A New Treatment Paradigm for Mental Illness in Australia: Medicine-Assisted Psychotherapy
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
The most common mental illnesses are:

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

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

Australian Bureau of Statistics 2018, National Health Survey First Results, cat. no. 4364.0.55.001, ABS, Canberra.
With Even Worse Outcome for ADF Veterans & First Responders

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

• 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 Affair 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)

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct costs of mental ill-health and suicide (a conservative estimate)</td>
<td>$43 - $51 billion per year</td>
</tr>
<tr>
<td>Diminished health &amp; life expectancy for those living with mental illness</td>
<td>$130 billion cost per year</td>
</tr>
<tr>
<td><strong>Total cost of mental illness and suicide to the Australian economy</strong></td>
<td>~$180 billion cost per year</td>
</tr>
</tbody>
</table>

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)
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

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Investment Banker & Engaged Philanthropist

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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

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 Liknaitzky  
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”
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.

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

Psilocybin-assisted therapy sessions Johns Hopkins Uni

Schenberg, E. E. S. (2018). Psychedelic-assisted psychotherapy... Frontiers in pharmacology, 9, 733
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.

Large population studies show no increase in risk for mental ill-health or addiction with lifetime use of classical psychedelics, compared with non-use.
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.”

4. Delivering Outstanding Clinical Results
• 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


Remission rates with psilocybin-assisted psychotherapy improve over time.

# At least 50% reduction in symptoms
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.

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

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

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

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.

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
5. Involvement of Major Institutions in Clinical Trials
Active Medicinal Psychedelic Research Programs
Recently Announced Centres for Psychedelic Research

Imperial College London

- 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

Prohibition as part of the “War on Drugs”

Number of Academic Publications
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
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.”
“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
6. Our Strategy
Awareness and Knowledge Building

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

Therapist Training

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

Access to Medically Approved Therapy

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

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?
Appendices
How you can help

Start conversations and share this information with your contacts.

Volunteer, all skill levels welcome!

Read our educational content and share.

Talk to your doctors and medical professionals

Fundraise or donate
We rely on community support.

Follow us on social media for the latest updates.

Talk to your local member of parliament

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 a Psychedelic Therapist Training Program for qualified and experienced clinicians.
Timeline: Current – December 2020
Budget: $450,000 ($150,000 over three years)

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

Development of ethical, legal and regulatory frameworks to ensure best practice, safety, accountability, and transparency.
Timeline: Current – November 2020
Budget: $100,000

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

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

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
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