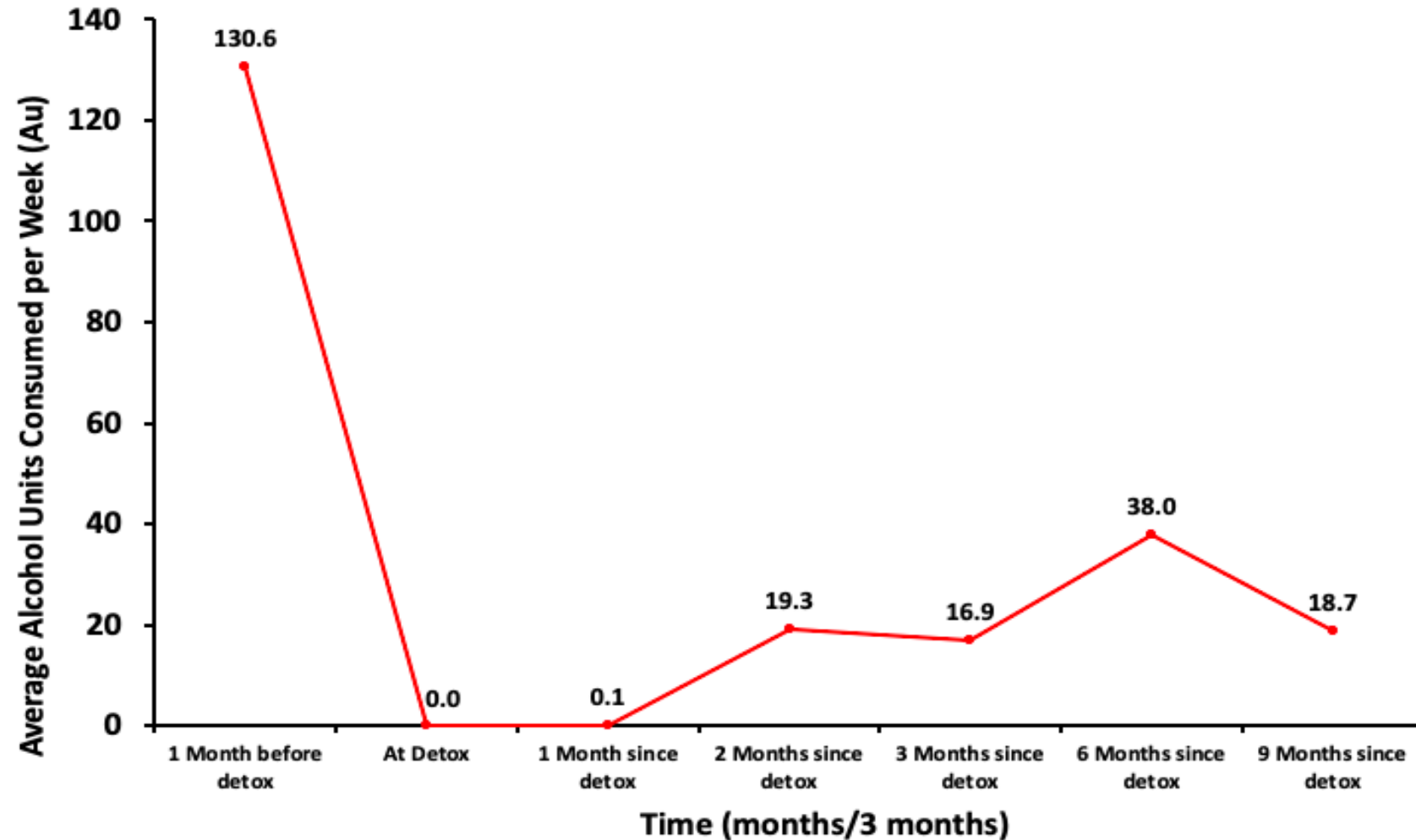
(Average scores across n=14)



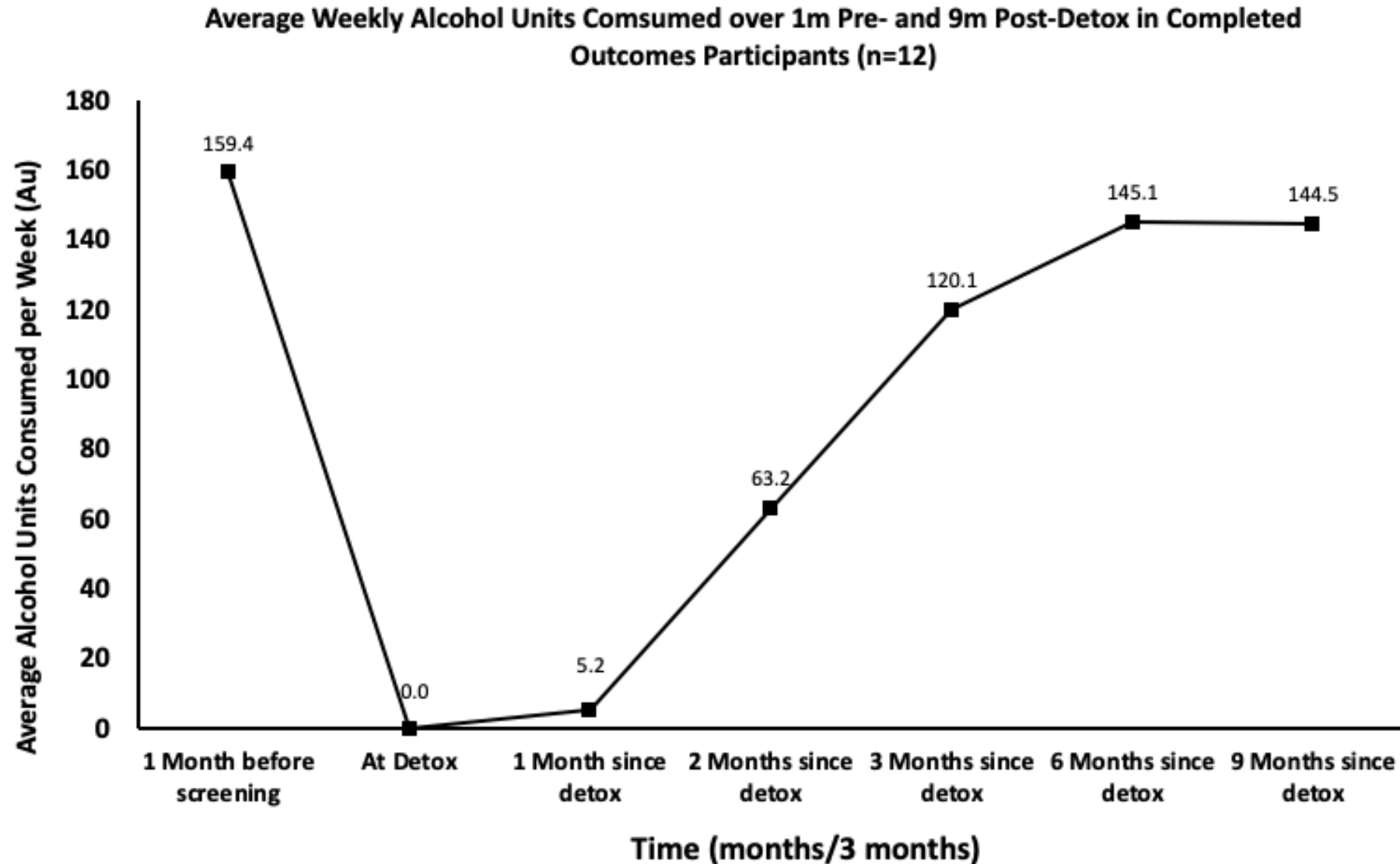
BIMA Drinking Behaviour Data:



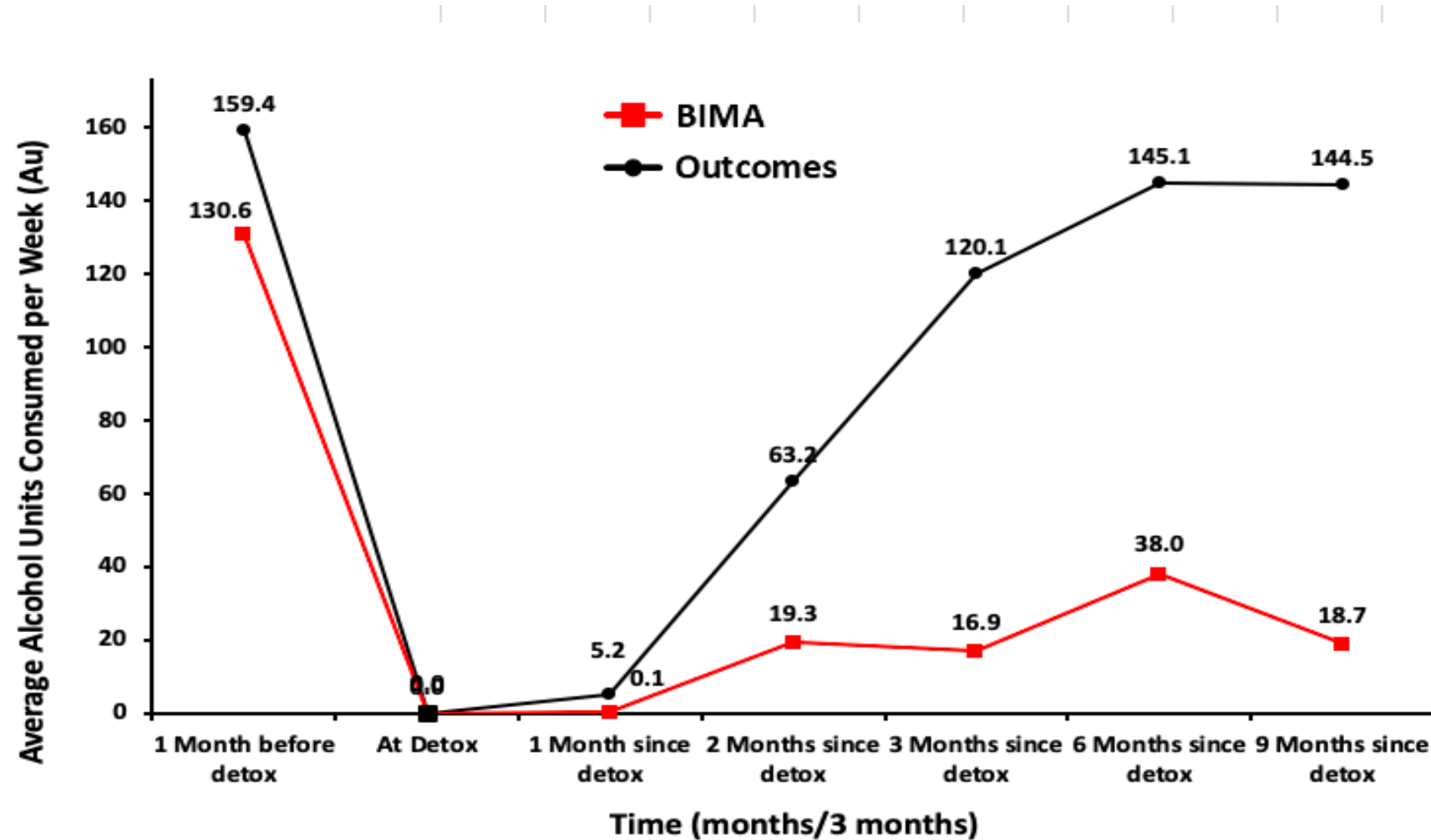
BIMA Drinking Behaviour Data:

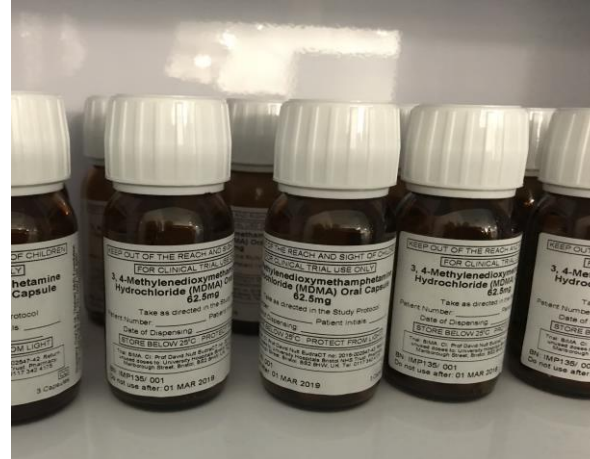


The OUTCOMES (Observational) Study:



BIMA Drinking Behaviour Data:





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

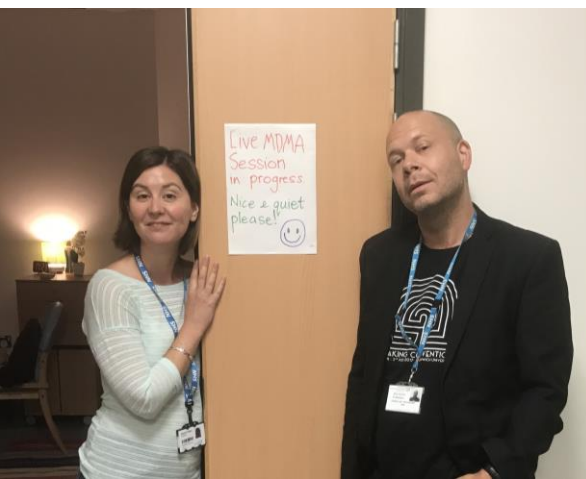
"For the first time in my life I can see clearly why I have been drinking and what I need to do to stop."

"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."



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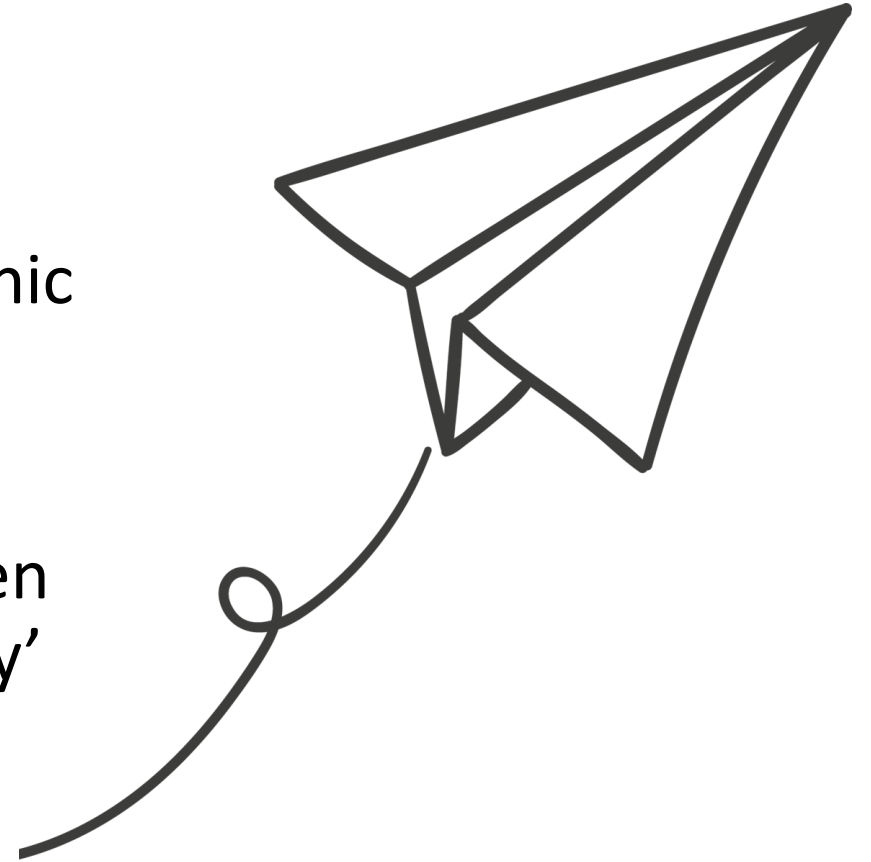
THE
LANCET

BMJ



The Future for MDMA-Assisted Psychotherapy?

- Much more than just PTSD
- Trauma (of some kind) underlies most chronic mental disorders
- Especially addictions
- MDMA (like classic psychedelics) can be seen as a 'non-specific adjuncts to psychotherapy' (Grof)
- So what are we doing in Bristol now.....???





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psychedelic research



PSYCHEDELIC CLINICS

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Dr. Ben Sessa
Chief Medical Officer



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Dr. Laurie Higbed
Lead Psychologist



Dr. Dawn DeCunha
Advisor



Dr. Mike Hart
Advisor