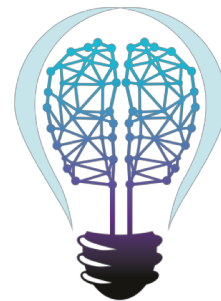


A new paradigm  
for mental health  
in Australia:  
**Medicinal psilocybin &  
MDMA to assist  
psychotherapy**



**MIND MEDICINE**  
A U S T R A L I A

# Mental illness in Australia - prevalence

- One in five (4.8 million) Australians aged 16-85 have current and chronic mental health or behavioural condition.
- Over 45% of Australians will experience mental illness in their lifetime.
- Most common mental illnesses in Australia are depression, anxiety, and substance use disorders (often occurring together).



Australian Bureau of Statistics 2018, National Health Survey First Results, cat. no. 4364.0.55.001, ABS, Canberra.  
 Australian Bureau of Statistics 2009, National Survey of Mental Health and Wellbeing: Summary of Results, 4326.0, 2007. ABS: Canberra.

# Mental illness in Australia - costs

- Adults with mental or behavioural illness nearly twice as likely to be unemployed or out of labour force (37.8%) than others (20.5%).
- Direct costs of mental illness at least \$28.6 billion annually, 2.2% of Australian GDP (in 2011).

Figure 7: Estimated direct health expenditure on mental health services in 2010-11 (\$m)

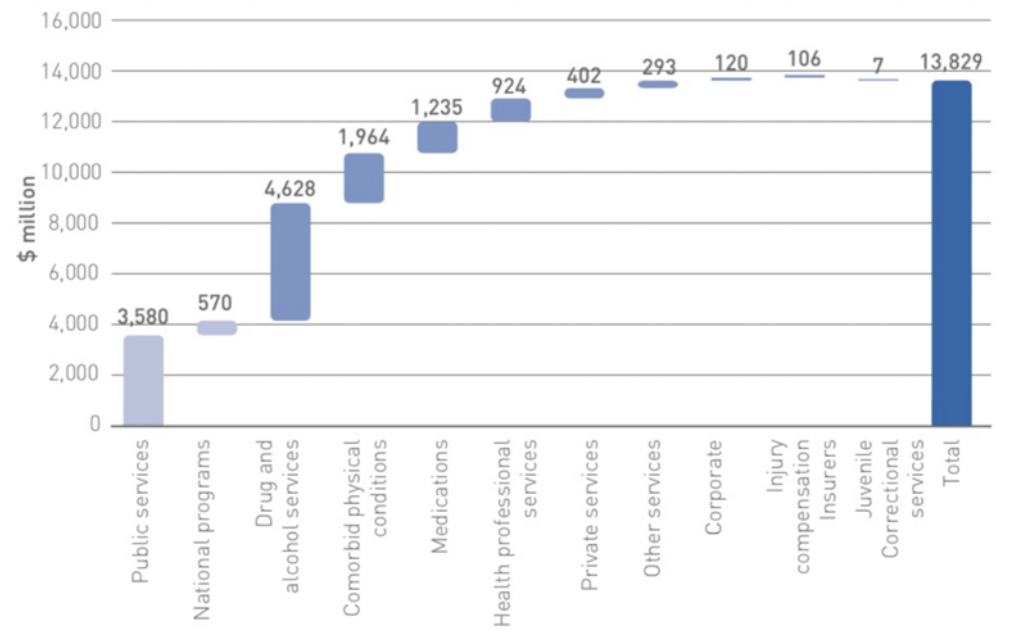
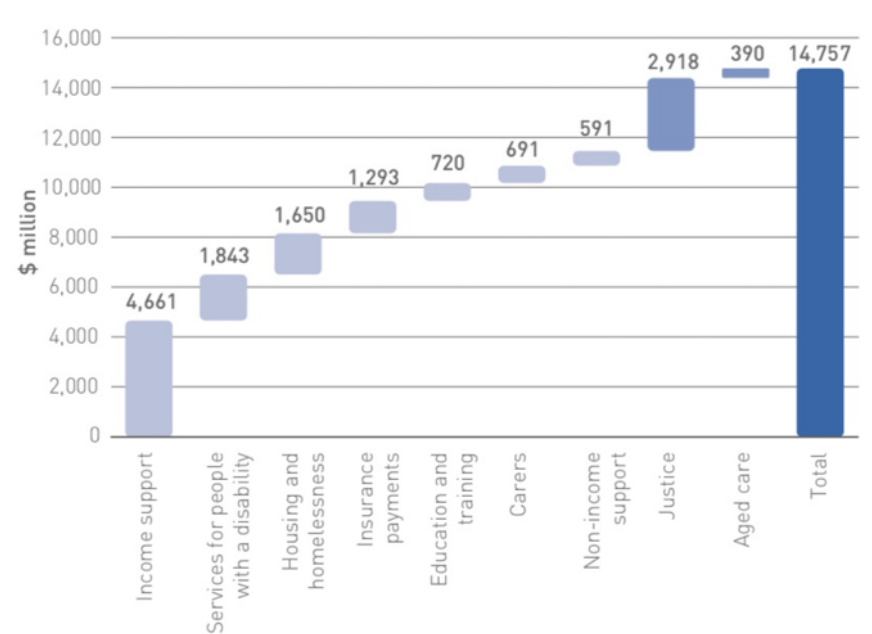


Figure 9: Estimated direct non-health expenditure to support people with mental illness in 2010-11 (\$m)



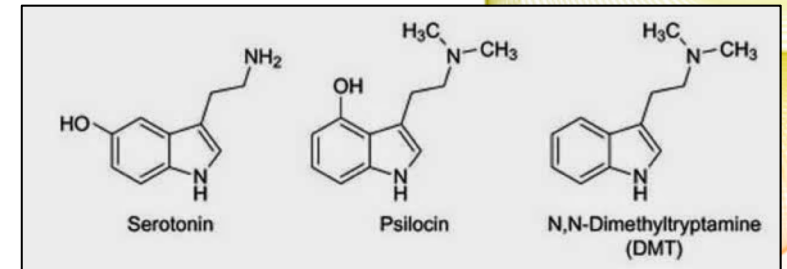
# Mental illness treatment outcomes

- In spite of vast global effort to understand and treat mental illness over decades, effectiveness of treatment remains inadequate.
- Eg: only 40 to 60% of depressed individuals respond to chemical or talk therapies, majority responders continue to experience sub-diagnostic symptoms, 50% to 80% relapse when treatment stops.
- With soaring rates, debilitating cost to life and economy, inadequate treatment options, and increasing rates of major mental illnesses, new approaches are urgently needed.

Belsher, G., & Costello, C. G. (1988). Relapse after recovery from unipolar depression: a critical review. *Psychological bulletin*, 104(1), 84.  
Hollon, S. D., Thase, M. E., & Markowitz, J. C. (2002). Treatment and prevention of depression. *Psych Science in the Public Interest*, 3(2), 39-77.  
Judd, L. L. (1997). The clinical course of unipolar major depressive disorders. *Archives of General Psychiatry*, 54(11), 989.

# What is Psychedelic-assisted Psychotherapy?

- 'Talk-therapy' alongside ingestion of medicinal psilocybin or MDMA.
- Therapy program with three distinct phases: (1) preparation; (2) acute medicinal experience; (3) integration.
- Approach emphasis: 'set and setting'; non-avoidance and curiosity; non-directive support during acute stage; respect for process.
- Experience commonly includes substantial increases in empathy, self-compassion, insightfulness, connectedness, meaningfulness.
- Facilitated by clinical psychologists and psychiatrists within appropriate medical facilities (MDs, nurses, equipment), but decorated as a living room to satisfy adequate 'setting'



# 30-year political suppression of psychedelic research and treatment

John Ehrlichman (senior Nixon aide) on War on Drugs:

*"The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the anti-war left and black people. You understand what I'm saying? We knew we couldn't make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did."*

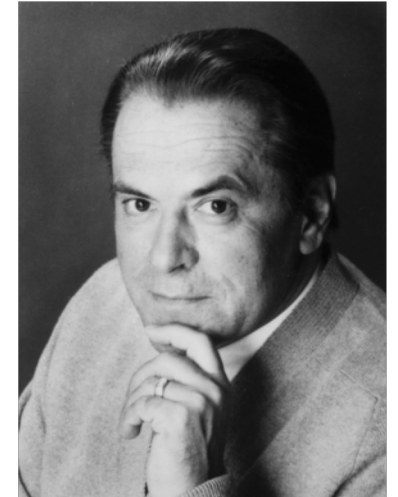
- Psychedelic use criminalised (Schedule 1)
- All research funding ceased
- Leary: 'most dangerous man' in America



# The Psychedelic Renaissance

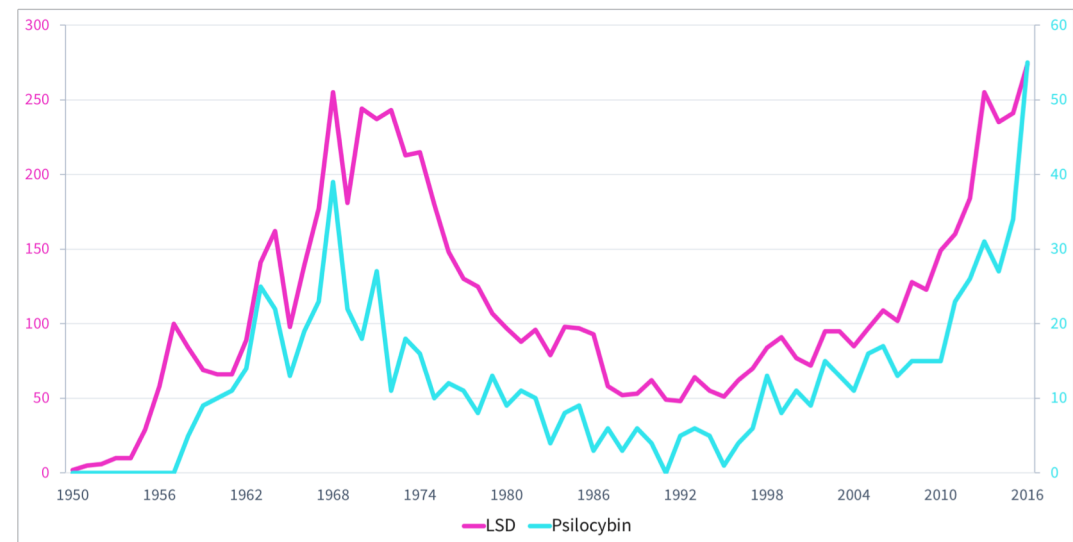
Dr Stanislav Grof, Psychiatrist and pioneering psychedelic researcher:

*"It does not seem to be an exaggeration to say that psychedelics, used responsibly and with proper caution, would be for psychiatry what the microscope is for biology and medicine or the telescope is for astronomy."*



## Current or recently completed trials:

- Psilocybin - 32 trials
- LSD - 8 trials
- Ayahuasca - 1 trial
- Ibogaine - 4 trials
- Salvinorin A - 4 trials
- MDMA - 48 trials



# Psilocybin and MDMA Results

- Medicinal MDMA effective for Post-Traumatic Stress Disorder (**PTSD**).
- Medicinal **psilocybin** and other 'classical psychedelics' (e.g., LSD, ayahuasca, iboga) effective for **depression, anxiety, addiction**.
- Phase 1 and 2 trial results have been remarkable in terms of the **strength, speed, and enduring outcomes** of the treatment effect.
- **Only 2-3 dosed sessions** with lasting impact (contrast conventional treatments: involves daily medication or weekly psychotherapy over long-term)
- Due to compelling results and urgent need, FDA has designated medicinal psilocybin and MDMA with '**breakthrough therapy**' status (fast-tracked).
- Current Phase 3 trials underway: **positive results will lead to schedule change and prescription regulation**.

Johnson, M et al. (2014). 5-HT<sub>2A</sub>R agonist psilocybin in the treatment of tobacco addiction. *Journal of Psychopharmacology*, 28-11:983-992.

Ross et al. (2016). Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial. *Journal of Psychopharmacology*, 30-12:1165-1180.

Carhart-Harris et al. (2016). Psilocybin with psychological support for treatment-resistant depression. *The Lancet*, 3-7:619-627.

Nutt, D. J., King, L. A., & Phillips, L. D. (2010). Drug harms in the UK: a multicriteria decision analysis. *The Lancet*, 376(9752), 1558-1565.



# Remarkable Treatment Outcomes

- Most *effective* treatments for mental illness show *effect sizes* in the order of  **$d=0.5$**  (a measure of treatment benefit, where 0.2='small'; 0.5='medium'; 0.8='large')
- **Psychedelic-assisted Psychotherapy effects are 'off the charts'**
  - Psilocybin for depression:  **$d=2.0-3.1$**
  - Psilocybin for end-of-life distress:  **$d=0.8-1.6$**
  - Psilocybin for alcoholism:  **$d=1.2-1.4$**
  - LSD for end-of-life distress:  **$d=1.1-1.2$**
  - MDMA for PTSD:  **$d=1.17-1.24$**



Psilocybin

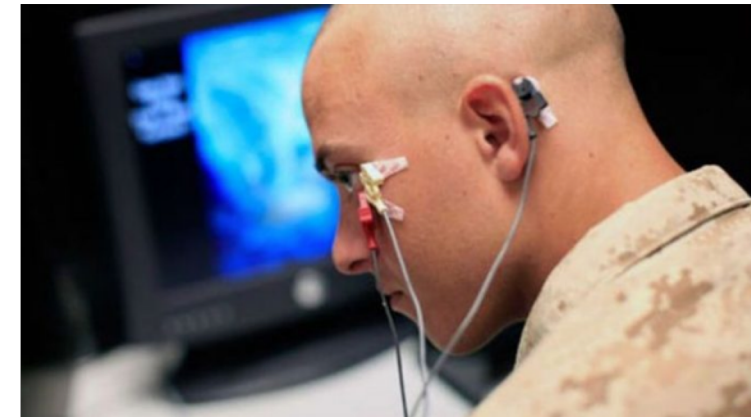


Placebo

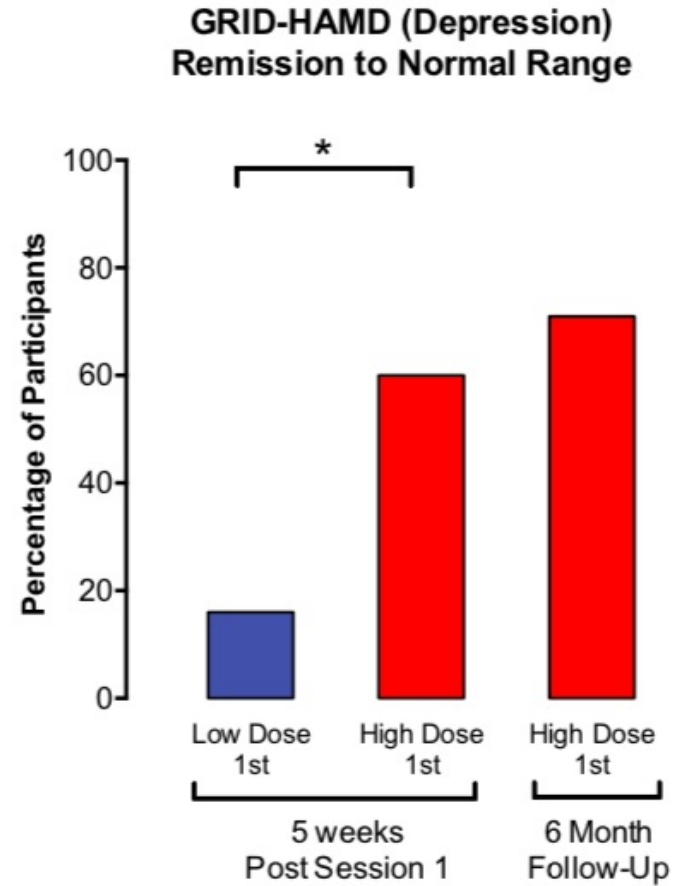
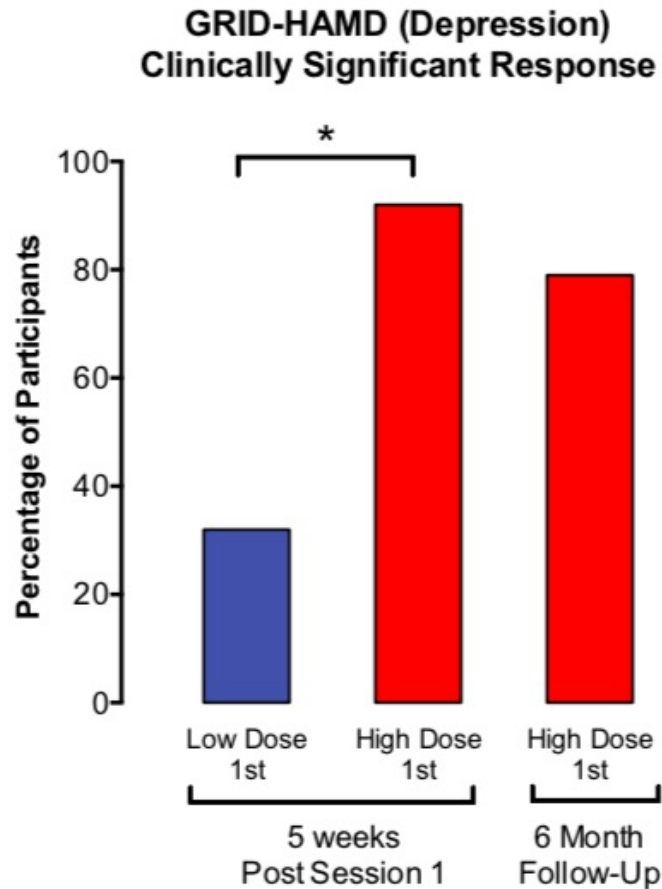
Schenberg, E. E. S. (2018). Psychedelic-assisted psychotherapy: a paradigm shift in psychiatric research and development. *Frontiers in pharmacology*, 9, 733.  
 Petri, G., Expert, P., Turkheimer, F., Carhart-Harris, R., Nutt, D., Hellyer, P. J., & Vaccarino, F. (2014). Homological scaffolds of brain functional networks. *Journal of The Royal Society Interface*, 11(101), 20140873.

# MDMA-assisted Psychotherapy

- MAPS Phase 2 trials: 107 participants, all treatment-resistant (average duration of PTSD=17.8 years); 56% no longer qualified for PTSD at 2-month follow-up, 68% had no PTSD at 12-months.
- Substantially better than psychotherapy alone.
- Sustained long-term benefits up to at least 4 years.
- All participants reported at least some persisting benefit.
- No negative effects on cognitive function; clinical studies of MDMA in nearly 800 participants, only 1 serious adverse event.

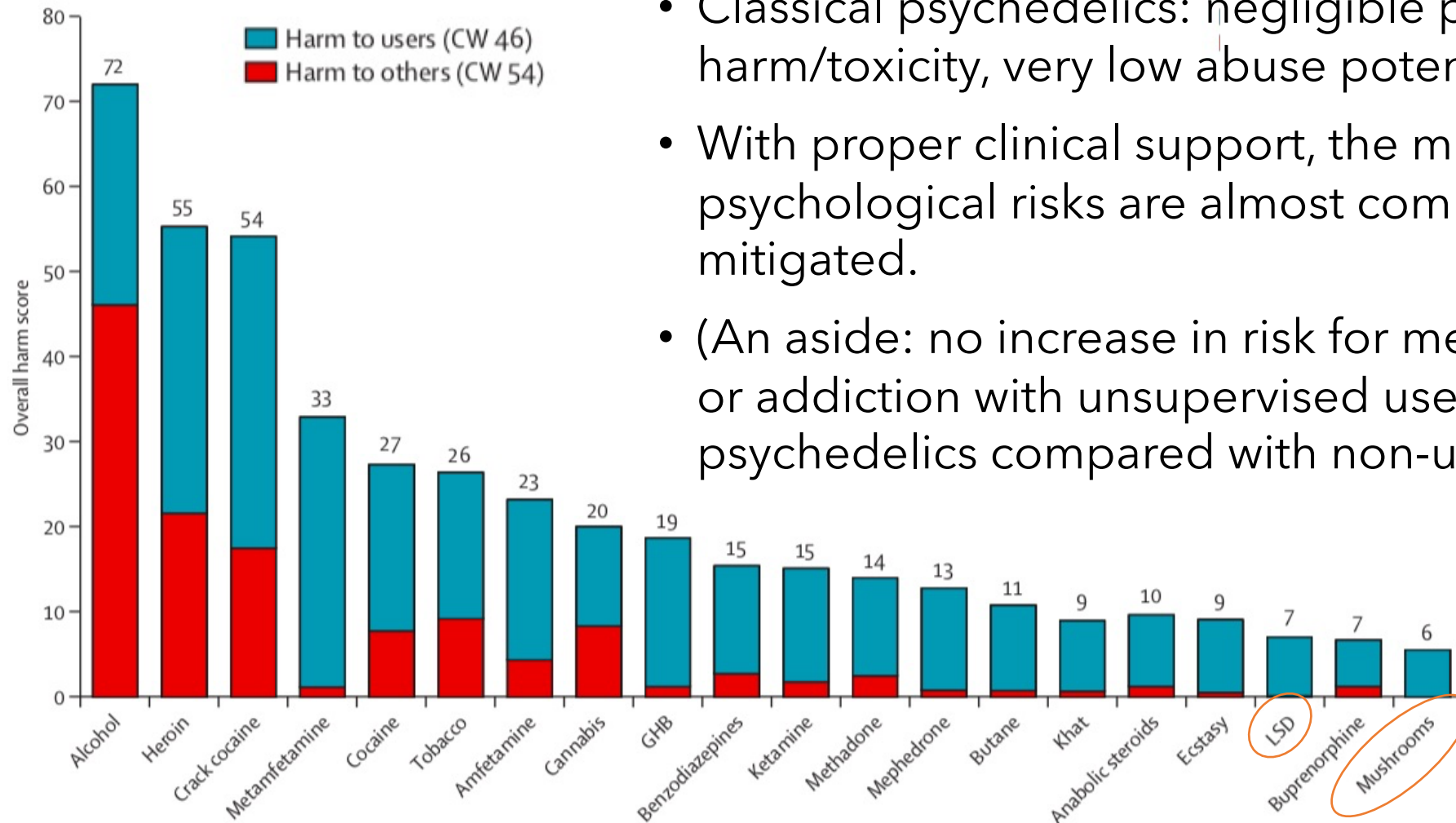


# Psilocybin-assisted Psychotherapy Sustained Outcomes



Griffiths, R. R. et al. (2016). Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. *Journal of psychopharmacology*, 30(12), 1181-1197.

# Safety of Psychedelic use



- Classical psychedelics: negligible physiological harm/toxicity, very low abuse potential.
- With proper clinical support, the minimal psychological risks are almost completely mitigated.
- (An aside: no increase in risk for mental ill-health or addiction with unsupervised use of classical psychedelics compared with non-use.)

# Example institutions with active psychedelic research program

HARVARD  
UNIVERSITY



UCLA



UNIVERSITY OF  
OXFORD

Imperial College  
London

UNIVERSITY OF  
CAMBRIDGE

CARDIFF  
UNIVERSITY



NYU

UFERN  
UNIVERSIDADE FEDERAL DO RIO GRANDE DO NORTE



Yale University

PRIFYSGOL  
CAERDYDD

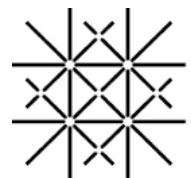
Maastricht  
University



University of  
Zurich<sup>UZH</sup>



University of  
BRISTOL



Universität  
Basel

UAB  
Universitat Autònoma  
de Barcelona



THE UNIVERSITY of  
NEW MEXICO

JOHNS HOPKINS  
MEDICINE  
SCHOOL OF MEDICINE

# Example empirical publications in leading journals

ORIGINAL INVESTIGATION

## Psilocybin can occasion mystical-type experiences having substantial and sustained personal meaning and spiritual significance

R. R. Griffiths · W. A. Richards · U. McCann · R. Jesse

Article

## Patients' Accounts of Increased "Connectedness" and "Acceptance" After Psilocybin for Treatment-Resistant Depression

Rosalind Watts<sup>1</sup>, Camilla Day<sup>1</sup>, Jacob Krzanowski<sup>1</sup>, David Nutt<sup>1</sup>, and Robin Carhart-Harris<sup>1</sup>

Journal of Humanistic Psychology  
2017, Vol. 57(5) 520–56  
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DOI: 10.1177/002216781770956  
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SPNAS

## Neural correlates of the LSD experience revealed by multimodal neuroimaging

Robin L. Carhart-Harris<sup>a,1</sup>, Suresh Muthukumaraswamy<sup>b,c,d</sup>, Leor Roseman<sup>a,e,2</sup>, Mendel Kaelen<sup>a,2</sup>, Wouter Droog<sup>b</sup>, Kevin Murphy<sup>a</sup>, Enzo Tagliazucchi<sup>f,g</sup>, Eduardo E. Schenberg<sup>h,i,j</sup>, Timothy Nestl<sup>a</sup>, Csaba Orban<sup>a,k</sup>, Robert Leech<sup>a</sup>, Luke T. Williams<sup>a</sup>, Tim M. Williams<sup>a</sup>, Mark Bolstridge<sup>a</sup>, Ben Sessa<sup>a,l</sup>, John McGonigle<sup>a</sup>, Martin I. Sereno<sup>m</sup>, David Nichols<sup>a</sup>, Peter J. Hellyer<sup>a</sup>, Peter Hobden<sup>b</sup>, John Evans<sup>b</sup>, Krish D. Singh<sup>b</sup>, Richard G. Wise<sup>b</sup>, H. Valerie Curran<sup>o</sup>, Amanda Feilding<sup>p</sup>, and David J. Nutt<sup>a</sup>

<sup>a</sup>Centre for Neuropsychopharmacology, Department of Medicine, Imperial College London, W12 0NN, London, United Kingdom; <sup>b</sup>Department of Psychology, Cardiff University Brain Research Imaging Centre, CF10 3AT, Cardiff, United Kingdom; <sup>c</sup>School of Pharmacy, University of Auckland, 1142 Auckland, New Zealand; <sup>d</sup>School of Psychology, University of Auckland, 1142 Auckland, New Zealand; <sup>e</sup>Computational, Cognitive and Clinical Neuroscience Laboratory, Department of Medicine, Imperial College London, W12 0NN, London, United Kingdom; <sup>f</sup>Institute of Medical Psychology, Christian Albrechts University, 24118 Kiel, Germany; <sup>g</sup>Brain Imaging Center and Neurology Department, Goethe University, 60528 Frankfurt am Main, Germany; <sup>h</sup>Dep.

Original Paper

## Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial

Roland R Griffiths<sup>1,2</sup>, Matthew W Johnson<sup>1</sup>, Michael A Carducci<sup>3</sup>, Annie Umbricht<sup>1</sup>, William A Richards<sup>1</sup>, Brian D Richards<sup>1</sup>, Mary P Cosimano<sup>1</sup> and Margaret A Klinedinst<sup>1</sup>

Psychopharm

Journal of Psychopharmacology  
2016, Vol. 30(12) 1181–1197  
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DOI: 10.1177/0269881116675513  
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## Enhanced Repertoire of Brain Dynamical States During the Psychedelic Experience

Enzo Tagliazucchi,<sup>1,\*</sup> Robin Carhart-Harris,<sup>2</sup> Robert Leech,<sup>3</sup> David Nutt,<sup>2</sup> and Dante R. Chialvo<sup>4</sup>

<sup>1</sup>Neurology Department and Brain Imaging Center, Goethe University, Frankfurt am Main, Germany  
<sup>2</sup>Imperial College London, Centre for Neuropsychopharmacology, Division of Experimental Medicine, London, United Kingdom  
<sup>3</sup>Computational, Cognitive and Clinical Neuroimaging Laboratory (C3NL), Division of Brain Sciences, Imperial College London, United Kingdom  
<sup>4</sup>Consejo Nacional de Investigaciones Científicas y Tecnológicas (CONICET), Buenos Aires, Argentina

## Implications for psychedelic-assisted psychotherapy: a functional magnetic resonance imaging study with psilocybin

R. L. Carhart-Harris, R. Leech, T. M. Williams, D. Erritzoe, N. Abbasi, T. Bargiotas, P. Hobden, D. J. Sharp, J. Evans, A. Feilding, R. G. Wise and D. J. Nutt

Articles

## Pilot study of the 5-HT<sub>2A</sub>R agonist psilocybin in the treatment of tobacco addiction

Matthew W Johnson<sup>1</sup>, Albert Garcia-Romeu<sup>1</sup>, Mary P Cosimano<sup>1</sup> and Roland R Griffiths<sup>1,2</sup>

Psychopharm

## THE LANCET Psychiatry

## Psilocybin with psychological support for treatment-resistant depression: an open-label feasibility study

Robin L. Carhart-Harris, Mark Bolstridge, James Rucker<sup>a</sup>, Camilla M J Day<sup>a</sup>, David Erritzoe, Mendel Kaelen, Michael Bloomfield, James A Rickard, Ben Forbes, Amanda Feilding, David Taylor, Steve Pilling, Valerie H Curran, David J Nutt

## Neural correlates of the psychedelic state as determined by fMRI studies with psilocybin

Robin L. Carhart-Harris<sup>a,b</sup>, David Erritzoe<sup>a,c</sup>, Tim Williams<sup>b</sup>, James M. Stone<sup>a</sup>, Laurence J. Reed<sup>a</sup>, Alessandro Colasanti<sup>a</sup>, Robin J. Tyacke<sup>a</sup>, Robert Leech<sup>d</sup>, Andrea L. Malizia<sup>b</sup>, Kevin Murphy<sup>e</sup>, Peter Hobden<sup>e</sup>, John Evans<sup>e</sup>, Amanda Feilding<sup>f</sup>, Richard G. Wise<sup>e</sup>, and David J. Nutt<sup>a,b,1</sup>

## Psychedelics Promote Structural and Functional Neural Plasticity

Calvin Ly,<sup>1</sup> Alexandra C. Greb,<sup>1</sup> Lindsay P. Cameron,<sup>2</sup> Jonathan M. Wong,<sup>2</sup> Eden V. Barragan,<sup>2</sup> Paige C. Wilson,<sup>3</sup> Kyle F. Burbach,<sup>4</sup> Sina Soltanzadeh Zarandi,<sup>1</sup> Alexander Sood,<sup>5</sup> Michael R. Paddy,<sup>3</sup> Whitney C. Duim,<sup>1</sup> Megan Y. Dennis,<sup>4,6,7</sup> A. Kimberley McAllister,<sup>5,8,9</sup> Kassandra M. Ori-McKenney,<sup>3</sup> John A. Gray,<sup>5,8</sup> and David E. Olson<sup>1,5,6,10,\*</sup>

<sup>1</sup>Department of Chemistry, University of California, Davis, Davis, CA 95616, USA

<sup>2</sup>Neuroscience Graduate Program, University of California, Davis, Davis, CA 95618, USA

<sup>3</sup>Department of Molecular and Cellular Biology, University of California, Davis, Davis, CA 95616, USA

<sup>4</sup>Genome Center, University of California, Davis, Davis, CA 95616, USA

<sup>5</sup>Center for Neuroscience, University of California, Davis, Davis, CA 95618, USA

<sup>6</sup>Department of Biochemistry and Molecular Medicine, School of Medicine, University of California, Davis, Sacramento, CA 95817, USA

<sup>7</sup>MIND Institute, University of California, Davis, Sacramento, CA 95817, USA

<sup>8</sup>Department of Neurology, School of Medicine, University of California, Davis, Sacramento, CA 95817, USA

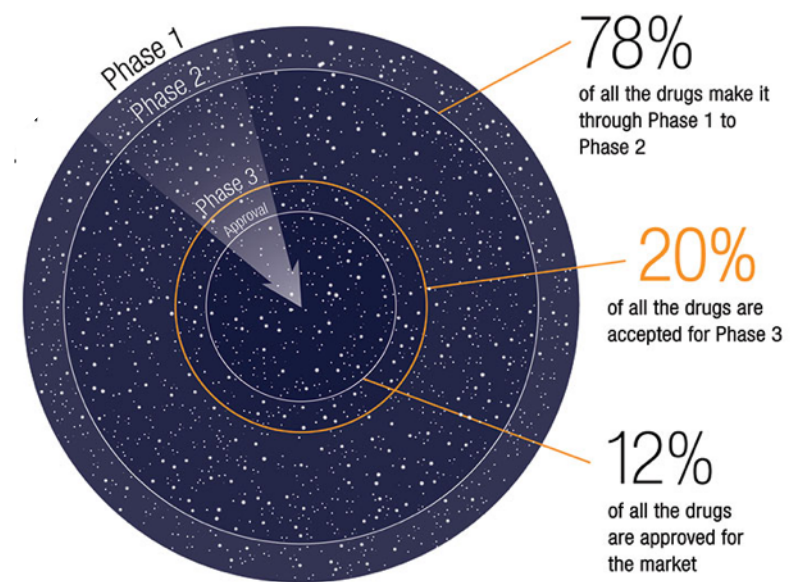
<sup>9</sup>Department of Neurobiology, Physiology, and Behavior, University of California, Davis, Davis, CA 95616, USA

IAS

# Results that are Breaking Through

- FDA '**breakthrough therapy**' designation for medicinal psilocybin and MDMA: only given to treatments for serious conditions that shows signs of being substantially better than available treatment.
- Israeli Ministry of Health '**compassionate use**' decision to provide MDMA-assisted psychotherapy to PTSD sufferers outside of a clinical trial, due to lack of effective alternatives.
- Denver (Colorado) will vote whether to **decriminalise** psilocybin possession in May 2019, and Oregon state will vote whether to fully **legalise** psilocybin in 2020

## The Universe of FDA Drug Approval



# Psychedelic Research – Australia's first trial

- First in Australia: Psilocybin-assisted psychotherapy for treatment of Australian palliative care patients who are experiencing depression and anxiety.
- Double-blind, placebo-controlled trial, 30 participants.
- Recruitment commences first half of 2019.
- Trial site and team from St Vincent's Hospital, sponsored by PRISM, funded by Mind Medicine Australia and Vasudhara.

125  
YEARS



ST VINCENT'S  
HOSPITAL  
MELBOURNE

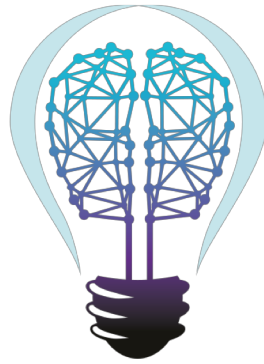


MIND MEDICINE  
AUSTRALIA



VASUDHARA





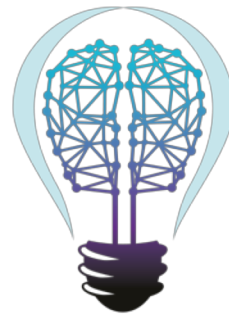
# MIND MEDICINE

## A U S T R A L I A

A registered charity (DGR-1 status) seeking to establish **safe and effective** psychedelic-assisted treatments for mental illness in Australia.

Operates as a nexus between medical practitioners, academia, government, regulatory bodies, philanthropists, and other partners.

Focus is wholly **clinical** - we do not advocate for recreational use, nor for changes to the law with respect to recreational use.



# MIND MEDICINE

## A U S T R A L I A

### Core aims:

1. **Reduce delay** between availability of adequate evidence and regulatory approval and implementation
2. Increase likelihood of **best practice** implementation following regulatory approval

### Broad activities:

- Research
- Education and events
- Partnerships
- Regulation and policy development
- Training and accreditation

# Who We Are

## Board of Directors



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CHAIR



Tania de Jong AM  
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Monojit Ray  
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Admiral Chris Barrie AC  
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Prof David Castle  
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Luke Mitchell  
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## Management



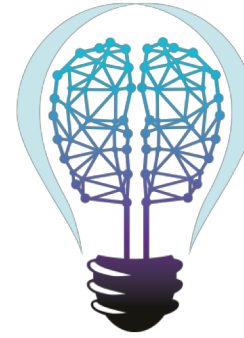
Dr Paul Likhaitzky  
Executive Officer



Melissa Warner  
Education Officer



Dr Martin Williams  
Scientific Officer



# MIND MEDICINE A U S T R A L I A

## Ambassadors



Professor David Nutt (UK)



Dr Rick Doblin (USA)



Dr Ben Sessa (UK)

## Advisory Panel



Prof Avni Sali AM  
Surgeon and Academic,  
Integrative Medicine



Patrycja Slawuta (USA)  
Behavioural Scientist



Dr David Caldicott  
Emergency Medicine  
Consultant



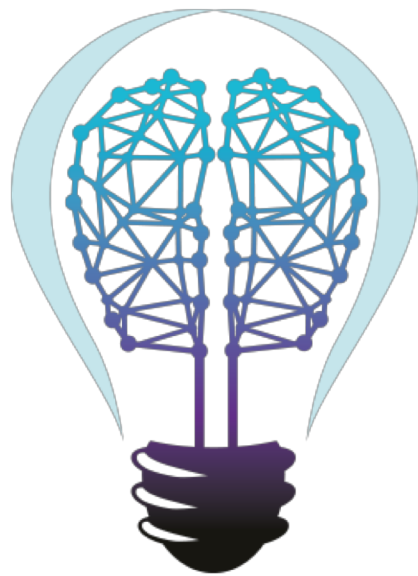
Dr Alex Wodak  
Physician



Dr Nigel Strauss  
Psychiatrist

Over 45% of Australians will experience a serious mental health illness during their lifetimes.

*What are you going to do about it?*



Join us!

**MindMedicineAustralia.org**

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