

A New Treatment Paradigm for Mental Illness in Australia: Medicine-Assisted Psychotherapy



MIND MEDICINE
A U S T R A L I A

Outline

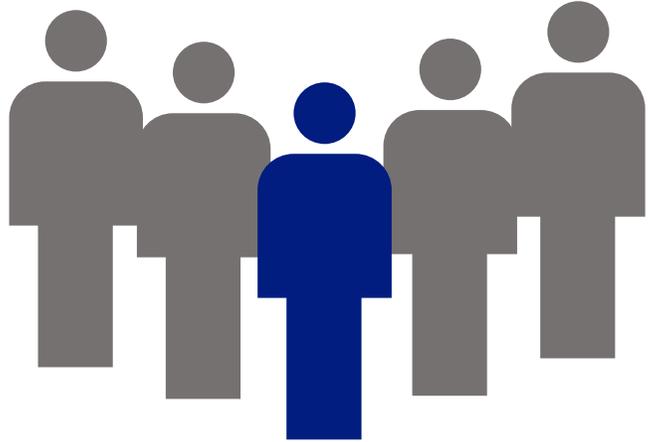


1. The Scale of the Problem in Australia
2. Mind Medicine Australia; Purpose and People Involved
3. Leveraging These “Breakthrough Therapies”
4. Delivering Outstanding Clinical Results
5. Involvement of Major Institutions
6. Viewed from a Historical Context
7. Our Strategy

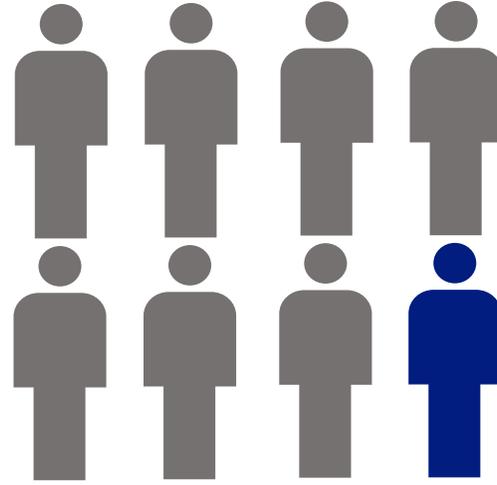


1. The Scale of the Problem in Australia

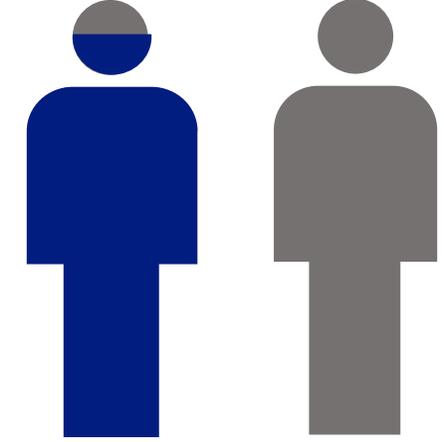
Mental Illness Now at Alarming Levels and Getting Worse



1 in 5 Australian adults
(4.8 million people)
have a chronic mental illness



1 in 8 Australians are now on
anti-depressants including 1 in
4 older Australians
(18% increase in last 5 years
95% increase in last 15 years)



Over 45% of Australians will
experience mental illness in
their lifetime

- The most common mental illnesses are:

Post-Traumatic Stress Disorder (PTSD), Other Anxiety Disorders, Depression and Substance use Disorders

With Even Worse Outcome for ADF Veterans & First Responders



	General Population*	ADF Veterans
Criteria (over 12 month period) for:	%	%
Mental Disorders	20	46
PTSD	6.4	17.7
Depression Episodes	4.1	11.2
Alcohol Disorder	4.3	12.9
Suicidal Ideation (Plans or Attempts)	2.2	21.7
Co-Morbidity	8.5	55.2

- 10% of **First Responders** have PTSD and 1 in 3 First Responders suffer from high psychological distress. They have suicidal thoughts at two times the rate of adults in the general population and one First Responder takes his or her own life every 6 weeks. (Beyond Blue)

*above 16 years of age

Veterans Information- Mental Health Prevalence: Department of Veterans Affairs 2018

General Population- 2007 National Survey of Mental Health & Wellbeing (ABS)

Leading to Massive People and System Costs



- Massive impact on sufferers, families and carers.
- Adults with a mental illness nearly twice as likely to be **unemployed** or out of the labor force than other Australians. There is also a strong correlation between **natural disasters** and mental illness.
- Mental illness is a primary cause of both **suicide** and **homelessness**.

The Australian Productivity Commission (2019 draft report)

Direct costs of mental ill-health and suicide (a conservative estimate)	\$43 - \$51 billion per year
Diminished health & life expectancy for those living with mental illness	\$130 billion cost per year
Total cost of mental illness and suicide to the Australian economy	~\$180 billion cost per year

Data from the Productivity Commission, Mental Health, Draft Report and Deloitte Access Economics.

But Treatment Outcomes Remain Inadequate



- There has been no improvement in treatment outcomes over the past 50 years.
- **Depression:** Only 35% of sufferers experience *remission* from pharmacotherapy (primarily anti-depressants) or psychotherapy.
 - 40-60% show some response but most experience some continuing symptoms – and between **50 - 80% relapse after treatment stops.**
 - Common side-effects of anti-depressants include insomnia, blurred vision, dry mouth, fatigue, GI distress, weight gain, nausea and sexual dysfunction.
- **PTSD:** Only 20 - 30% of sufferers show some *response* to pharmacotherapy and only about 50% respond to any treatments. *Remission* rates much lower.

A “more of the same approach” is not going to solve the problem.

Holmes et al (2018) and Cuijpers (2017)

De Maat et al (2006) Relative efficacy of psychotherapy and pharmacotherapy in the treatment of depression: A meta analysis 16(5): 566-578

Judd, L. L. (1997). The clinical course of unipolar major depressive disorders. Archives of General Psychiatry, 54(11), 989.



2. Mind Medicine Australia Purpose and People Involved

Purpose of Mind Medicine Australia



- Australian registered charity (with DGR-1 status) seeking to broaden the treatment paradigm available to medical practitioners and their patients and improve treatment effectiveness by establishing, safe, accessible and effective Medicine-Assisted Psychotherapy in Australia for major Mental Illnesses.
- Primary focus on Medical Psilocybin (for Depression) and Medicinal MDMA (for PTSD) Psychotherapies.
- Indications of success:
 - These therapies become an **integral part** of our Mental Health System;
 - With **high remission rates** leading to a **substantial improvement** in our Mental Health Statistics;
 - And **accessible** and **affordable** to all Australians in need.

Board of Directors



Board



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Engaged Philanthropist*



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Business Entrepreneur.
Previous director at
Haven Foundation*

Management & Ambassadors



Management



Tania de Jong AM
Executive Director

Social entrepreneur, business woman, global speaker and soprano



Ilan Hayman
Operations Manager

10 years business operations experience across NFP & healthcare sectors. PwC Alumnus



Melissa Warner
Education and Communications Officer
Neuroscientist & Management Committee of PRISM.



Erin Whelan
Office & Events Administrator
Extensive experience in Events Management. Masters in Public Health.



Dr Martin Williams
Scientific Officer
Post doctoral fellow at Monash University & President of PRISM

Ambassadors



Dr Rick Doblin (USA)
Executive Director of MAPS, sponsor of the Phase 3 Trial of MDMA-Assisted Psychotherapy for the treatment of PTSD



Prof Roland Griffiths (USA)
Head of the Centre for Psychedelic and Consciousness Research at Johns Hopkins University school of Medicine



Prof David Nutt (UK)
Head of Neuropsychopharmacology at Imperial College London



Dr Ben Sessa (UK)
Psychiatrist and Author of the "Psychedelic Renaissance". Currently leading the world's first clinical study using MDMA to treat alcohol addiction

Advisory Panel Members



Psychiatrists



Prof David Forbes
*Director Phoenix
Australia, Centre for
Posttraumatic Mental
Health*



Prof Jayashri Kulkarni
*Professor of Psychiatry,
The Alfred, Monash
University*



Dr James Rucker (UK)
*Consultant Psychiatrist
& Senior Clinical
Lecturer at Kings
College London*



Dr Nigel Strauss
*Melbourne based
Consultant Psychiatrist*



Prof John Tiller
*Professor Emeritus of
Psychiatry, University
of Melbourne*

Researchers, Clinical Psychologists and Behavioural Scientists



Dr Robin Carhart-Harris
*Head of Centre for
Psychedelic Research,
Imperial College
London*



**A/Prof Matthew
Johnson**
*Psychedelic researcher,
Johns Hopkins
University*



Dr Paul Likhaitzky
*Research Psychologist,
Deakin University*



Prof. Greg Murray
*Clinical Psychologist,
Director Swinburne
University Centre for
Mental Health &
Fellow of APS*



Prof David Nichols
*Chemical Biology and
Medicinal Chemistry at
the University of North
Carolina*



Prof Janis Phelps
*Founder & Director of
the California Institute
of Integral Studies
Centre for Psychedelic
Therapies & Research*



Patrycja Slawuta
*Behavioural Scientist
based in New York*



Dr Rosalind Watts
*Lead of the Imperial
College, Psilocybin and
Depression Study*

Advisory Panel Members



Medical Practitioners



Dr David Caldicott
*Emergency Medicine
Consultant*



Dr Alex Wodak
*Physician and President
of Australian Drug Law
Reform Foundation*



Prof Avni Sali AM
*Founder & Director of
the National Institute of
Integrated Medicine*

Other Relevant Disciplines



Greg Barns
Barrister



Sean O'Carroll
*Psychotherapist in
private practice and
educator*



Wade Davis CM
*PhD & Professor of
Anthropology & Chair
of Cultures and
Ecosystems at Risk
University of British
Columbia*



Dennis McKenna
*PhD, Ethno-
pharmacologist, Author
& Founding Board
Member at the Heffter
Research Institute*



Thomas Pogge
*Philosopher & Director
of the Global Justice
Program at Yale*



Nigel Pollard
*Company director, Chair
Natural Health Science
Foundation Inc. NY*



3. Leveraging These “Breakthrough Therapies”

Expanding the Medical Treatment Options



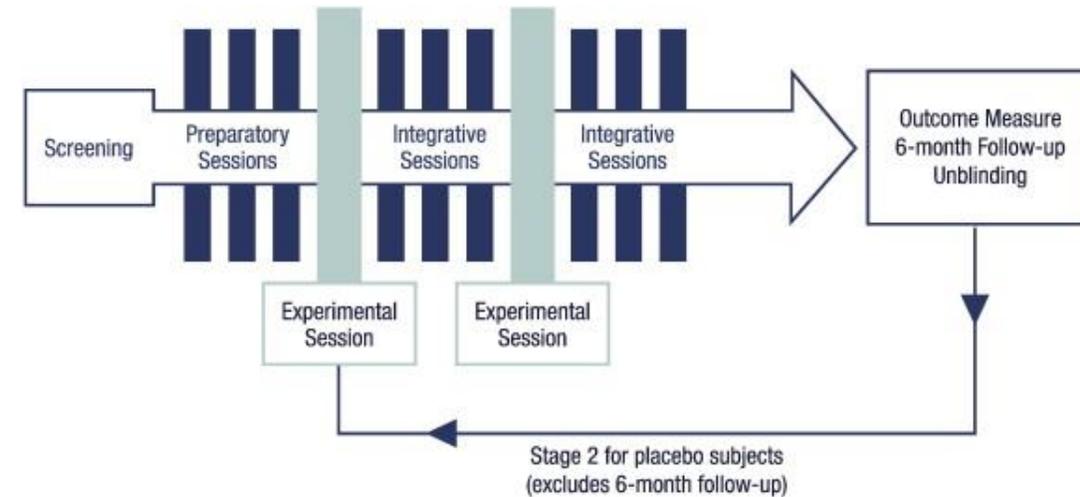
- Primary focus on two broad types of Medicine-Assisted Psychotherapies based on strong clinical evidence:
 1. **Medical Psilocybin** for ***Depression*** and possibly ***OCD*** and ***Addiction***.
 2. **Medicinal MDMA** for ***Post Traumatic Stress Disorder (PTSD)*** and possibly the treatment of ***Addiction***.
- Only 2-3 dosed sessions in contrast to conventional treatments (involving daily medications and/or weekly psychotherapy).
- Very Safe in a medically controlled environment and non-addictive.
- With both being granted “**Breakthrough Therapy Designation**” by the Food and Drug Administration (FDA) in the United States to fast-track the approval process.



Administered in a Medically-Controlled Environment



- Three distinct phases: (1) preparation; (2) acute medicinal experience; (3) integration
- Facilitated by psychiatrists and psychologists within appropriate medical facilities (MDs, nurses, equipment)
- Emphasises non-avoidance and curiosity
- Commonly creates substantial increases in self-awareness, self-compassion, insight, connectedness and meaning



Example timeline for psychedelic assisted psychotherapy sessions

Multidisciplinary Association of Psychedelic Studies (MAPS)



With a Strong Medicinal Safety Record



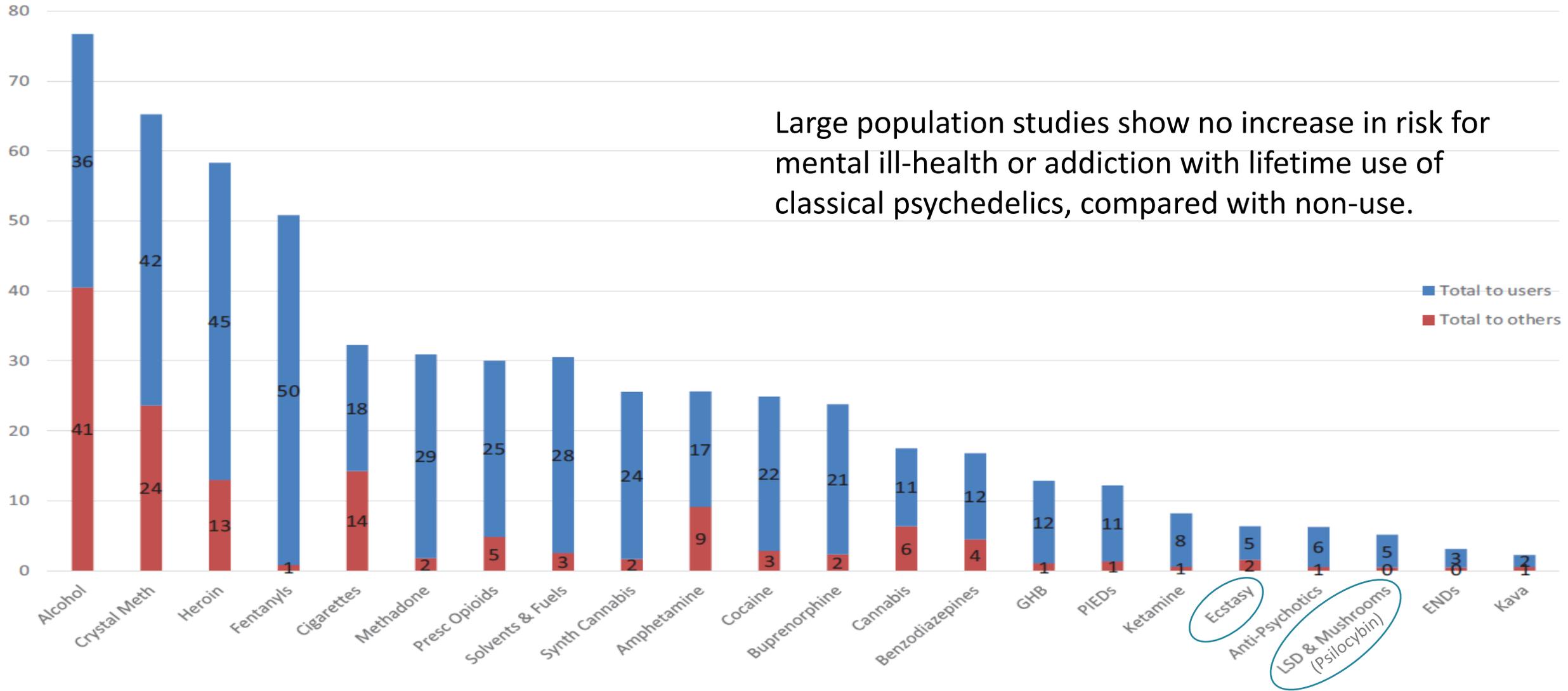
Medicinal Psilocybin

- Negligible physiological harm and toxicity with very low potential harm profile and **non-addictive**.
- With proper clinical support and screening, minimal psychological risks (fear, panic, re-traumatisation) are almost completely mitigated.
- A 2015 review found there to be no link between psychosis and psychedelic use.

Medicinal MDMA

- **High doses well in excess of therapeutic amounts** may be neurotoxic but strong safety record in a medically controlled environment with clear protocols and **non-addictive**.
- In clinical studies of MDMA in nearly 800 participants using medically controlled doses, only 1 adverse event (heart rate above pre-set limit) and this was rapidly resolved

And Strong Safety Evidence Across Broad Populations



Nutt, D and Castle, D, et al. (2019) The Australian drug harms ranking study, Journal of Psychopharmacology, Vol 33, Issue 7

Patient Testimonials



- *“There simply aren’t words to describe the experience but I can say that **the usual negative self-narration that I have had vanished completely**. It was replaced by a sense of beautiful chaos, a landscape of unimaginable colour and beauty. I began to see that all of my concerns about daily living weren’t relevant, that they were a result of a negative spiral. I also felt that I was learning without being taught, that intuition was being fed. Fleeting feelings from my past came back, memories too, both of which seemed long forgotten.”*
- *“Although it’s early days yet, **the results are amazing**. I feel more **confident and calm** than I have in such a long time. My outlook has changed significantly too, I’m more aware that it’s pointless to get wrapped up in endless negativity. [...] **At its most basic, I feel like I used to before the depression.**”*
- *“I felt like I went through **15 years of psychological therapy in one night.**”*



Psychedelic-assisted therapy session Multidisciplinary Association of Psychedelic Studies (MAPS).



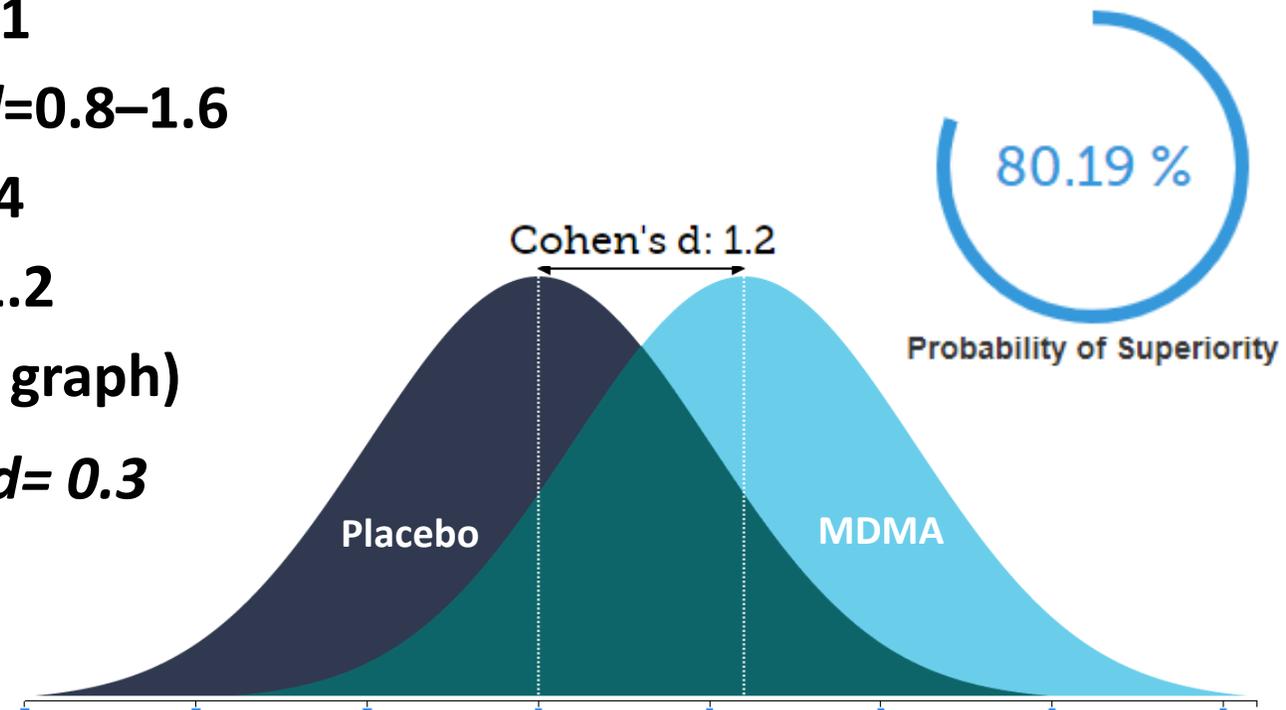
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4. Delivering Outstanding Clinical Results

Remarkable Treatment Outcomes



- Most **effective** treatments for mental illness show **effect sizes** in the order of **$d=0.5$** (where **0.2**=‘small’; **0.5**=‘medium’; **0.8**=‘large’ treatment benefit)
- 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: **$d=1.17-1.24$** (see graph)
- Antidepressants (SSRI’s) for depression: **$d= 0.3$**



Treating the Cause: Medicinal Psilocybin Assisted-Psychotherapy for Depression



Alters communication between brain networks, such as the Default Mode Network (DMN), which are associated with many mental illnesses

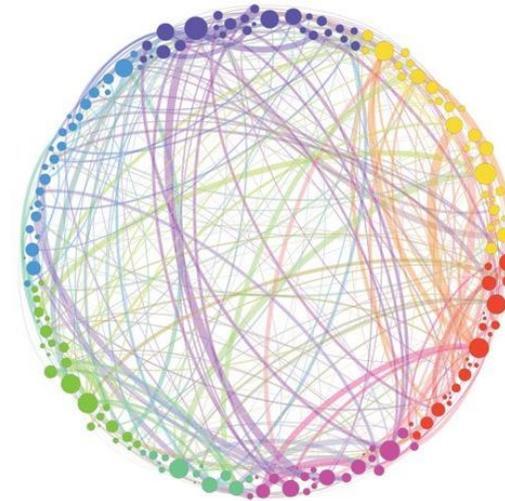


Enabling patients to ‘break out’ of repetitive and rigid styles of thinking, feeling and behaving.

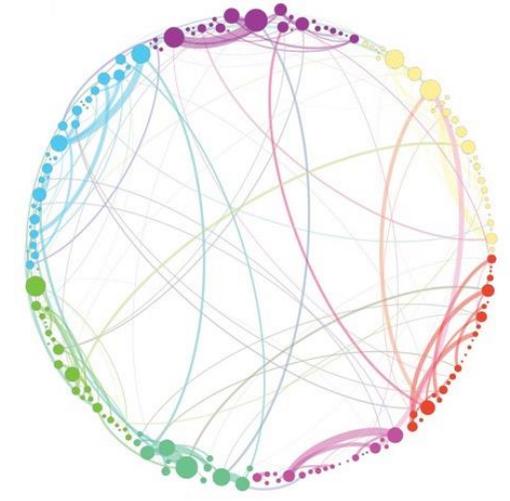


Promotes a form of “active coping”, restoring patient agency.

Increased communication between brain networks (based on fMRI scans)



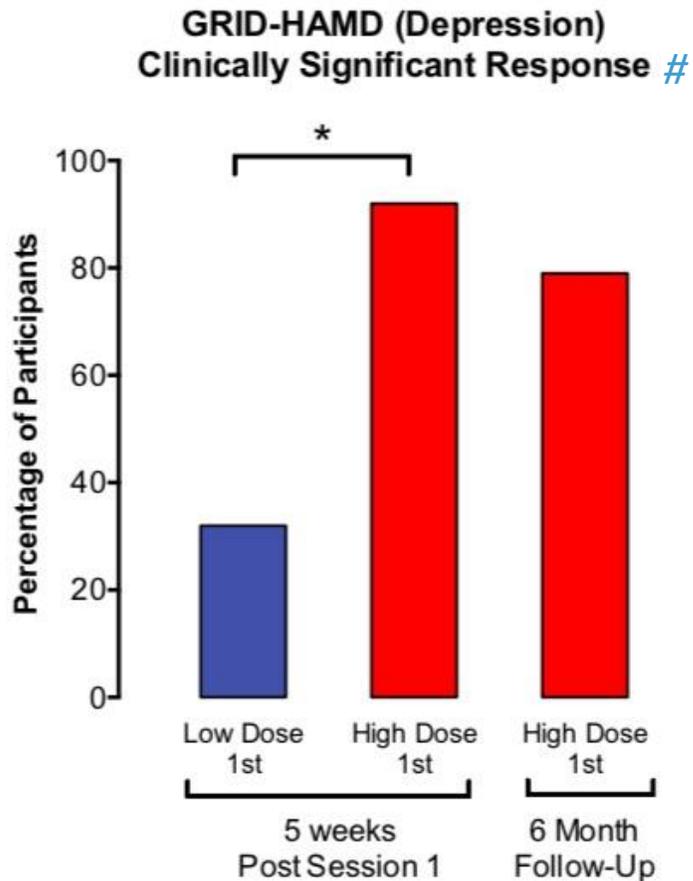
Psilocybin



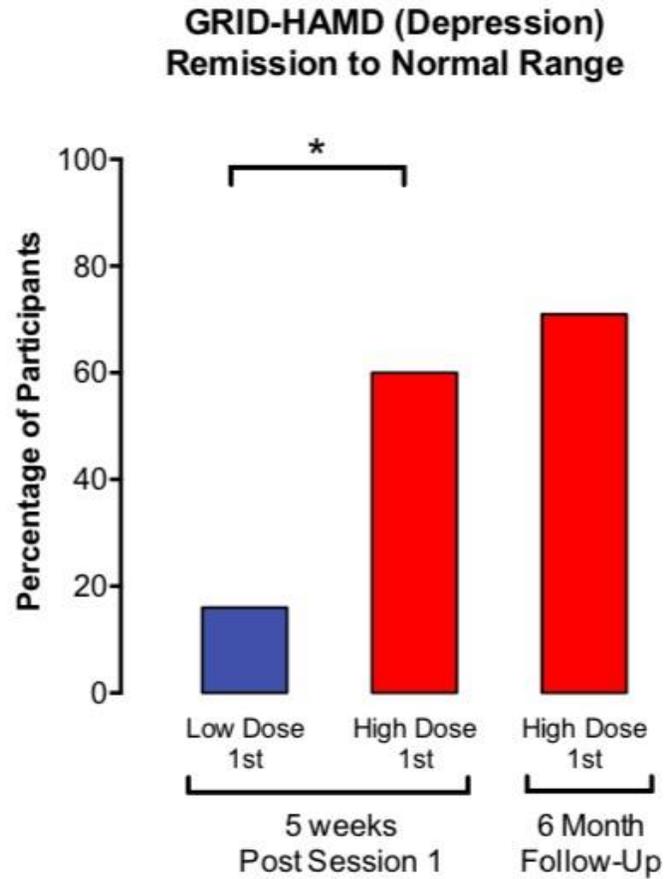
Placebo

Source: Beckley Foundation, United Kingdom.
Based on clinical trials at Imperial College, London

Delivering Outstanding Trial Results



At least 50% reduction in symptoms



**Remission rates with
psilocybin-assisted
psychotherapy improve
over time.**



Treating the Cause: Medicinal MDMA Psychotherapy for PTSD



MDMA is not Ecstasy. Substances sold illegally often have adulterants and are often taken in risky settings with higher doses.



Not therapy by itself but a catalyst for the therapeutic process.



Decreases fear and defensiveness while increasing empathy, trust and safety.



In a MAPS Phase 2 trial there were 105 participants, all with treatment resistant PTSD (who on average had PTSD for 18 years), led to remission in 52% of cases immediately and in **68% at the 12 month follow up.**



Decreases the activity of the amygdala - associated with traumatic memory.

Results that are Building Momentum



- Trials also planned/underway using **Medicinal Psilocybin assisted-psychotherapy** for **Depression in Early-Stage Dementia** (Johns Hopkins), **Anorexia** (Imperial College) and **Obsessive-compulsive disorder (OCD)** (MAPS) and **Medicinal MDMA-assisted psychotherapy** for **Alcohol Addiction** (Imperial College)
- Israeli Ministry of Health ‘compassionate use’ decision to provide Medicinal-MDMA psychotherapy to PTSD sufferers outside of a clinical trial, due to lack of effective alternatives
- Denver (Colorado) and Oakland (California) decriminalised psilocybin possession in 2019. States of Oregon and California likely to vote in 2020 on whether to legalise medicinal psilocybin.



Key questions for Australia are Timeliness, Availability & Access



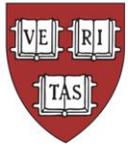
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5. Involvement of Major Institutions in Clinical Trials

Active Medicinal Psychedelic Research Programs

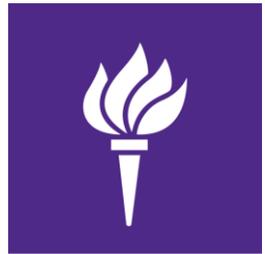


HARVARD
UNIVERSITY



UCLA

Imperial College
London

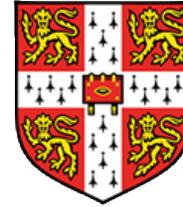


NYU

UFERN
UNIVERSIDADE FEDERAL DO RIO GRANDE DO NORTE



University of
Zurich^{UZH}



UNIVERSITY OF
CAMBRIDGE



Yale University



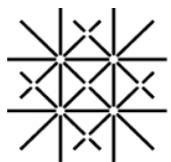
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THE UNIVERSITY of
NEW MEXICO

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MEDICINE
SCHOOL OF MEDICINE

Recently Announced Centres for Psychedelic Research



Imperial College London



THE CENTRE FOR
PSYCHEDELIC RESEARCH

- Established 2019
- Head: Dr Robin Carhart-Harris
- Focuses on the action and clinical use of psychedelics with a particular focus on the treatment of depression
- Two main research themes: the use of psychedelics in mental health care; and as tools to probe the brain's basis of consciousness.
- Aims to develop a research clinic that could help to gather additional clinical evidence and become a prototype for the licensed psychedelic care facilities of the future



JOHNS HOPKINS

Center for Psychedelic &
Consciousness Research



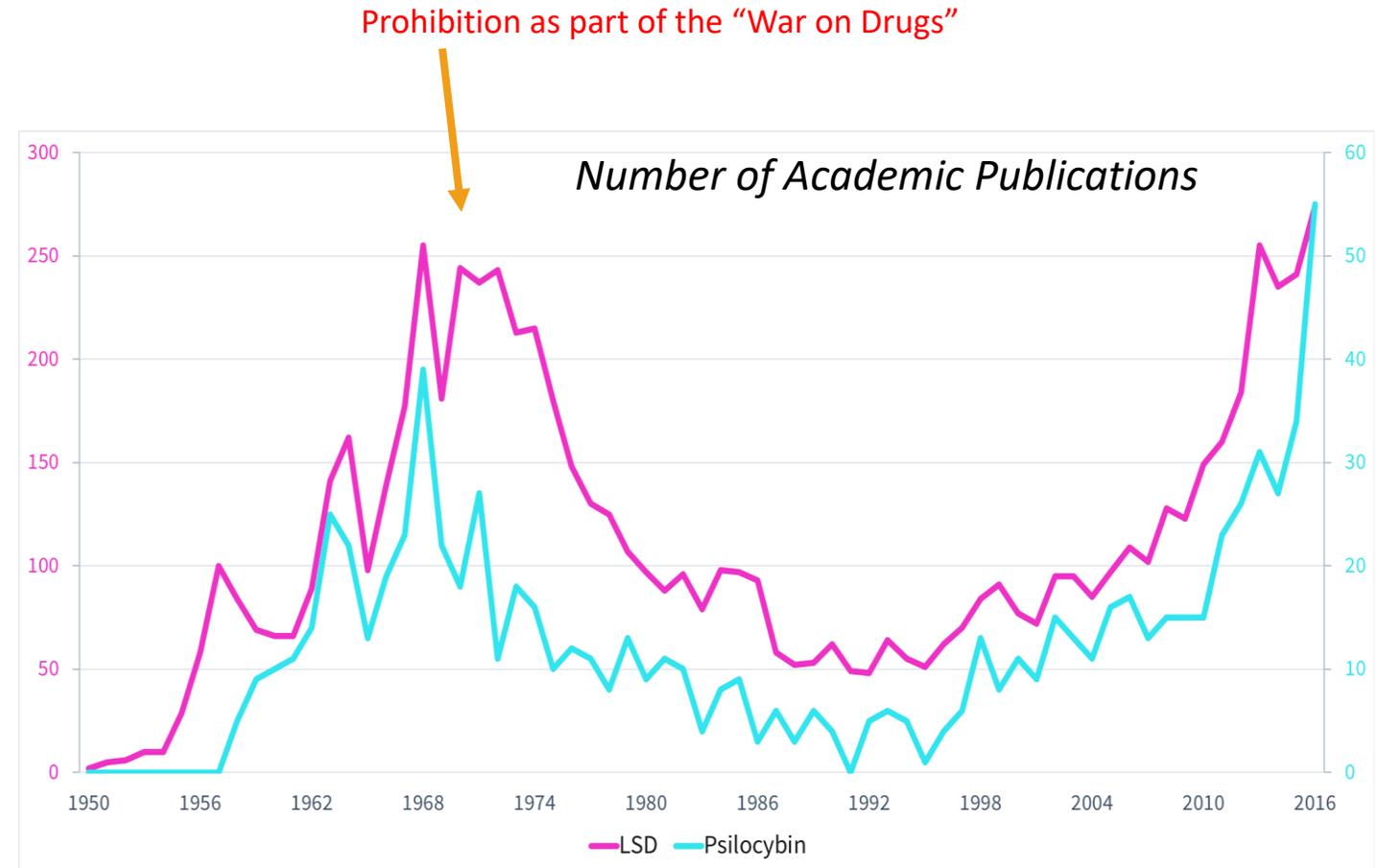
- Established 2019
- Head: Prof Roland Griffiths
- Focus on new indications (opioid addiction, Alzheimer's disease, post-traumatic stress disorder, Lyme disease syndrome, anorexia nervosa, and alcohol use in people with major depression); and precision medicine treatments tailored to individual patients' needs
- Will also investigate creativity and well-being in healthy volunteers towards supporting human thriving

Supported by a Massive Increase in Clinical Trials



Over **110** current or recently completed clinical trials:

- MDMA - 56 trials
 - PTSD
 - Social anxiety in Autistic adults
 - Addiction
 - Existential distress
- Psilocybin - 37 trials
 - Depression • Addiction
 - Anorexia • Existential anxiety
 - Headache • OCD
- LSD - 11 trials
- Ibogaine - 4 trials
- Salvinorin A - 4 trials
- Ayahuasca - 1 trial



Including Australia's first clinical trial at St. Vincent's Hospital in Melbourne



- **Medicinal Psilocybin-assisted psychotherapy** for treatment of Australian **palliative care patients** who are experiencing **depression and anxiety**
- Double-blind, placebo-controlled trial, 30 participants - commenced 2019
- Trial site and team from St Vincent's Hospital, sponsored by PRISM, funded by Mind Medicine Australia and Vasudhara
- **More trials to be announced at major research institutions**





6. Viewed From a Historical Context

Medicinal Psychedelics Through History

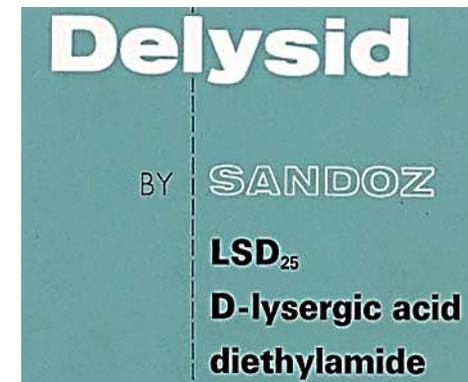


Used in ancient times for healing purposes in both indigenous cultures and Western civilisations. The ancient Greek ritual, the “Eleusinian Mysteries”, attended by the likes of Plato, Aristotle, and Cicero involved a likely honeyed psychedelic drink ‘Kykeon’.

“...For by their means we... have gained the power not only to live happily, but also to die with a better hope.” Cicero (Roman senator and Stoic philosopher), Laws II, xiv, 36

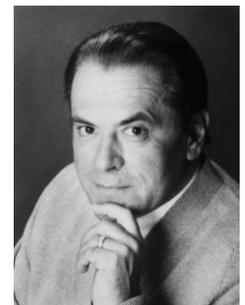


- **16 November 1938** - Sandoz (now owned by Novartis) becomes first pharmaceutical company to synthesise LSD as possible medicine for migraine and later went on to synthesise psilocybin.
- **In the 1950s and 60s** over 40,000 patients took part in therapeutic psychedelic sessions. Psychedelics were considered the “next BIG thing” in psychiatry.



Dr Stanislav Grof, Psychiatrist and pioneering psychedelic researcher:

“...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.”



Caught Up in the War on Drugs for 30+ years



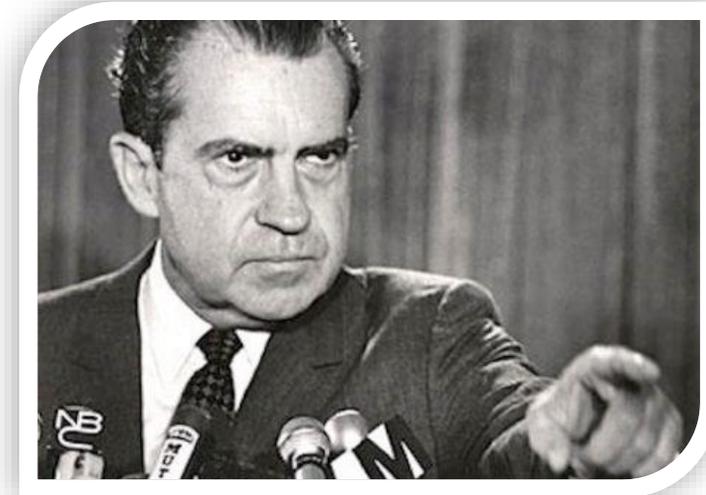
*“The Nixon [presidency]...had two enemies: the anti-war left and black people. You...We knew we couldn’t make it illegal to be either against the war or blacks, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt 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.**” (John Ehrlichman- senior Nixon aide)*

- Psychedelic use criminalised from 1970
- All research funding stopped until the late 1990s

“This is the worst censorship of research and medical treatment in the history of humanity.”

Professor David Nutt

Head of Neuropsychopharmacology, Imperial College UK





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6. Our Strategy

Four Key Strategic Areas



Awareness and Knowledge Building

- Education & events
- Major International Medical Summit November 2020
- Promoting & funding relevant research

Access to Medically Approved Therapy

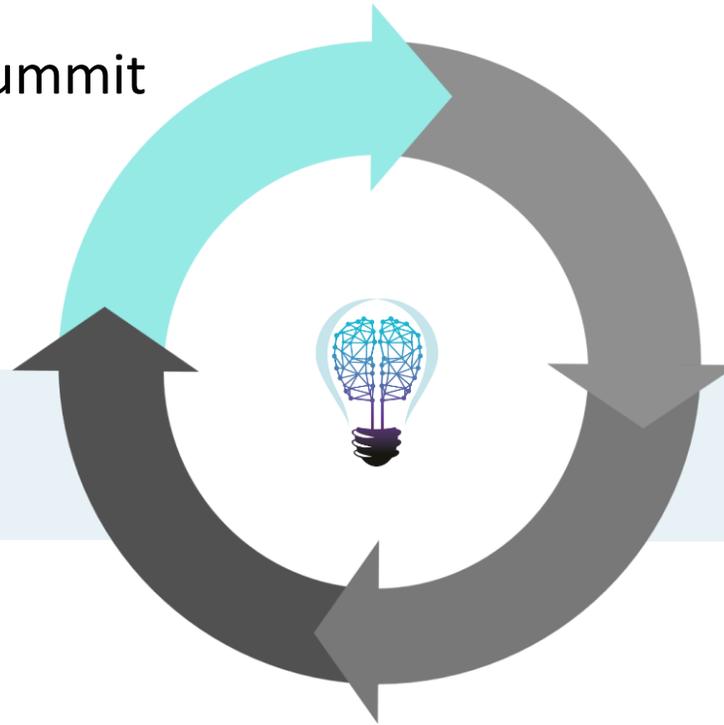
- Preferred legal & ethical framework
- Medicine sourcing & protocols
- Rollout strategy

Therapist Training

- Introductory two day Summit workshop November 2020
- Accredited part time course to commence 2021

Asia-Pacific Centre of Excellence

- Applied research & prototype clinic
- Supply chains & agri-business
- Education & economic analysis



Our focus is wholly clinical – we do not advocate for recreational use, nor for changes to the law with respect to recreational use.

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

What are we going to do about it?



MindMedicineAustralia.org

hello@mindmedicineaustralia.org

@MindMedicineAU

Level 1, 10 Dorcas St,
South Melbourne, VIC, 3205



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Appendices



How you can help



Start conversations and share this information with your contacts.



Fundraise or donate
We rely on community support.



Volunteer, all skill levels welcome!



Follow us on social media for the latest updates.



Read our educational content and share.



Talk to your local member of parliament



Talk to your doctors and medical professionals



Attend our educational events and 2020 Summit to learn more!

Mind Medicine Australia - Projects



A two-day **International Summit on Psychedelic Therapies for Mental Illness** in November 2020 in Melbourne

Timeline: Current – Nov 2020
Gross Budget: \$250,000



Development of **ethical, legal and regulatory frameworks** to ensure best practice, safety, accountability, and transparency.

Timeline: Current – November 2020
Budget: \$100,000



Establishment of an **Asia-Pacific Centre of Excellence** for the multidisciplinary exploration and development of medicinal psychedelic-assisted psychotherapy treatments for mental illness.

Fundraising Timeline: Current – 2025
Budget: \$30M including from future research grants



Development of a **Psychedelic Therapist Training Program** for qualified and experienced clinicians.

Timeline: Current – December 2020
Budget: \$450,000 (\$150,000 over three years)



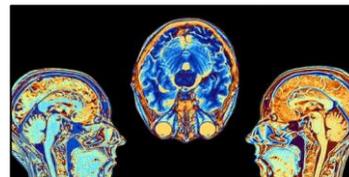
Increase awareness through events – including talks, documentaries, panels, and discussion forums – to enhance interest, knowledge, and support for clinical psychedelic research and therapy.

Timeline: Current - ongoing
Budget: \$75,000 per year



A **health economics model of psychedelic medicine**, estimating the true cost-effectiveness of psychedelic-assisted treatments for mental illness.

Timeline: Current – June 2020
Budget: \$80,000



Supporting **Australian Clinical Research and Development trials** to test and optimise the safety and effectiveness of psychedelic-assisted psychotherapy for mental illness in the Australian context.

Timeline: January 2020 – January 2022
Budget: \$400,000



2-day pre-summit therapist training + 2-day public summit 16-19 November 2020, Melbourne, Australia

Mind Medicine Australia will hold a two-day International Summit on Psychedelic Therapies for Mental Illness in November 2020 in Melbourne, bringing together clinicians, scientists, academics, mental and public health professionals, philanthropists, Government, law and policy makers, business, industry, and other interested stakeholders.

Key themes will include:

- The current state of mental health in Australia and existing treatments and the need for change
- Ethical, legal, and implementation frameworks for psychedelic treatments
- Clinical outcomes of psychedelic treatment for mental illness
- Therapeutic mechanisms of psychedelic treatments
- Enhancing effectiveness and minimising risks for psychedelic treatment
- The way forwards for Australia: Challenges and preparation towards creating a new paradigm