

LABORATORY OF THE FUTURE?

AUSTRALIA'S PRESCRIPTION PSYCHEDELIC
ROLL OUT AND OTHER INNOVATIONS IN THE
LAND OF OZ

PAUL LIKNAITZKY, PHD

HEAD, CLINICAL PSYCHEDELIC LAB

DIRECTOR, MONASH PSYCHEDELIC EDUCATION PROGRAM

DEPT OF PSYCHIATRY

SCHOOL OF CLINICAL SCIENCES

MONASH UNIVERSITY

www.monash.edu/psychedelics

Paul.L@monash.edu

PSYCHEDELIC SCIENCE AFFILIATIONS & DISCLOSURES

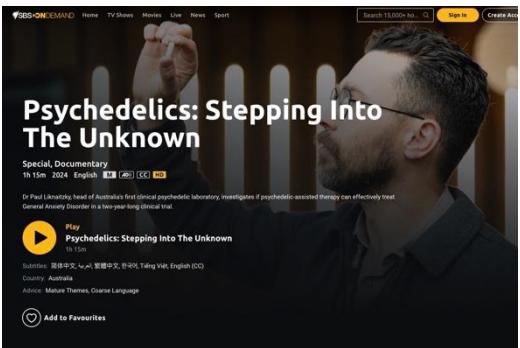
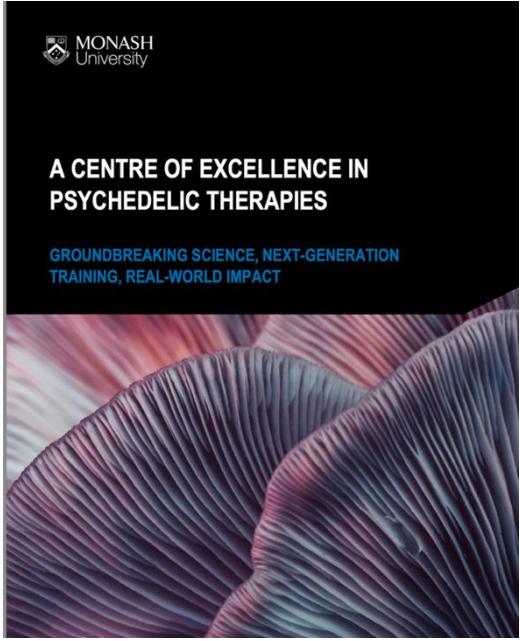
Founder, Head: Clinical Psychedelic Lab, Dept Psychiatry, Monash University (Aus)

Adjunct Senior Research Fellow: School of Psychological Sciences, Monash University (Aus)

Scientific Advisory: MIND Foundation (Germany); Natural Medtech (Aus); Emyria (Aus); Toga Health (Aus); Otsuka (USA)

Research funding: MRFF (Australian Government); Beckley Psytech (UK); Cybin Inc (CA); Incannex Healthcare (Aus/USA); Multidisciplinary Association for Psychedelic Studies (USA).

AUSTRALIA'S FIRST PSYCHEDELIC LAB



PSYCHEDELIC PSYCHIATRY – SECOND WAVE

HARVARD
UNIVERSITY



UCLA



Imperial College
London

UNIVERSITY OF
CAMBRIDGE



UNIVERSITY OF
OXFORD



NYU

Maastricht
University



University of
Zurich UZH



Yale University



University of
BRISTOL

Universität
Basel

ST VINCENT'S
HOSPITAL
MELBOURNE

Stanford
University



UAB
Universitat Autònoma
de Barcelona

MACQUARIE
University
SYDNEY-AUSTRALIA



MONASH
University



COMPASSION
Navigating Mental Health Pathways



delix



atai
LIFE SCIENCES



GILGAMESH



MindMed



Beckley
Psytech



GH Research



MAPS
Public Benefit
Corporation



Cybin



B-MORE



Small Pharma



Lusaris
THERAPEUTICS



Usona
Institute



journey colab



Mindset
Pharma



CaaMTech



ceruvia



TRYp
THERAPEUTICS



EMPYREAN
INNOVATIONS



TACTOGEN



ONSERO



HEFFTER
RESEARCH INSTITUTE



Lophora



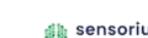
PSYBIO
THERAPEUTICS



RETURNHEALTH



sensorium
THERAPEUTICS



ALGERNON
PHARMACEUTICALS



PSY
THERAPEUTICS



ASRI
ALEXANDER SHULGIN RESEARCH INSTITUTE



LOBE



Albert.
Labs



HARMADRUG



PSYLO



Revive
Therapeutics



Clearmind



reunion
NEUROSCIENCE



psilera
BIOSCIENCE



Incannex



DIAMOND
THERAPEUTICS



Reset
Pharma



BEXSON
BIOMEDICAL



MYND
Life Sciences



Psyence



SiloPharma



BRIGHT
MINDS



Clerkenwell Health



BetterLife
Pharma



NOVA
MENTIS
LIFE SCIENCE



Awakn



Clexio
Biosciences



wesana



MIKAL
CHAM



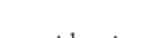
ENVERGE
BIOSCIENCES



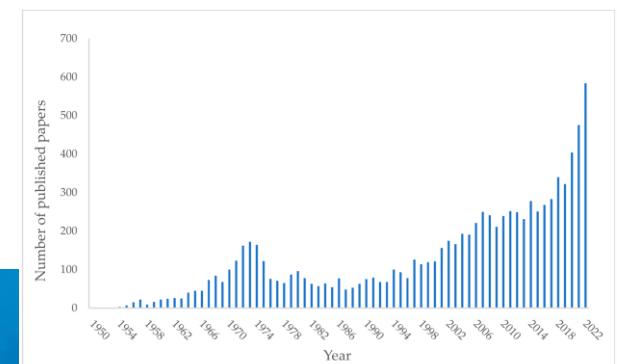
Mindstate
Design Labs



Alvarius

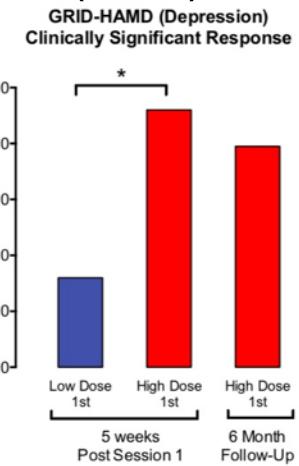


MYDECINE
MEDICINE EXPLAINED

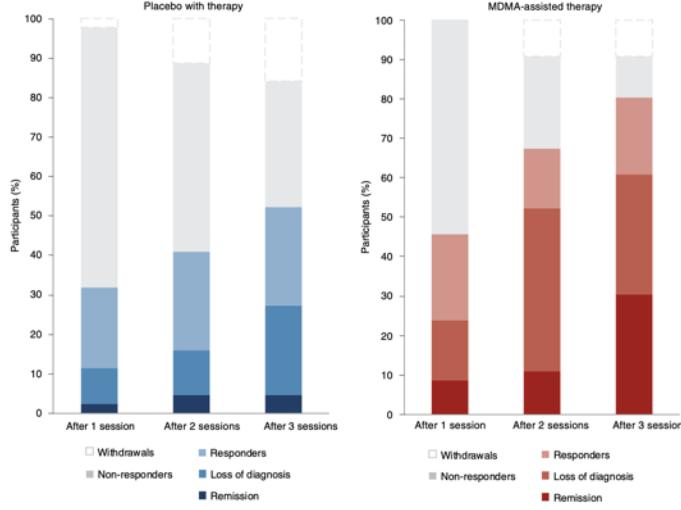


WHAT'S ALL THE EXCITEMENT ABOUT?

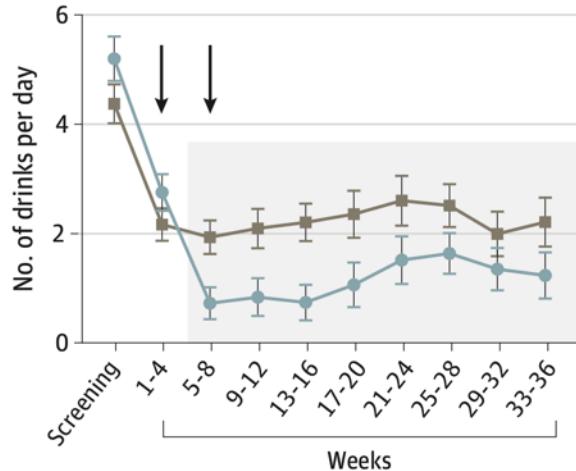
Psilo/EoL Distress (JHU)



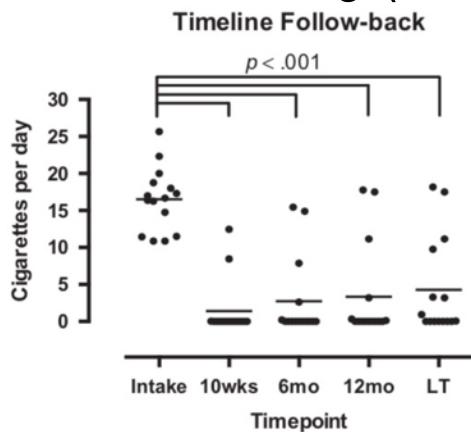
MDMA/PTSD (MAPS)



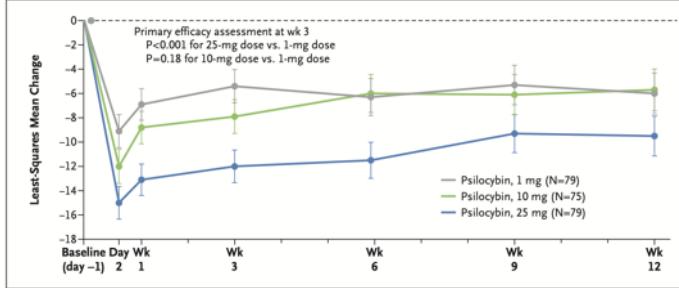
Psilo/AUD (NYU)



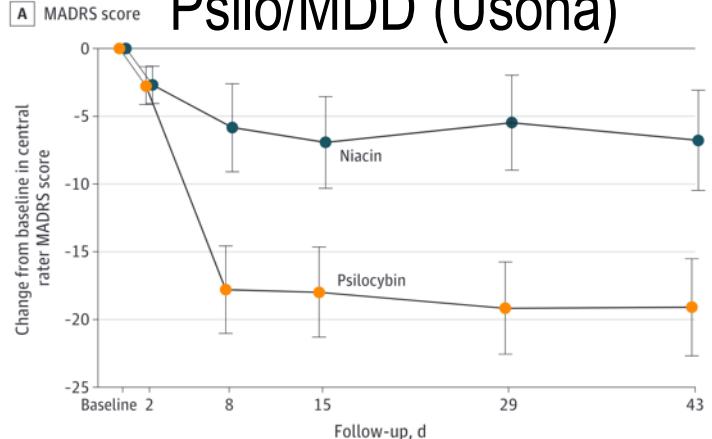
Psilo/Smoking (JHU)



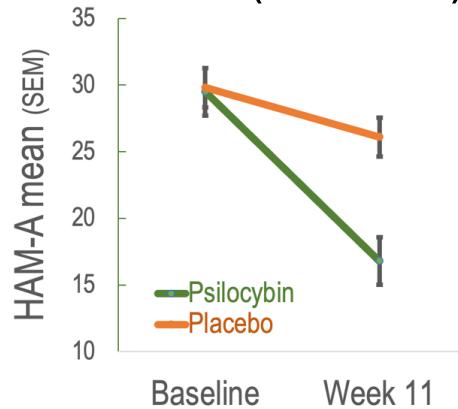
Psilo/TRD (Compass)



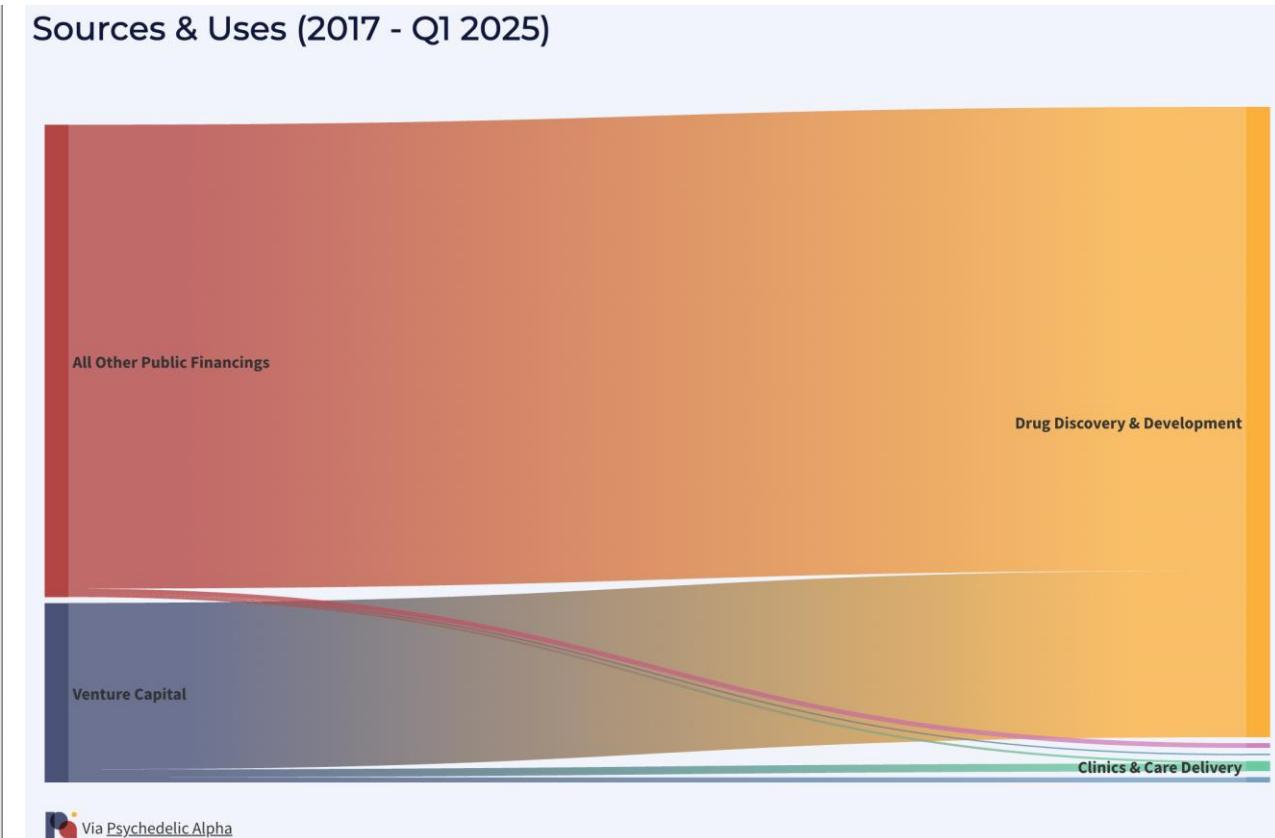
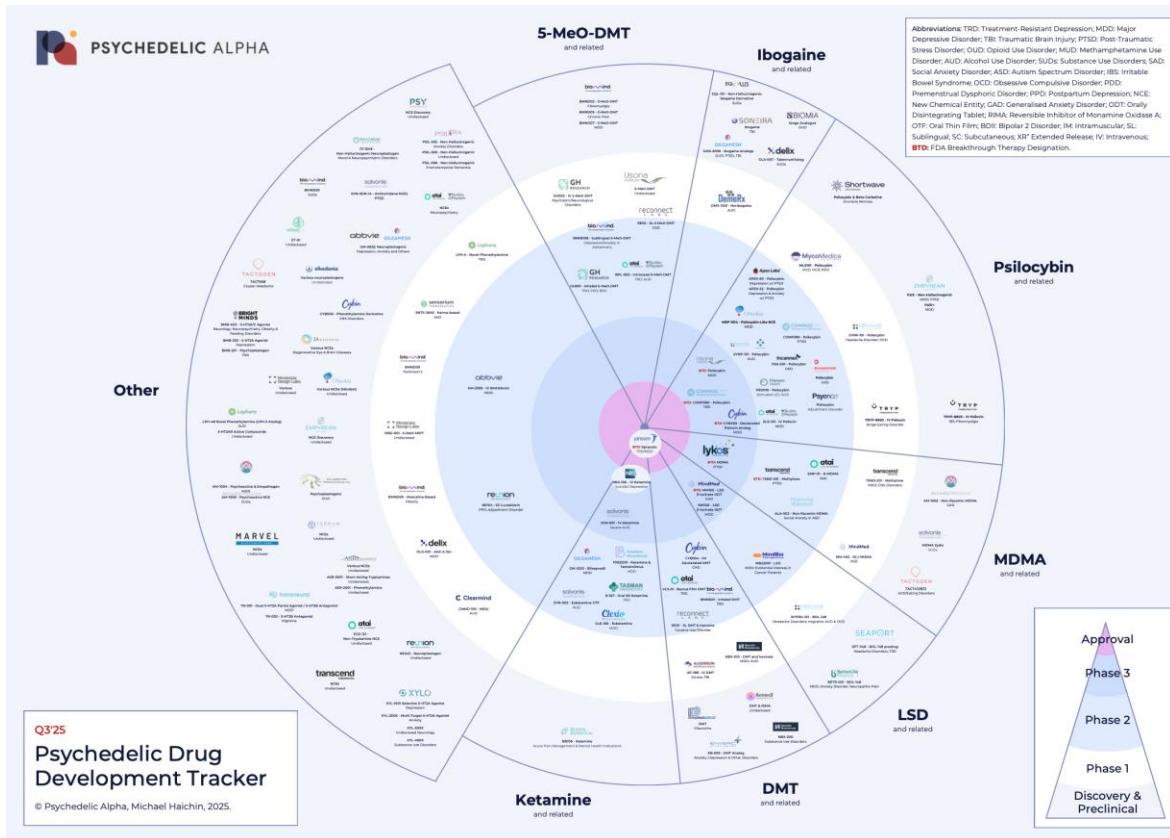
Psilo/MDD (Usona)



Psilo/GAD (Monash)



WHERE ARE WE HEADED? ...FOLLOW THE MONEY



The PAT field is drifting toward 'narrowness'

- **Narrow Targets** → Symptoms, late-stage pathology; misses prevention, wellbeing, contextual drivers ...
- **Narrow Training** → Basic support, manuals, knowledge; misses the centrality of relationship, personal-professional dev, therapeutic character/presence ...
- **Narrow Translation** → Products, usual-care; misses psychedelic-specific, system-level design...



INNOVATION IN:

- 1. ACCESS**
- 2. REGULATION**
- 3. IMPLEMENTATION**

ACCESS: DOWN- SCHEDULED PSYCHEDELICS

WORLD-FIRST DOWNSCHEDULING

- Bifurcated down
- MDMA for PTS
- Psychiatrists (+)
- Application to H
- Application to T
- Some State/Terr
- RANZCP guideli
- Announced 3rd Q



MDMA (3,4-methylenedioxymethamphetamine) and psilocybin for therapeutic purposes for psychiatrist prescribers

February 2023



THE AUTHORISED PRESCRIBER SCHEME

At recent update, Sep 2025:

- MDMA APs = 30
- Psilocybin APs = 26
- Total unique patients treated with MDMA = 87
- Total unique patients treated with psilocybin = 47

Schedule 10 – prohibition of sale, use and supply

Schedule 9 – prohibited substances

Schedule 8 – controlled substances

Schedule 7 – dangerous poisons

Schedule 6 – label use of poison

Schedule 5 – label use of caution

Schedule 4 – prescription only medicines

Schedule 3 – pharmacist only medicines

Schedule 2 – pharmacy medicines



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WORLD-FIRST DOWNSCHEDULING

CONCERNS

- Rolled out too quickly – particularly in Aus context?
- Inadequate monitoring, not harmonised?
- Inadequate reporting, not public?
- No working group or formal collaborative learning process established?
- **Does not afford multisite best-practice development**



Access to MDMA (3,4-methylenedioxymethamphetamine) and psilocybin for therapeutic purposes
[Information for psychiatrist prescribers](#)

Version 2.0, February 2023



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WORLD-FIRST DOWNSCHEDULING

COMFORTS

- Numerous guardrails – HREC, RANZCP, TGA, state Gov, drug + therapy, AP/therapist training...
- Opportunity to successfully treat greater number and diversity of patients?
- Real-world implementation – develop best-practice, train professionals, assess cost-effectiveness, etc?
- **May afford a ‘soft launch’:** compared to drug approval, more barriers to entry, guardrails, caution, scrutiny... (and likely capacity development).



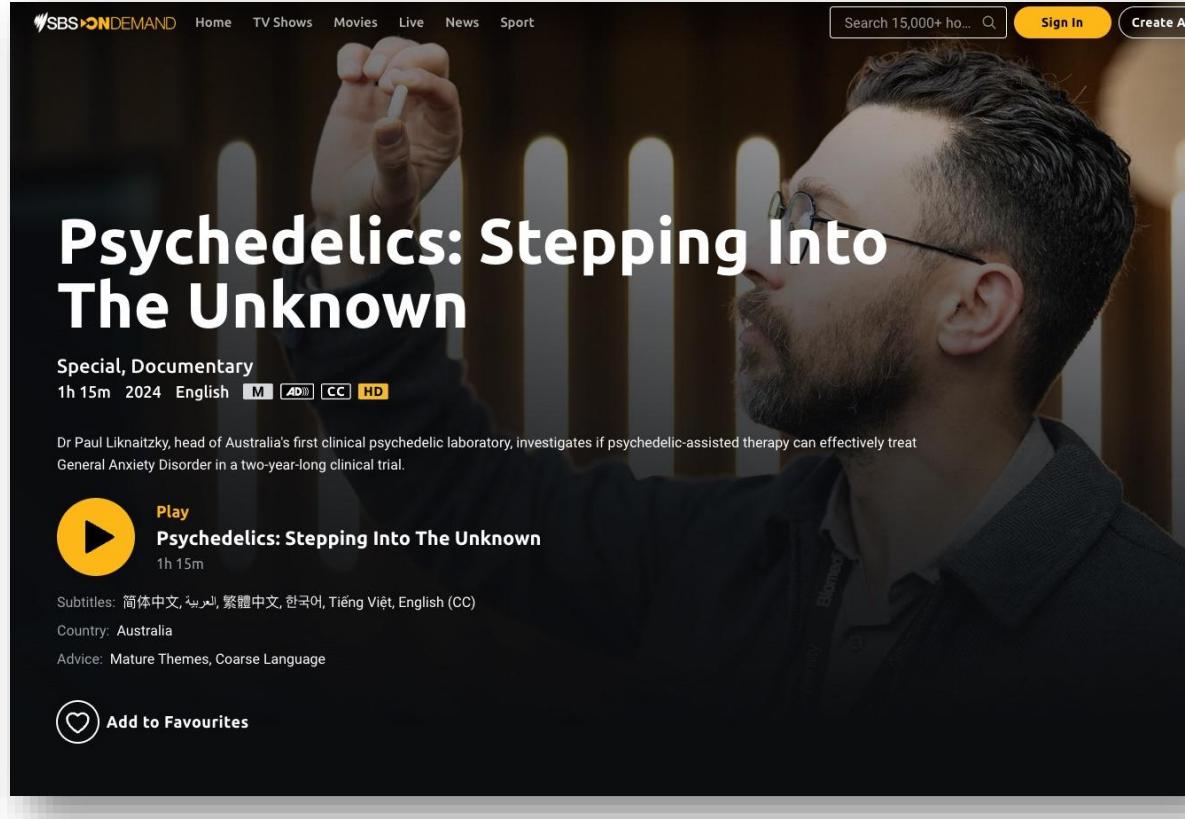
Access to MDMA (3,4-methylenedioxymethamphetamine) and psilocybin for therapeutic purposes
[Information for psychiatrist prescribers](#)

Version 2.0, February 2023



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WORLD-FIRST DOWNSCHEDULING



The image is a screenshot of the SBS OnDemand website. At the top, the navigation bar includes 'Home', 'TV Shows', 'Movies', 'Live', 'News', 'Sport', a search bar 'Search 15,000+ ho...', and buttons for 'Sign In' and 'Create Account'. The main content area features a documentary thumbnail for 'Psychedelics: Stepping Into The Unknown'. The thumbnail shows a man with a beard and glasses looking upwards. The title 'Psychedelics: Stepping Into The Unknown' is displayed in large white text. Below the title, it says 'Special, Documentary' and '1h 15m 2024 English M AD CC HD'. A description follows: 'Dr Paul Liknaitzky, head of Australia's first clinical psychedelic laboratory, investigates if psychedelic-assisted therapy can effectively treat General Anxiety Disorder in a two-year-long clinical trial.' A large yellow 'Play' button is centered on the thumbnail. Below the thumbnail, the following details are listed: 'Subtitles: 简体中文, हिन्दी, 繁體中文, 한국어, Tiếng Việt, English (CC)', 'Country: Australia', and 'Advice: Mature Themes, Coarse Language'. At the bottom, there is a 'Add to Favourites' button with a heart icon.



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REGULATION: **TOOLS NOT** **TREATMENTS**

TOOLS NOT TREATMENTS



TOOLS NOT TREATMENTS

- Addressing the ‘liability’ of psychotherapy for pharma R&D
- Psychedelics as tools, not treatments: a la **anaesthetics**
- Reframing Psychedelic Regulation:
 - Product regulators can focus on ‘therapeutic states’ as endpoints (e.g., distress tolerance)
 - Practice regulators can focus on procedure (medical, psychotherapeutic)
- Implications:
 - **Averts ‘race to the bottom’** in psychedelic practice
 - Supports **best-practice** development
 - Dramatically **expands ‘addressable market’!**

Check for updates

Review

Reframing psychedelic regulation: Tools, not treatments

Max Wolff^{1,2} , Natalie Gukasyan³ , Leor Roseman⁴ and Paul Liknaitzky^{5,6} 

Abstract
Current regulation frameworks for medicines struggle to address the combination of pharmacological and psychotherapeutic elements in psychedelic therapy. We propose a more appropriate and advantageous approach may be to regulate psychedelic drugs as therapeutic tools or adjuncts to psychotherapy, rather than as treatments for specific mental disorders. Drawing parallels with anesthetics, which facilitate various medical procedures (through inducing a loss of sensation or consciousness) while not being treatments in themselves, we argue that a primary medical purpose of psychedelic drugs is to facilitate psychotherapeutic treatments. Reframing psychedelic regulation to accommodate this use would allow drug regulators to focus on relevant acute drug effects, rather than therapeutic outcomes that result from complex interactions between these effects and psychotherapeutic interventions; more appropriate authorities could then regulate the psychotherapy. This approach could limit the emerging trend in psychedelic drug development that views psychotherapy as a strategic liability and seeks to de-emphasize or remove it to the potential detriment of safe and durable clinical outcomes.

Keywords
Psychedelics, regulation, psilocybin, MDMA, psychotherapy

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Drug Science

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IMPLEMENTATION:

FIFO-PAT

KEY CHALLENGES FOR PAT CLINICS

- Expensive
- Clinics few and far between
- Protocols not adequately tailored
- Limited continuity-of-care
- Difficult to determine client suitability
- Opportunity for durable outcomes can be missed



THE FIFO-PAT APPROACH

- Cheaper
- Location-independent
- Tailored
- Preserves continuity-of-care
- Improves screening / suitability
- Potential for more durable outcomes?



FIFO-PAT-201 OVERVIEW



Sekula



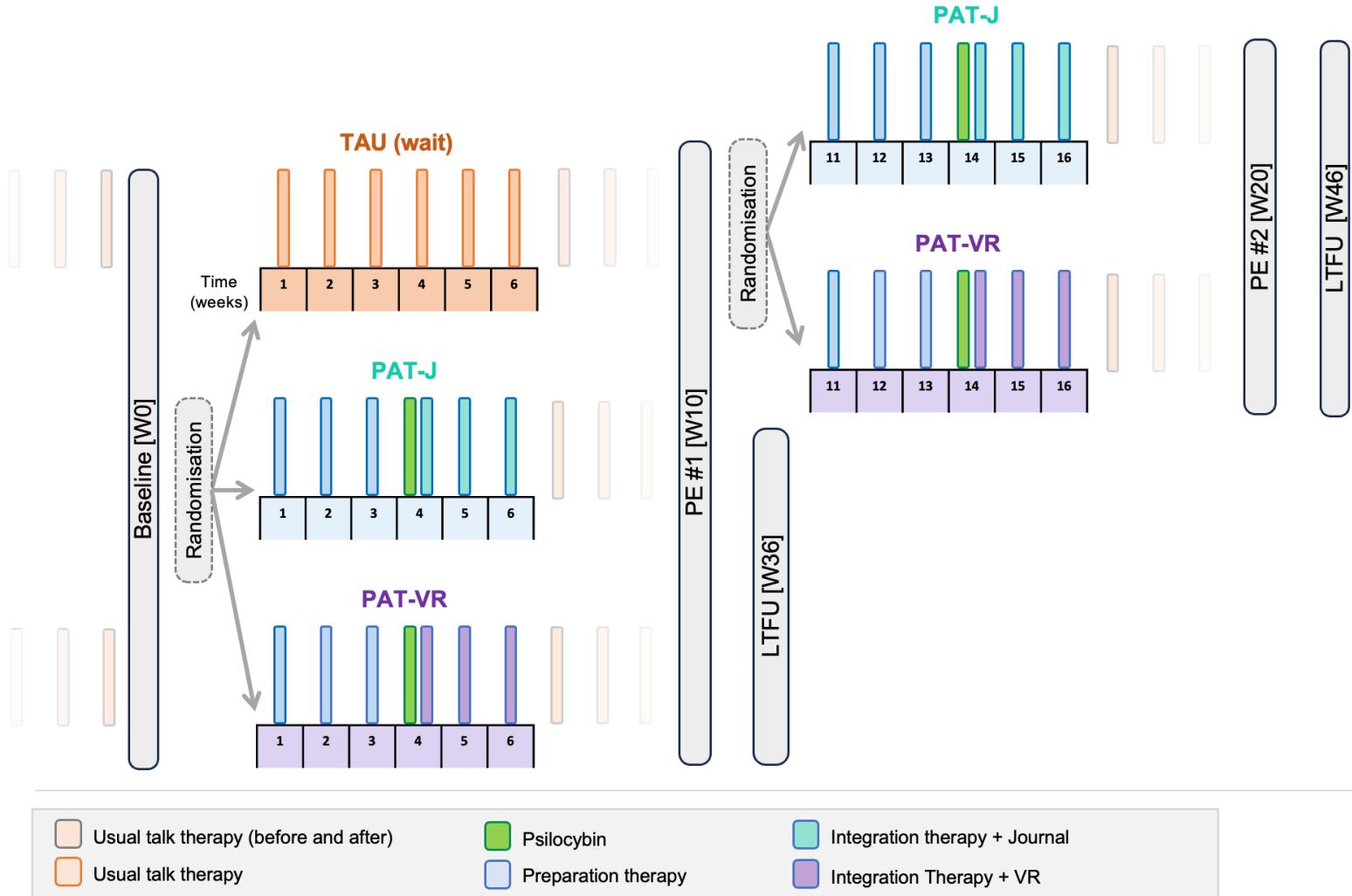
Puspanathan



Spektor

- **Rationale:** Distributed model of PAT in community may be more accessible and beneficial
- **Design:** Sequential, randomised, TAU-controlled trial
- **Intervention:** Psilocybin-assisted psychotherapy with self-directed extended integration adjuncts
- **Participants:** 30 people with Major Depressive Disorder
- **Outcomes:** Feasibility, safety, acceptability, preliminary efficacy:
↓ depression, ↑ functioning

FIFO-PAT-201



TRANSLATIONAL R&D: BEYOND PRODUCTS

Developing modular, distributed system-level design for service quality: training, supervision, protocols, infrastructure, monitoring, community, compliance, approvals...

Prescriber
PAT Practitioner
PAT nurse/medico
PAT Training
Prescriber Training
Hlth of peer-support

Treatment room
AV + storage
Medication
Drug storage
Medical equipment
Digital platform

PAT protocol
Screening protocol
Risk protocol
Ext'd Integration
Monitoring
Cmtn peer-support



TRANSLATIONAL R&D: BEYOND PRODUCTS

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Prescriber Training

Prof peer-support

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PAT protocol

Screening protocol

Risk protocol

Ext'd Integration

Monitoring

Clin peer-support



TRANSLATION: BEYOND PRODUCTS

- **Counterpoint to quality decay:** Pharma R&D and regulation drifting pharmaco-centric, constrained within standard care models/contexts
- **System design and integration:** Protect PAT-specific therapeutic integrity while bridging into health services
- **Dual mandate:** Solve simultaneously for access and quality

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