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

Carhart-Harris et al. (2016). Psilocybin with psychological support for treatment-resistant depression. The Lancet, 3-7:619-627.
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: $d=1.17-1.24$

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

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
- Imperial College London
- University of Oxford
- NYU
- University of UFRN
- University of Cambridge
- Yale University
- Cardiff University
- Prifysgol Caerdydd
- University of Bristol
- Maastricht University
- University of Zurich (UZH)
- Johannes Gutenberg University of Mainz
- Universitat Autònoma de Barcelona
- The University of New Mexico
- Johns Hopkins University 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, and R. Jesse

Neural correlates of the LSD experience revealed by multimodal neuroimaging
Robin L. Carhart-Harris, 1,2,3,4,5 Suresh Muthusubramaniam, 1,2,6,7,8,9 Leon Rosenbaum, 1,2,6,7,8,9,10 Mendel Kaelber, 1,2,6,7,8,9,10 Wouter Droog, 1,2,6,7,8,9 Kevin Murphy, 1,2,6,7,8,9 Enoa Tagliazucchi, 1,2,6,7,8,9,10 Eduardo S. Schenberg, 1,2,6,7,8,9,10 Timothy Redf, 1,2,6,7,8,9 Csaba Orbai, 1,2,6,7,8,9 Robert Leech, 1,2,6,7,8,9 Luke T. Williams, 1,2,6,7,8,9 Tim M. Williams, 1,2,6,7,8,9 Mark Bodnarski, 1,2,6,7,8,9 Ben Novak, 1,2,6,7,8,9 John McGregor, 1,2,6,7,8,9 Martin J. Sereno, 1,2,6,7,8,9 David Nichols, 1,2,6,7,8,9 Peter J. Helyer, 1,2,6,7,8,9 Peter Hobden, 1,2,6,7,8,9 John Evans, 1,2,6,7,8,9 Krish D. Singh, 1,2,6,7,8,9 Richard G. Wise, 1,2,6,7,8,9,11,12 Valerie Carson, 1,2,6,7,8,9 Amanda Feilding, 1,2,6,7,8,9,10,11 and David J. Nutt 1,2,6,7,8,9,10,11

Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial
Roland R. Griffiths, 1–2, Matthew W. Johnson, 1 Michael A. Carducci, 1 Annie Umbricht, 1 William A. Richards, 1 Brian D. Richards, 1 Mary P. Cosimano, 1 and Margaret A. Klinefelter 1

Enhanced Repertoire of Brain Dynamical States During the Psychedelic Experience
Enzo Tagliazucchi, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Robin Carhart-Harris, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Robert Leech, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 David Nutt, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and Dante R. Chialvo 1, 2, 3, 4, 5, 6, 7, 8, 9, 10

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

Psilocybin with psychological support for treatment-resistant depression: an open-label feasibility study
Robin L. Carhart-Harris, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 Matt Budde, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 James Rusk, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 Gemma McDonagh, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 David Orton, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 Mendieta, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 Michael R. Bremfield, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 James A. Rickard, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 Ben Farley, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 Amanda Feilding, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 David Taylor, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 Steen Polo, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 Vanessa Conran, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11

Neural correlates of the psilocybin state as determined by fMRI studies with psilocybin
Robin L. Carhart-Harris, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 David Erritzoe, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Tim Williams, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 James M. Stone, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Laurence J. Reed, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Alessandro Colasanti, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Robyn J. Tyacke, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Robert Leech, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Andrea L. Malizia, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Kevin Murphy, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Peter Hobden, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 John Evans, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Amanda Feilding, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 Richard G. Wise, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 and David J. Nutt, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10

Implications for psychedelic-assisted psychotherapy: a functional magnetic resonance imaging study with psilocybin
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
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.
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.
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
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Over 45% of Australians will experience a serious mental health illness during their lifetimes.

*What are you going to do about it?*