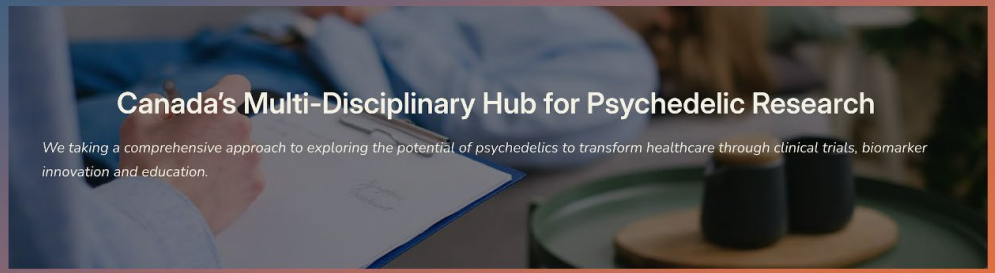
Centre for Psychedelics Health & Research



PRESENTATIONS & PANEL

Clinical Trials Ontario

Psilocybin and the Past and Future of Care

Leaders in history and culture, psychiatry, and clinical research explore past uses and perceptions of psilocybin, as well as clinical trials that are currently underway in Canada and the opportunities and challenges shaping the future of psychedelic-assisted care.



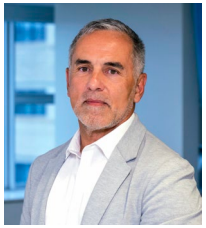
Dr. Ishrat Husain
Department Head, UHN's Centre for Mental Health and Program Medical Director, UHN-CAMH Partnership



Dr. Claudio Soares
Professor of Psychiatry, Queen's University; Director, Centre for Psychedelics Health and Research at Providence Care Hospital & Queen's University



Justin Jennings
Senior Curator, Archaeology of the Americas, Royal Ontario Museum



Claudio N Soares MD, PhD, FRCPC, MBA

Professor, Department of Psychiatry, Queen's University, Canada
Executive Director, the Canadian Menopause Society
Director, Centre for Psychedelics Health and Research
Immediate Past President, the Menopause Society



Disclosures:
Research Grants: CIHR, SEAMO, Ontario Centre for Innovation, Otsuka, Eisai, Clairvoyant, Diamond Therapeutics, Atai Therapeutics, Ontario Brain Institute

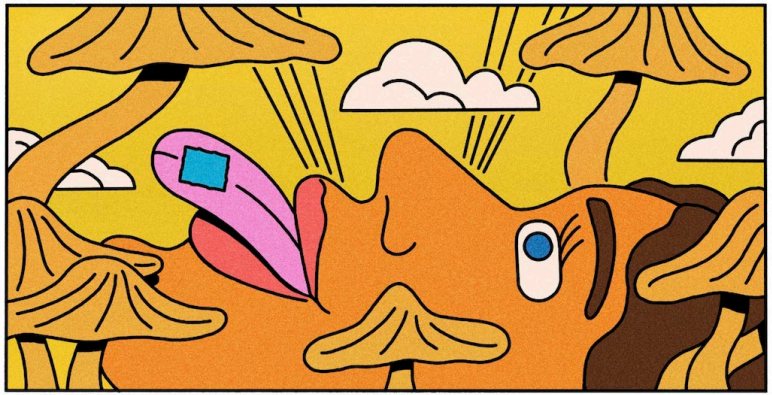
Advisory Board Member: Bayer, Eisai, Lundbeck, Otsuka, Idorsia, AbCellera

School of Medicine
Queen's University Kingston, Ontario
Queens University

The Menopause Society

CANADIAN MENOPAUSE SOCIETY
SOCIÉTÉ CANADIENNE DE MÉNOPAUSE

THE NEW YORKER 100



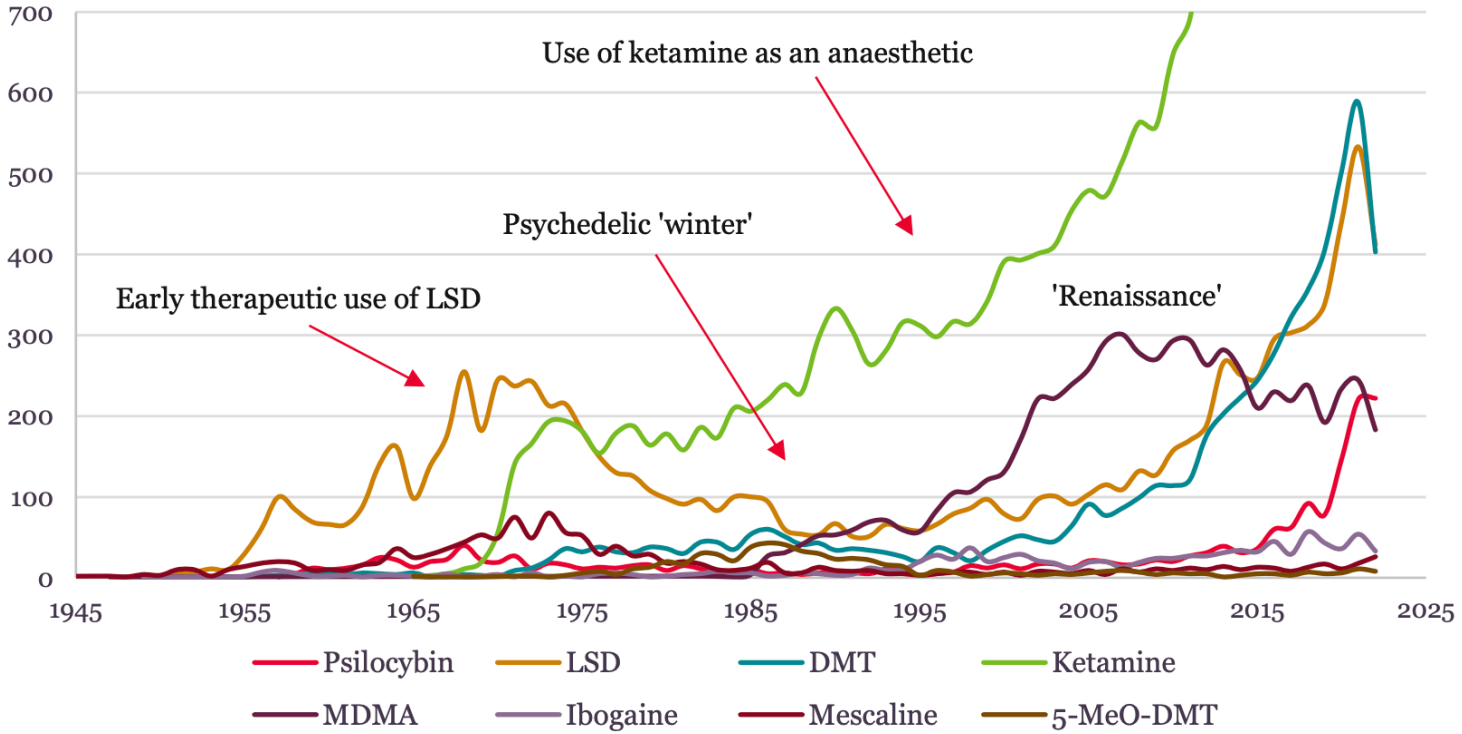
The New York Times



May 2018

August 2024

Number of psychedelic research papers has exploded in the last century



Source: PubMed - date accessed: 26/09/22, H&P estimates

Current FDA Landscape

New IND Applications to DP: 2000 to 2021





Unpublished internal analysis; includes research and commercial INDs
Psychedelics included: ayahuasca, DMT, LSD, MDMA, psilocybin



Challenges to overcome.....

Science - Methodology, generalizability of findings, scalability of results

Regulatory - contracts, REB/IRBs, pathways for commercialization. Regulatory oversight

Socio-cultural - Risk for cultural appropriation, exploitation – e.g., peyote, ayahuasca; stigma; pressures for legalization

Unknown- Risks with broader recreational use/liberalization
Long-term safety, potential abuse
Long-term sustainability of effects



Centre for Psychedelics Health & Research (CPHR)

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CAN-BIND



Centre for Psychedelics Health & Research (CPHR)

- **Multi-professional, multi-disciplinary** (Psychiatry, Oncology, Nursing, Palliative Medicine)
- **Clinical trials - A hub and a catalyst** for the design, implementation, and execution of clinical trials on psychedelics
- **New technologies** applied to psychedelic research - **biomarkers, precision medicine**



Centre for Psychedelics Health & Research (CPHR)

- **Multi-professional, multi-disciplinary, Clinical Trial Hub**
  - Demoralization, existential distress in end-of-life cancer
  - Depression
  - Depression and Trauma in Women
  - Generalized Anxiety Disorders
  - Eating Disorders

- **New technologies, new agents**
  - DMT
  - Psilocybin
  - EEG, Wearables

OncoDaily

$17.9 MILLION

from Canadian Cancer Society and Brain Canada for CCS Breakthrough Team Grants

Mar 19, 2025

Groundbreaking Canadian Cancer Society-funded research aims to reshape the future of advanced cancer



$5.4 million – (U of Calgary, Queen's)
Focus on existential distress, demoralization and hopelessness in people living with advanced cancer - **Psilocybin and mindfulness**



$5.9 million (Bruyère Health Research Institute, Sinai Health), a platform to connect patients with RCTS for palliative care - **use of psilocybin (microdosing) for existential distress in palliative care**



CPHR members co-applied successfully for both grants; it will host clinical trials and train HCPs and researchers for both projects.



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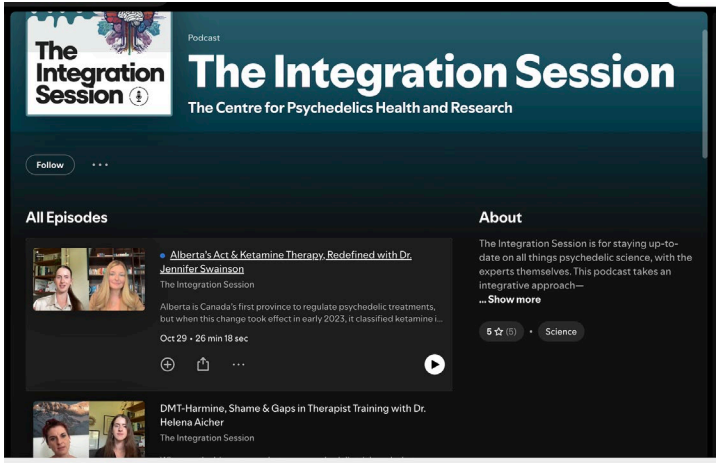
- **The knowledge synthesis and dissemination, and regulatory strategies** for psychedelic health

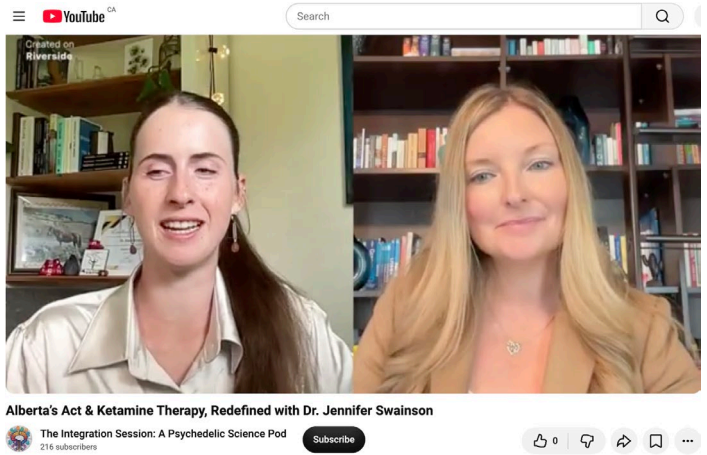
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Knowledge synthesis and dissemination









A Phase 2a, Placebo-Controlled Randomized, Double-Blind Trial to Evaluate the Safety, Tolerability, and Preliminary Efficacy of Psilocybin Oral Solution in Adults with Generalized Anxiety Disorder

Primary Objective

- To evaluate the safety and tolerability of 3 mg psilocybin in an oral solution administered once daily in adults who meet criteria for generalized anxiety disorder (GAD).

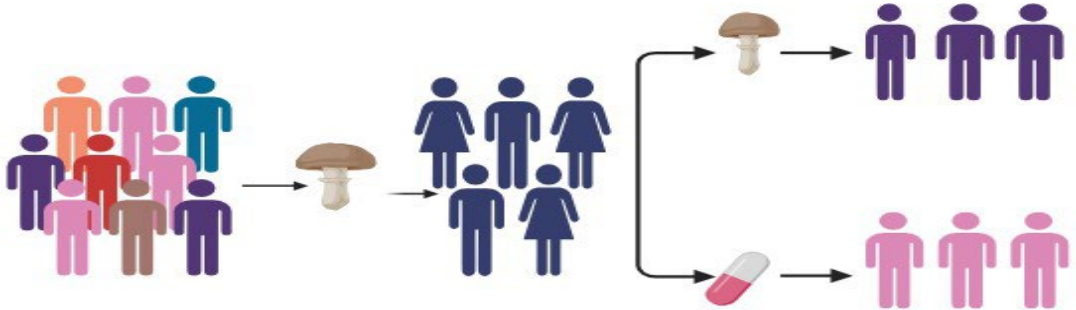
Secondary Objective

- To assess the preliminary efficacy of 3 mg psilocybin in an oral solution administered once daily in the treatment of adults who meet criteria for GAD.



Psilocybin

3mg oral solution



-28 days | Wk 1-4 | Wk 4-8

Placebo

Data Collection



Clinical



EEG

Safety Panel



Blood

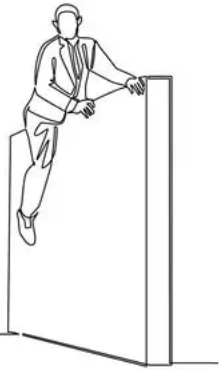
Population

18-70 y/o
GAD dx

Weekly visits for monitoring and IP accountability/dispensing



Some hurdles to overcome....



- SOPs for IP storage, dispensing and accountability
- Obtaining approval from REB, Health Canada
- SOPs to ensure safe at-home use prior to first IP dispensing
- Reporting of AES when psychedelics are used daily at a low dose