



Outline



- 1. The Scale of the Mental Health Problem in Australia
- 2. Mind Medicine Australia: Purpose and People Involved
- 3. Turning the Tide with "New" Breakthrough Therapies
- 4. Historical Context and Future Potential
- 5. The Strategy of Mind Medicine Australia



1. The Scale of the Mental Health Problem in Australia

Mental Illness Now at Alarming Levels and Getting Worse*





- 1 in 5 Australian adults
 (4.8 million people)
 had a chronic mental illness pre-COVID-19*
- As a result of the COVID-19 pandemic, 4 in 5 Australians now report poor mental health and 34% of Australians said their mental health had declined in the pandemic**



- 1 in 8 Australians are now on antidepressants including 1 in 4 older Australians
 (18% increase in last 5 years
 95% increase in last 15 years)
- 1 in 30 children on antidepressants as young as 4 years of age



- Over 45% of Australians will experience mental illness in their lifetime
- Globally, there has been an estimated increase of more than 129 million cases of major depression (53.2mn) and anxiety (76.2mn) disorders during the pandemic due to the combined effects of the pandemic and lockdown measures***

The most common mental illnesses are:

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

^{*}Impact before recent bushfires and current COVID-19 pandemic **Smiling Mind state of mind report 2021

^{***} The Lancet (2021), Global prevalence and burden of depressive and anxiety disorders in 204 countries and territories in 2020 due to the COVID-19 pandemic. Australian Bureau of Statistics 2018, National Health Survey First Results, cat. no. 4364.0.55.001, ABS, Canberra PsychWatch Australia, April 2019 with information from Department of Human Services, Canberra Australian Bureau of Statistics 2009, National Survey of Mental Health and Wellbeing: Summary of Results, 4326.0, 2007. ABS: Canberra.

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 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).

Leading to Massive People and System Costs and Immense Suffering

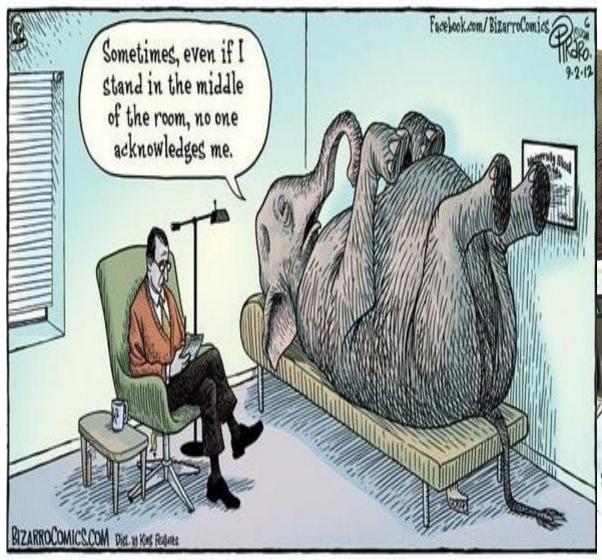


- Massive impact on sufferers, families and carers.
- Adults with a mental illness nearly twice as likely to be unemployed or out of the labor force than other Australians. 59% of Australian workers say they have a mental health condition.
- Strong correlation between natural disasters and mental illness.
- Mental illness is a primary cause of both suicide and homelessness.

The Australian Productivity Commission (2020 final report)	
Direct costs of mental ill-health and suicide (a conservative estimate)	\$43 - \$70 billion per year
Diminished health & life expectancy for those living with mental illness	\$150 billion cost per year
Total cost of mental illness and suicide to the Australian economy	~\$220 billion cost per year

The Elephant in the Room = Lack of Innovation in Treatments for Mental Illness







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 continuing symptoms and between **50 80% relapse after treatment stops**.
 - Common side-effects of anti-depressants include insomnia, psychosis, 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 as low as 5%.

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



2. Mind Medicine Australia Purpose and People Involved

Purpose of Mind Medicine Australia



- Mind Medicine Australia (MMA) is a charity that helps to alleviate the suffering caused by mental illness in Australia through expanding the treatment options available to medical practitioners and their patients. We are establishing safe and effective psychedelic-assisted treatments to cure a range of mental illnesses. Founded by Tania de Jong AM and Peter Hunt AM.
- Primary current focus on medicinal psilocybin (for Depression) and medicinal MDMA (for PTSD) Psychotherapies. Also interested in other psychedelic medicines including ketamine, ibogaine and DMT.
- Indications of success:
 - These therapies become an integral part of our Mental Health System;
 - Achieving 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



Peter Hunt AM
Chair
Investment Banker &
Engaged Philanthropist



Tania de Jong AM
Deputy Chair
Social Entrepreneur, Business
woman, Global Speaker and
Soprano



Admiral Chris Barrie AC

Past Chair of the

Australian Defence Force
(1998-2002) and

Strategic Leadership

Consultant



Prof Jane Burns Chair, Centre for Mental Health at Swinburne University and Health Strategist



Dr Eli KotlerPsychiatrist and
Director of Medicine at
Malvern Private
Hospital



Dr Simon Longstaff AO *Executive Director of the Ethics Centre*



Monojit Ray Corporate Advisor and former PWC Tax & Legal Partner



The Hon Andrew Robb AO

Australia's Minister for

Trade and Investment
(2013-2016).

Chair of AsiaLink



Nicholas Smedley
Investment Banker &
Business Entrepreneur.
previous Director at
Haven Foundation

Management





Tania de Jong AM
Executive Director
Social Entrepreneur, Business
woman, Global Speaker and
Soprano



Gavin Abeyratne *Chief Marketing Officer (CMO)*



Ilan Hayman
Operations Manager
Business operations
experience across NFP &
healthcare sectors. PwC
Alumnus



Nicole Hearnden *Events & Partnership Manager*



Scott Edwards Chapters, Partnerships and Marketing Coordinator



Grace McNieAdministration, Education and Program Coordinator



Julia NeubauerDigital Communications,
Design and Social Media
Consultant

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 William Richards (USA)
Psychologist in the Center
for Psychedelic and
Consciousness Research at
the Johns Hopkins School of
Medicine



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



Psychiatry



Dr Scott T. Aaronson (USA)

Director of Clinical

Research Programs,

Sheppard Pratt Health

System, A/Prof, University

of Maryland



Prof Malcolm Hopwood Ramsay Health Care Professor of Psychiatry, University of Melbourne



Dr Tanveer Ahmed *Psychiatrist, author and columnist, Adjunct lecturer at UNSW*



Prof Michael Berk
NHMRC Senior Principal
Research Fellow Deakin
University, head of the
IMPACT institute



Prof Ashley Bush NHMRC Senior Principal Research Fellow -Melbourne Dementia Research Centre



Dr Ted CassidyPsychiatrist and

Co-Founder of TMS

Australia



Dr Mark Cross Psychiatrist, SANE Board Director



A/Prof Sathya Rao
Executive Clinical
Director, Spectrum,
Personality Disorder
Service & Adjunct
Clinical Associate
Professor, Monash
University



Dr Linda Kader
Psychiatrist &
psychotherapist, The
Royal Melbourne and
The Royal Children's
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Prof Andrew Lawrence
NHMRC Principal
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Prof Paul Fitzgerald
Professor of Psychiatry at
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Director of the Epworth
Centre for Innovation in
Mental Health



Dr Rachel Yehuda (USA)
Professor of Psychiatry
and Neuroscience at the
Icahn School of Medicine
at Mount Sinai



Psychiatry (cont.)



Dr Lynette Chazan
Psychiatrist,
Psychoanalytic
Psychotherapist &
Teacher



Dr George HalaszConsultant Child and
Adolescent Psychiatrist and
Adjunct Senior Lecturer,
Monash University



Dr Reid Robison (USA)
Psychiatrist,
Psychedelic Researcher
and Chief Medical
Officer at Novamind



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



Dr Dan Engle (USA) *Psychiatrist*



Dr Stuart Saker General Adult Psychiatrist with interest in Veterans' Mental Health



Prof John Tiller Professor Emeritus of Psychiatry, University of Melbourne



Dr Mark Ryan *Psychiatrist*



Dr John Webber *Psychiatrist and Author*



Medical Practitioners



Dr Gabor Maté CM (Canada) Physician and Author



Dr David Caldicott *Emergency Medicine Consultant*



Dr Lynn Marie Morski (USA) Physician and President of the Psychedelic Medicine Association



Prof Ian E. Brighthope
Director of Nutrition
and Environmental
Medicine, NIIM



Dr Arne RubinsteinFounder & CEO, The
Rites of Passage
Institute



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



Dr Alex WodakPhysician and President
of Australian Drug Law
Reform Foundation



Dr Jack Springer *Emergency Physician*



Research, Clinical Psychology and Behavioural Science



Dr James Fadiman (USA) Psychologist and cofounder Institute of Transpersonal Psychology



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



Professor Robin Carhart-Harris (UK) Ralph Metzner Distinguished Professor, Weill Institute for Neurosciences and University of California San Francisco



Prof Gregg Henriques (USA) Clinical Psychologist, and Professor, James Madison University



Francoise Bourzat (USA)
Counselor and Author



Prof Matthew Johnson (USA) Susan Hill Ward Professor of Psychedelics at Johns Hopkins University School of Medicine



Dr Patrycja Slawuta(USA)

Behavioural Scientist
based in New York



Robert Falconer (USA) IFS Practitioner



Dr Gabby Agin-Liebes (USA) Clinical Psychologist



Prof Dr Karl J. Friston (UK) Theoretical Neuroscientist and authority on brain imaging



Dr Suzy Green Clinical and Coaching Psychologist (MAPS) and Founder & CEO of The Positivity Institute



Pharmacology



Michael Kornhauser Pharmaceutical and Clinical Trial Research Specialist



PhD, Ethnopharmacologist, Author
& Founding Board
Member at the Heffter
Research Institute



Prof David Nichols (USA)
Chemical Biology and
Medicinal Chemistry at
the University of North
Carolina

Religion



Rev Graham Long AM Pastor Emeritus, The Wayside Chapel



Imam Tawhidi Islamic scholar, educator, best-selling author and global speaker



Rabbi Dr Laibl Wolf Dean and Founder of the Spiritgrow Wellness Centre, Melbourne, Australia. A graduate of Law and Psychology

Pharma/Natural Medicine



Rabbi Jeffrey Kamins
OAM
Rabbinic Advisor and
Director of Voiceless

Law



David HeilpernBarrister and Solicitor
of the High Court of
Australia and Author



Greg Barns
Barrister



Scott Leckie
Human Rights Lawyer
and Senior Fellow,
Monash University



Prof lan Freckelton *Barrister*



Dr Alberto Villoldo (USA)
Founder the Four Winds
Society, Director the Center
for Energy Medicine (Chile)



Tommy Huppert *Founder and CEO Cannatrek Limited*



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



Dr Paul Macleman *Corporate Advisor*



Jeremy Weate (Canada) Chief Executive Officer, Eastra Health



Other Relevant Disciplines



Johann Hari Author



Dr Mahsheed Ansari Lecturer in Islamic Studies & Contemporary Islam, Charles Sturt University



Dr Wade Davis CM (Canada)

PhD & Professor of

Anthropology & Chair of

Cultures and Ecosystems at

Risk University of British

Columbia



Amanda Feilding (UK) Founder and executive director of the Beckley Foundation, UK



Prof Paul Frijters (UK)
Research Fellow
London School of Economics



Wesley Enoch AM
Writer and Director



Dr Ingmar Gorman (USA)Psychologist and

Co-Founder of Fluence



Dr Michael Winkelman (USA)
Leader in neurotheological
perspectives on shamanism,
traditional healing practices, and
altered states of consciousness



Other Relevant Disciplines



Mark Joiner
Business Strategist and
Finance Executive



Rob Moodie AM
Professor of Public Health at
the University of Melbourne
and Adviser to the World
Health Organisation (WHO)



Adam Grunsell AM CSC Rear Admiral at Australian Navy



Cathy Burke Speaker, Author, Global Change Maker



Dr Albert Garcia-Romeu (USA) *Member of the Psychiatry and Behavioral Sciences faculty at Johns Hopkins University*



Dr Thomas Pogge (USA)Philosopher & Director of the
Global Justice Program at
Yale



Elizabeth Bryan AM Chairman of IAG



Prof Margaret Somerville

Bioethicist



3. Turning the Tide with "New" Breakthrough Therapies

Expanding the Medical Treatment Options



- Primary focus on two broad types of medicine-assisted psychotherapies based on strong clinical evidence:
 - 1. Medicinal psilocybin for depression and possibly OCD and addiction.
 - Medicinal MDMA for PTSD and possibly the treatment of addiction.
 - Only 2-3 dosed sessions in contrast to conventional treatments (involving daily medications and/or weekly psychotherapy).
 - Medicine are 'curative' not palliative.



- 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



- **Facilitated by** psychiatrists and psychologists within clinical facilities (MDs, nurses, monitoring equipment)
- Only 1-3 sessions with an active dose in contrast to conventional pharmacotherapy (involving ongoing daily medications)
- Three distinct phases:
 - (1) preparation; (2) acute medicinal experience; (3) integration

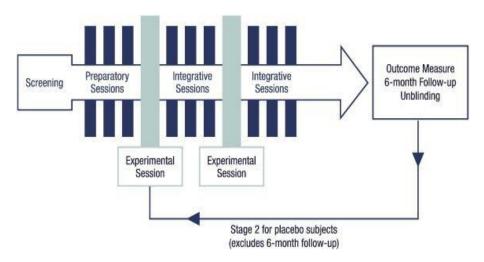


Figure: Medicine-assisted psychotherapy protocol (MAPS)

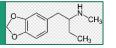
- Emphasises non-avoidance and curiosity
- Commonly creates substantial increases in self-awareness, self-compassion, insight, connectedness and meaning

Medicinal Psilocybin



- 1-2 active doses of medicinal psilocybin in protocols
- Best suited for depression, anxiety, eating disorders, OCD
- Increases mental flexibility and sensitises the patient to the therapeutic environment
- Psilocybin provides a profound personal experience through dream like imagery and connected feeling
- It has been proposed that integration occurs in a window after treatment where the patient is more open to change

Medicinal MDMA



- 2-3 active doses of medicinal MDMA in protocols
- Best suited for PTSD or disorders with underlying trauma (such as addiction)
- Disarms a hyper responsive nervous system, allowing a patient to safely approach trauma memories without becoming overwhelmed
- Memories are re-encoded without traumatic emotional connection
- Integration supports the patient to process and move through the traumatic event(s) and connect to the present

With a Strong Clinical Safety Record



Medicinal Psilocybin

Medicinal MDMA

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.

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.

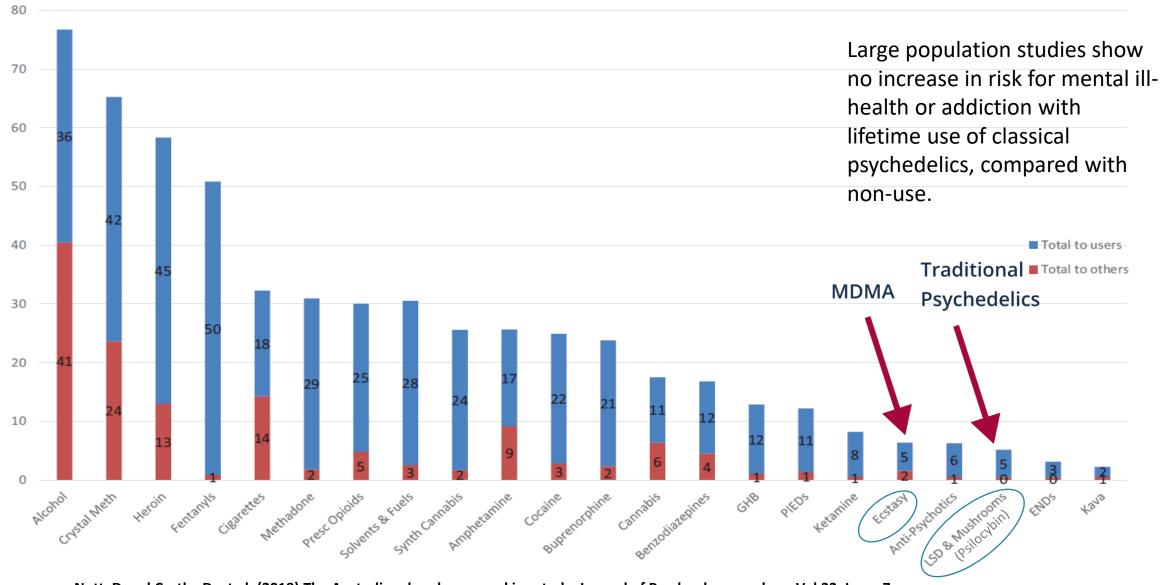
In clinical studies of MDMA in over 3000 participants using medically controlled doses, only 1 adverse event (heart rate above pre-set limit) and this was rapidly resolved.



Psilocybin-assisted therapy sessions Johns Hopkins Uni

And Strong Safety Evidence Across Broad Populations





Patient Testimonials



- "Trauma creates a prison in the mind, leaving countless Australians shackled by mental illness...I believe psychedelic therapy, responsibly administered in a safe and supported environment, is the key to unlocking those prison doors... In desperation, from a place of abject hopelessness, I turned to safe and supported Ayahuasca psychedelic therapy. One week of intensive treatment provided transformational healing. I'm honoured to be an example of what is possible with guided psychedelic therapy, and it is my passion to help my brothers and sisters in arms find their own healing journey." Joel Harrop, Veterans of War, ex-ADF Veteran
- "...everyone deserved to have this experience... that if everyone did, no one could ever do harm to another again ... wars would be impossible to wage." New York University end-of-life study participant
- "I felt like I went through 15 years of psychological therapy in one night." MDMA-Assisted Therapy patient, Israel Trial participant
- "MDMA is the reason my son has a father instead of a folded flag."
 - US Army SGT (R) Jon Lubecky @jonlubecky

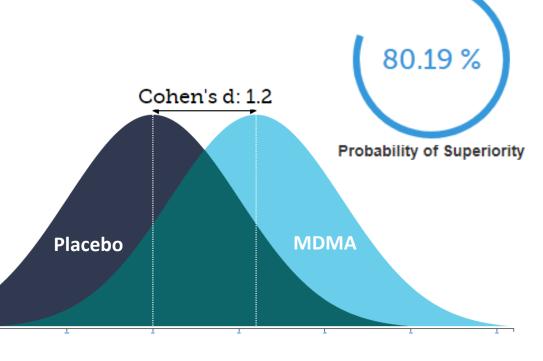


Medicine-assisted therapy session Multidisciplinary Association of Psychedelic Studies (MAPS).

Delivering Remarkable Treatment Options



- 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)
- Medicine-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.

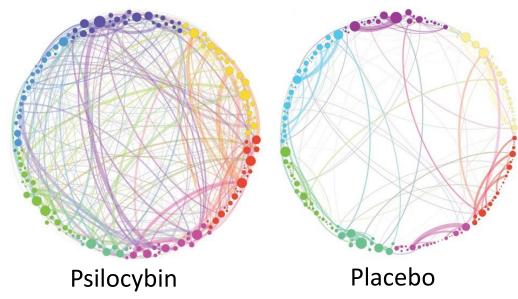


Enabling patients to 'break out' of repetitive and rigid styles of thinking, feeling and behaving.



Promotes a form of "active coping", restoring patient agency.

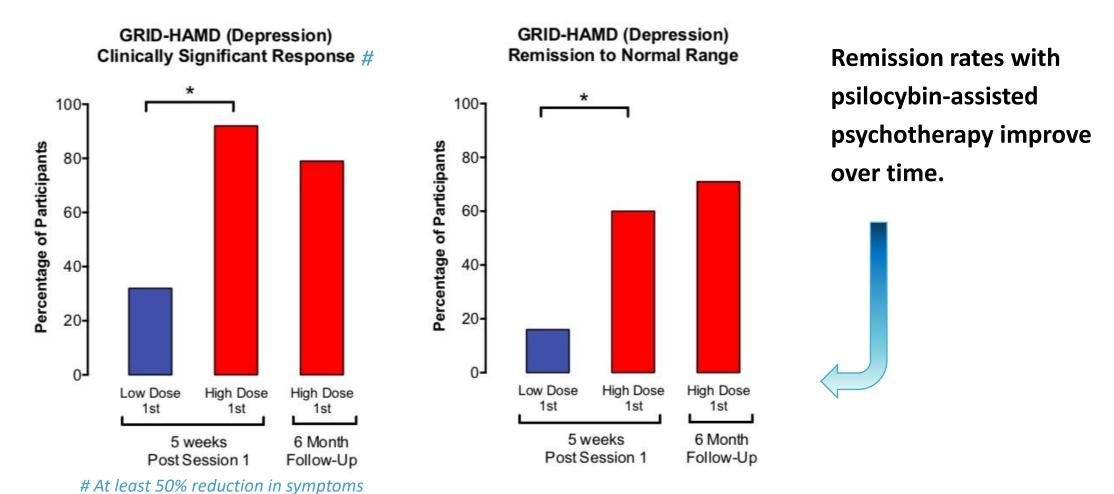
Increased communication between brain networks (based on fMRI scans)



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

Delivering Outstanding Trial Results





A graph showing the percentage of participants who improved on measures of depression and anxiety, at five weeks and six months, in a Johns Hopkins study.

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, <u>all with treatment resistant</u> 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.

Phase 3 trial taking place at 15 research sites in the U.S., Canada, and Israel. Interim analysis of the data revealed 90% or greater probability that there will be statistically significant results when all participants have been treated. MDMA is likely to be prescribable in 18 months in USA.

Recent Significant Trials





The Nature Medicine Journal (May 2021) highlights the ground-breaking MAPS' Phase 3 trial results.

- The highly statistically significant results and excellent safety record suggest MDMA-assisted therapy will be an effective treatment for severe, chronic PTSD.
- 67% of participants who received three MDMA-assisted therapy sessions no longer qualified for a PTSD diagnosis and 88% experienced a clinically meaningful reduction in symptoms.
- The pivotal Phase 3 trial treated 90 patients with severe, chronic PTSD from any cause with an average duration of 14 years and replicated the results of Phase 2 trials.
- Study participants included patients with PTSD caused by combat-related events; accidents; abuse; and sexual harm; 84% have a history of developmental trauma. (Mitchell, J.M., Bogenschutz, M., Lilienstein, A. et al. 2021).

Imperial College Trial Results (2021)

Results published in one of the world's top medical journals (The New England Journal of Medicine) demonstrate that two sessions of psilocybin-assisted psychotherapy were as effective in treating moderate to severe depression over the course of six weeks as daily intake of SSRI antidepressants combined with psychotherapy.

- Additionally, remission rates were twice as high in the psilocybin group as in the antidepressant group.
- Psilocybin had quicker effects and was of greater magnitude in reducing depressive symptoms.
- Additionally, those who received psilocybin reported far fewer side effects and feelings of anxiety and suicidal ideation were also reduced significantly. (Carhart-Harris et al., 2021).



Results that are Building Momentum



- Trials also planned/underway using medicinal psilocybin assisted-psychotherapy for dementia (Johns Hopkins), anorexia (Imperial College) and obsessive-compulsive disorder (OCD) (MAPS) and medicinal MDMA-assisted psychotherapy for alcohol addiction (Imperial College).
 Studies are also commencing to examine psilocybin for weight loss, Parkinson's, schizophrenia and autism spectrum disorder.
- Regulatory schemes in the US (Expanded Access), Australia (Special Access) and Israel (Compassionate Use) enable physicians to apply to the Regulator for approval to treat patients suffering from treatment resistant PTSD with Medicinal-MDMA and psilocybin psychotherapy for depression outside of a clinical trial. Switzerland has a similar scheme allowing LSD, Psilocybin and MDMA to be used with psychotherapy.
- The **Australian Govt** announced (March 2021) **\$AUD15m** would be put towards clinical trials using psychedelic drugs as part of global efforts to advance innovative treatments.
- Australia's TGA conducted an independent review (August 2021) of MMA's rescheduling applications for psilocybin and MDMA into the therapeutic value, risks and benefits of these substances.
- Numerous US States have decriminalised psilocybin possession recently.
- Oregon (USA) became the first state to legalise psilocybin for therapeutic use in November 2020, other States to follow.
- Canadian government allows (August 2020) terminally ill patients to access psilocybin-assisted psychotherapy to help ease anxiety, and also for PTSD patients.
- The German government has approved a phase 2B study on psilocybin for treatment-resistant depression and is providing millions of Euros
 to the project.

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Through Institutions with Active Psychedelic Research Programs





Imperial College London









MONASH University











Yale University



















9 recently announced Centres of Excellence



Imperial College London



- Imperial College London (UK)
- Established 2019
- Head: Dr Robin Carhart-Harris (Member of MMA Advisory Panel)
- Focuses on the action and clinical use of psychedelics with a particular focus on the treatment of depression and eating disorders.





- Johns Hopkins (USA)
- Established 2019
- Head: Prof Roland Griffiths (MMA Ambassador)
- 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.



- UC Berkeley Center for the Science of Psychedelics (USA)
- Established 2020
- Head: UC Berkeley neuroscientist Michael Silver
- Will conduct research using psychedelics to investigate cognition, perception and emotion and their biological bases in the human brain.



- NYU Langone Center for Psychedelic Medicine (USA)
- Established 2021
- Head: Michael Bogenschutz, MD
- Transdisciplinary areas of focus: psychiatry, medicine and preclinical research.



- University of Texas: Center for Psychedelic Research & Therapy (USA)
- Established 2021
- Head: Greg Fonzo and Charles B. Nemeroff
- Focuses on military veterans living with post-traumatic stress disorder, adults experiencing prolonged grief disorder or depression, and those who have experienced childhood trauma.

9 recently announced Centres of Excellence







- COMPASS Pathways with Sheppard Pratt for Advanced Diagnositics and Therapetics (USA)
- Established 2021
- Head: Scott Aaronson MD, Psychiatrist and Director of Clinical Research at Sheppard Pratt (Member of MMA Advisory Panel)
- Will model the "clinic of the future", showcasing the best thinking in science, therapy, technology, and design. Working as a research facility and innovation lab, it will generate evidence to shape therapy models in mental health care, train and certify therapists, conduct clinical trials including proof-of-concept studies, and prototype digital solutions to improve patient experience.



- The Neuromedicines Discovery Centre at Monash University (Australia)
- Established 2021
- Head: Professor Arthur Christopoulos (Member of MMA Advisory Panel) and Professor Chris Langmead
- The NDC's research is focused on finding better treatments for common psychiatric illnesses, including depression, post-traumatic stress disorder, obsessive compulsive disorder, anxiety, and substance use disorders.



- The Icahn School of Medicine at Mount Sinai Center for Psychedelic Psychotherapy and Trauma Research (USA)
- Established 2021
- Head: Rachel Yehuda, PhD, Professor of Neuroscience and Psychiatry (Member of MMA Advisory Panel)
- Pursues a multipronged clinical and research approach to discovering novel and more efficacious therapies for posttraumatic stress disorder (PTSD), depression, anxiety, and other stress-related conditions in the veteran and civilian population.



- The Center for the Neuroscience of Psychedelics (USA)
- Established 2021
- Head: Jerrold F. "Jerry" Rosenbaum
- Seeks to understand how psychedelics facilitate changes in brain structure and function, with focus on psilocybin for patients with treatment-resistant depression, and MDMA for patients with treatment-resistant PTSD.



4. Historical Context & Future Potential

Medicinal Psychedelics Through History



Used 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'.

Ancient Times





Sandoz (now owned by Novartis) becomes first pharmaceutical company to synthesise LSD as possible medicine for migraine and later went on to synthesise psilocybin.

1938

Canadian government allows terminally ill patients to access psilocybin-assisted psychotherapy to help ease anxiety.



2020











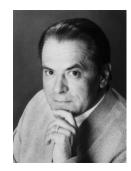
1912

Merck develops MDMA and used with psychotherapy in the 1970s

1950s

& 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

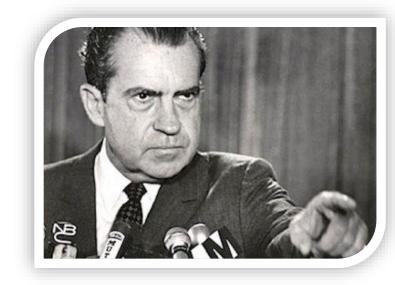


"The Nixon [presidency]...had two enemies: the anti-war left and black people. You...We knew we couldn't make it illegal to be either against the war or blacks, but by getting the public to associate the hippies with marijuana and blacks with heroin, and then criminalizing both heavily, we could disrupt 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
- MDMA use criminalised in the 1980s
- Resulting in minimal research funding 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

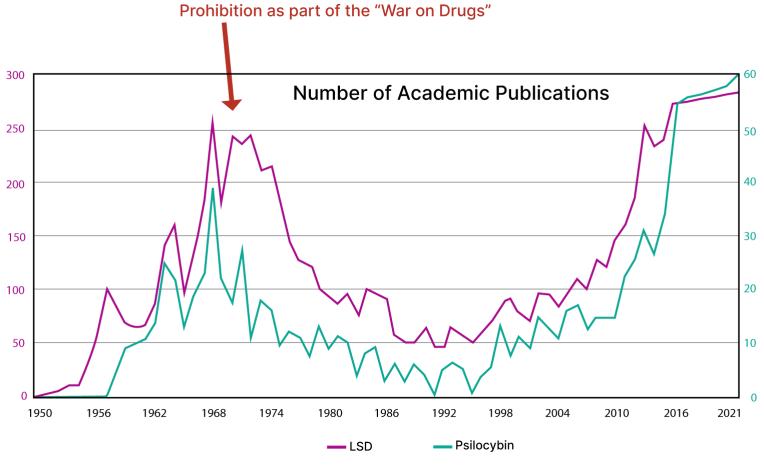


But Now Supported by a Massive Increase in Clinical Trials

Over **160** current or recently completed clinical trials including:

- MDMA 94 trials
 - PTSD
 - Social anxiety in Autistic adults
 - Addiction
 - Existential distress
- Psilocybin 73 trials
 - Depression
- Addiction

- Anorexia
- Existential Anxiety*
- Headache
- OCD
- LSD 16 trials
- Salvinorin A 5 trials
- Ibogaine 4 trials
- DMT 4 trials
- 5-MeO-DMT 2 trials
- Ayahuasca 2 trials



^{*} Including Australia's first clinical trial at St Vincent's Hospital in Melbourne, part funded by Mind Medicine Australia

Exponential Growth Across the Sector



- Lancet Commission reports that the rise of mental health disorders will cost the global economy \$USD16 trillion by 2030.*
- 18 months ago, there was only a single for-profit company focused on developing psychedelic assisted therapies. Now there are over 30 companies focused on psychedelic medicine and actively raising capital in North America, Canada and Europe.
- The for-profit sector and investor interest around the world, focused on the development and application of these therapies, has continued to rapidly expand with the potential size of the market estimated to be around \$US15-20B with growth forecasted up to \$US200B in the near future.

(The Lancet Commission on global mental health and sustainable development. The Lancet. 392. 10.1016/S0140-6736(18)31612-X.)

























Trials Stage	Market Focus	Ownership	Market Cap	
Clinical trials	Psilocin and therapy	Public	\$USD 1.6B	
Preclinical trials	Nutraceutical/psychedelics	Public	\$USD 53M	
Clinical trials	Medicine discovery	Public	\$USD 770M	

Exponential Growth Across the Sector







Numinus









MINDCURE

Trials Stage	Market Focus	Ownership	Market Cap
Preclinical trials	Medicine/device development	Public	\$USD 13.3M
Medicine development	Psychedelic therapies	Public	\$USD 174M
Medicine development	Medicine processing/therapies	Public	\$USD 78M
Preclinical studies	Nutraceutical/psychedelics	Public	\$USD 51M
Clinical trials	Medicine development	Public	\$USD 117M
Preclinical studies	Therapy centre/medicine dev.	Public	\$USD 82M
Medicine development	Medicine production	Public	\$USD 33.9M
Medicine development	Medicine production	Public	\$USD 18.9M



5. The Strategy of Mind Medicine Australia

Four Key Strategic Areas



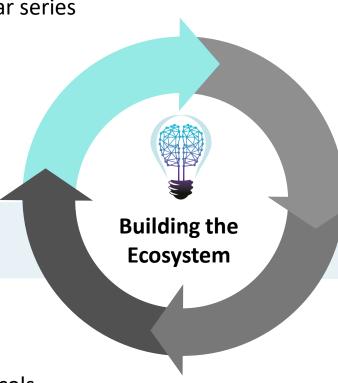
Awareness and Knowledge Building

Education & events, including free webinar series

- Major International Medical Summit November 2021
- Promoting & funding relevant research
- State & regional chapters (Over 30 chapters)

Access to Medically Approved Therapy

- Preferred legal & ethical frameworks
- Psychological support services
- Medicine Rescheduling, Sourcing & Protocols
- Rollout strategy



Professional Development Program

- Introductory two day workshop November 2021
- Part-time professional course for health practitioners commenced in 2021 (2 intakes) with 4 intakes planned for 2022
- General shorter courses and workshops

Engagement with University Sector and Novel Research

- Establishment of Neuromedicines
 Discovery Centre at Monash University
- Engagement with other universities to promote research, development and economic analysis and rollout plans.



What are we going to do about it?









Appendices



"I view the next five years as an absolutely golden window. There's an opportunity to use relatively small amounts of money to have billions of dollars of impact [in terms of helping people heal mental illness] and to affect millions of lives... There just aren't that many opportunities that are so dramatically obvious... If you want to bend the arc of history, I think this is one of the best opportunities you will ever have."

- Tim Ferriss

We need your support. Please donate today.

MINDMEDICINEAUSTRALIA.ORG/DONATE



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 and join our State and Regional chapters!



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. Become a leader - Join the CPAT course.



Attend our educational events learn more!

Key questions for Australia are Timeliness, Availability & Access

Your donation supports:





Professional Development Program

This includes our Certificate in Psychedelic-Assisted Therapies programme, as well as shorter workshops to prepare mental health professionals for the future.



Awareness and Knowledge Building

We organise educational events, film screenings, conferences and also have local chapters open to the public.



Access to Medically Approved Therapy

We promote changes in legislation, promote legal and ethical frameworks, provide psychological support services, develop clinical rollouts and medicine manufacturing capabilities.



Engagement with University sector and novel research

Engagement with universities to promote research, development and economic analysis and rollout plans.

Mind Medicine Australia - Projects





Expansion of **Southern** Hemisphere's first Certificate in **Psychedelic-Assisted Therapies.**

Timeline: Current – December 2025 **Budget**: \$450,000 (\$150,000 over

three years)



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

Timeline: Current – November 2023

Budget: \$100,000



Development of Australia's first peak body and a national practitioner CPAT Register to govern and provide a framework for diverse practitioners from a range of professions; provide security to patients; and develop clinical protocols.

Budget: \$350,000



Increase awareness and educate the public and medical professionals through events - including talks, documentaries, workshops and discussion forums, our Global Webinar and Podcast Series – to enhance interest, knowledge, and support for clinical psychedelic research and therapy.

Timeline: Ongoing

Budget: \$250,000 per annum



A health economics model of psychedelic medicine, estimating the true costeffectiveness of medicineassisted psychotherapies for mental illness in an Australian context.

Timeline: Current – Dec. 2022 Budget: \$80,000 - \$120,000



Develop our innovative Chapters and Volunteers model further to amplify our advocacy efforts, outreach and education nationally and throughout New Zealand (and potentially Asia-Pacific). Provide further professional development and skills training for volunteers in this rapidly emerging field. **Budget:** \$150,000-250,000 per annum

Budget: \$10,000,000

Supporting Australian clinical research and development trials to test and optimise the safety and effectiveness of medicine-assisted psychotherapy for mental illness in the Australian context. **Budget:** from \$750,000 to support

novel trials



Medicine Availability and clinic rollout

Agribusiness

Manufacturing

Clinic rollout

Timeline: Current

Certificate in Psychedelic-Assisted Therapies (CPAT)



The Certificate in Psychedelic-Assisted Therapies by Mind Medicine Australia (MMA CPAT) has been developed primarily to meet the anticipated demand for trained therapists to provide regulatory-approved and research-backed psychedelic-assisted therapies for the treatment of mental ill-health in Australia. It is also expected that trained clinicians will be needed to work in research trials as they expand in Australia.

We welcome applications from the following professionals:

- Psychologists
- Psychiatrist and Medical Practitioners
- Occupational Therapists
- Social Workers
- Nurses
- Registered Psychotherapists and Counsellors
- Paramedics

"One of the things I've been doing a lot in the last year is teaching on the Mind Medicine Australia training course, which I think is the best course in the world for educating people about how to use psychedelics and how to develop, through that, in Australia, several hundred people who have the competencies and knowledge to potentially be therapists for this kind of treatment."

Professor David Nutt (UK), ABC News, Dec 2021

Fundamentals of Psychedelic-Assisted Therapy Online Course



PSYCHOLOGICAL SUPPORT SERVICES

A safe and professional psychological service for those who want support regarding psychedelics, plant medicines, and their emotional health and wellbeing.

- Individual counselling
 - Via Skype or phone
 - Group Integration
- Professional Consultation
 - Training

- Supervision
- Bulk billing
- Private health
 - NDIS

Contact us at:

psychologicalsupport@mindmedicineaustralia.org



RESCHEDULING NEXT STEPS

15 December 2021:

The TGA released Notice of final decision to NOT Reschedule the Medical Use of MDMA for Treatment Resistant PTSD and the Medical Use of Psilocybin for Treatment Resistant Depression as Part of Therapy.

Mind Medicine Australia intends on resubmitting rescheduling applications to the TGA for these medicines in March 2022.

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WE ORGANISED THE MOST IMPORTANT MENTAL HEALTH SUMMIT IN THE SOUTHERN HEMISPHERE



DR RICK DOBLIN (USA) Executive Director of MAPS (Multidisciplinary Association for Psychedelic Studies)



PROFESSOR DAVID NUTT (UK) Head of Neuropsychopharmacology at Imperial College London and Chief Research Officer at Awakn Life Sciences



DR GABOR MATÉ (CANADA) Renowned Trauma and Addiction Physician



JOHANN HARI (UK) Journalist and Bestselling Author



(USA) Professor in the Departments of Psychiatry and Neurosciences at the Johns Hopkins University School of Medicine



DR BEN SESSA (UK) Chief Medical Officer at Awakn Life Sciences, Psychiatrist, Researcher and Writer



PROFESSOR ROBIN CARHART-HARRIS (USA) Ralph Metzner Distinguished Professor, Weill Institute for Neurosciences and University of California San Francisco



DR WILLIAM RICHARDS (USA) Psychologist in the Center for Psychedelic and Consciousness Research



FRANÇOISE BOURZAT (USA) DR ALBERTO VILLOLDO (USA) Founder the Four Winds Society, Director the Center for Energy Medicine (Chile)



DR JENNIFER MITCHELL (USA) Professor in the Departments of Neurology and Psychiatry and Behavioral Sciences at UCSF



PROFESSOR MATTHEW JOHNSON (USA) Susan Hill Ward Professor of Psychedelics at Johns Hopkins University School of Medicine



DR WADE DAVIS CM (CANADA) Professor of Anthropology & BC Leadership Chair in Cultures and Ecosystems at Risk at the University of British Columbia



DR PATRYCJA SLAWUTA (USA) Behavioural Scientist



DR REID ROBISON (USA) Psychiatrist, Psychedelic Researcher and Chief Medical Officer at Novamind



DR LYNN MARIE MORKSI (USA) President of the Psychedelic Medicine Association



RONAN LEVY (CANADA) Co-Founder and the Executive Chairman of Field Trip Health



DR. SRINIVAS RAO (USA) Co-Founder & Chief Scientific Officer, atai Life Sciences



Psychedelic Guide Trainer

and Author

DR LYLE OBERG (CANADA) KELSEY RAMSDEN (CANADA) Co-Founder and CEO at Co-Founder, CEO & President at Mindcure



JOSEPH ARAUJO (CANADA) Co-Founder and Chief Scientific Officer of Mindset Pharma and the CEO and President of InterVivo Solutions



DR MICHAEL WINLO

Managing Director, Emyria



ADMIRAL CHRIS BARRIE AC Former Head of the Australian Defence Force and Strategic Leadership Consultant



HON ANDREW ROBB AO Former Minister for Trade, Investment and Tourism in Australia



JOHN SKERRITT Deputy Secretary, Health Products Regulation Group



DR SIMON LONGSTAFF AO **Executive Director of The Ethics** Centre



ARTHUR CHRISTOPOULOS Professor of Analytical Pharmacology and Molecular Neuropsychopharmacologist



DR ELI KOTLER Psychiatrist and Director of Medicine at Malvern Private Hospital



TANIA DE JONG AM Founder Creative Universe, Creativity Australia, Creative Innovation Global and Mind Medicine Australia



PETER HUNT AM Investment Banker & engaged Philanthropist; Founder Women's Community Shelters and Mind Medicine Australia



Join your Local Chapter!

We have over 30+ FREE Chapters around Australia and New Zealand. Be part of a like-minded community and help to create a new paradigm for mental health!

Join a Chapter near you today: mindmedicineaustralia.org

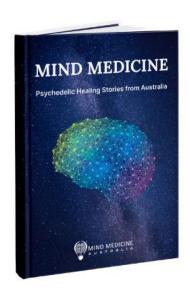
Our Merchandise



Support the future of psychedelic medicine by purchasing from our shop! We offer t-shirts, tote bags, our book of Australian healing stories, greeting cards, face masks and more...











Shop now!

Go to: shop.mindmedicineaustralia.org