Exploring Psilocybin in Canadian Palliative Care: Unveiling History, Definitions, and Legal Landscapes

Project ECHO
Palliative Care - Canada
BY Pallium Canada

Host: Dr. José Pereira

Presenters: Dr. Ronald Shore and Dr. Jean Mathews

Date: 11 March 2024

Territorial Honouring

The Palliative Care ECHO Project

The Palliative Care ECHO Project is a 5-year national initiative to cultivate communities of practice and establish continuous professional development among health care providers across Canada who care for patients with life-limiting illness.

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The Palliative Care ECHO Project is supported by a financial contribution from Health Canada. The views expressed herein do not necessarily represent the views of Health Canada.

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Introductions

Host

Dr. José Pereira, MBChB, CCFP(PC), MSc, FCFP, PhD
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Professor, Division of Palliative Care, Department of Family Medicine, McMaster University, Hamilton, ON, Canada
Scientific Advisor and Co-Founder, Pallium Canada

Presenters

Dr. Jean Jacob Mathews, MBBS MD
Assistant Professor, Division of Palliative Medicine
Departments of Medicine & Oncology, Queen's University

Dr. Ronald Shore, MPA, PhD
Research Scientist, Psychedelics
Assistant Professor, Department of Psychiatry
Queen's Health Sciences
Queen's University, Kingston, On.

Guest Panelists

Dr. Kylea Potvin, MD FRCPC
Medical Oncologist
London Regional Cancer Program
Associate Professor
Western University

Geneviève Lalumière, BScN, RN MN
Clinical Nurse Specialist and Coordinator
Regional Palliative Consultation Team
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Medical Lead, Pain/Palliative Care, Tom Baker Cancer Centre, Calgary
Co-Lead, Alberta Provincial Palliative Team

Conflict of Interest

Pallium Canada

- Non-profit.
- Partially funded through a contribution by Health Canada.
- Generates funds to support operations and R&D from course registration fees and sales of the Pallium Pocketbook.

Host/Presenters

- Jose Pereira: Scientific Advisor, Pallium Canada.
- Ronald Shore: Dr. Shore currently owns share in a psychedelics-oriented retreat centre.
- Jean Mathews: Nothing to disclose.

Welcome and Reminders

- For comments, please use the chat function.
- For questions, please use the Q&A function, these questions will be addressed at the end of the session.
- This session is being recorded—this recording and slide deck will be emailed to registrants within the next week.
- Remember not to disclose any Personal Health Information (PHI) during the session.

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Topics

- The problem- existential distress when facing a life-limiting illness
- Evidence for currently available solutions- psychotherapeutic and psychopharmacological
- Evidence for psilocybin in palliative care
- Limitations and future directions

The problem-existential distress

- Mental distress experienced by those facing imminent death and associated with demoralization, absence of purpose or meaning, hopelessness, isolation, and loss of dignity
- Aka death anxiety, depression, demoralization, hopelessness etc.
- Prevalent in 30-40% of patients with a palliative diagnosis (Mitchell 2011)
- Associated with decreased QoL, increased health care utilization, requests for hastened death and suicidal ideation, and decreased survival

Mitchell AJ, Chan M, Bhatti H, Halton M, Grassi L, Johansen C, Meader N. Prevalence of depression, anxiety, and adjustment disorder in oncological, haematological, and palliative-care settings: a meta-analysis of 94 interview-based studies. Lancet Oncol. 2011 Feb;12(2):160-74. doi: 10.1016/S1470-2045(11)70002-X. Epub 2011 Jan 19. PMID: 21251875.

Current solutions- psychotherapeutic

- Dignity therapy (Chochinov 2011)
- CBT (Greer 2012)
- Meaning-centered psychotherapy (Breitbart 2015)
- CALM therapy (Rodin 2018)
- Specialized palliative care as dyadic coping intervention (von Heymann-Horan 2019)

Breitbart W, Rosenfeld B, Pessin H, Applebaum A, Kulikowski J, Lichtenthal WG. Meaning-centered group psychotherapy: an effective intervention for improving psychological well-being in patients with advanced cancer. J Clin Oncol. 2015 Mar 1;33(7):749-54. doi: 10.1200/JCO.2014.57.2198. Epub 2015 Feb 2. PMID: 25646186; PMCID: PMC4334778.

Chochinov HM, Kristjanson LJ, Breitbart W, McClement S, Hack TF, Hassard T, Harlos M. Effect of dignity therapy on distress and end-of-life experience in terminally ill patients: a randomised controlled trial. Lancet Oncol. 2011 Aug;12(8):753-62. doi: 10.1016/S1470-2045(11)70153-X. Epub 2011 Jul 6. PMID: 21741309; PMCID: PMC3185066.

Rodin G, Lo C, Rydall A, Shnall J, Malfitano C, Chiu A, Panday T, Watt S, An E, Nissim R, Li M, Zimmermann C, Hales S. Managing Cancer and Living Meaningfully (CALM): A Randomized Controlled Trial of a Psychological Intervention for Patients With Advanced Cancer. J Clin Oncol. 2018 Aug 10;36(23):2422-2432. doi: 10.1200/JCO.2017.77.1097. Epub 2018 Jun 29. PMID: 29958037; PMCID: PMC6085180.

Greer JA, Traeger L, Bemis H, Solis J, Hendriksen ES, Park ER, Pirl WF, Temel JS, Prigerson HG, Safren SA. A pilot randomized controlled trial of brief cognitive-behavioral therapy for anxiety in patients with terminal cancer. Oncologist. 2012;17(10):1337-45. doi: 10.1634/theoncologist.2012-0041. Epub 2012 Jun 11. PMID: 22688670; PMCID: PMC3481900.

von Heymann-Horan A, Bidstrup PE, Johansen C, Rottmann N, Andersen EAW, Sjøgren P, von der Maase H, Timm H, Kjellberg J, Guldin MB. Dyadic coping in specialized palliative care intervention for patients with advanced cancer and their caregivers: Effects and mediation in a randomized controlled trial. Psychooncology. 2019 Feb;28(2):264-270. doi: 10.1002/pon.4932. Epub 2018 Nov 15. PMID: 30353600.

Cochrane Database Syst Rev. 2008 Apr; 2008(2): CD005537.
Published online 2008 Apr 16. doi: 10.1002/14651858.CD005537.pub2
PMCID: PMC6464138
PMID: 18425922

Psychotherapy for depression among incurable cancer patients

Tatsuo Akechi, Toru Okuyama,✉ Joji Onishi, Tatsuya Morita, and Toshi A Furukawa

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- 10 RCTs, 780 participants
- 6 included in meta-analyses: four studies used supportive psychotherapy, one used cognitive behavioural therapy, and one used problem-solving therapy
- When compared with treatment as usual, psychotherapy was associated with a significant decrease in depression score (SMD = -0.44)

Meta-Analysis > Psychooncology. 2018 Nov;27(11):2531-2545. doi: 10.1002/pon.4829.
Epub 2018 Aug 2.

Effects of existential interventions on spiritual, psychological, and physical well-being in adult patients with cancer: Systematic review and meta-analysis of randomized controlled trials

Natalie Bauereiß [1], Stefanie Obermaier [1], Selçuk Erol Özünal [1], Harald Baumeister [1]

Affiliations + expand

PMID: 29958339 DOI: 10.1002/pon.4829

- 30 RCTs, 3511 participants
- Meaning-centred interventions (*n*= 8), supportive-expressive groups (*n* = 9), cognitive-existential therapy (*n* = 2), life review (*n* = 4), dignity therapy (*n* = 4), and hope interventions (*n* = 3). Length of interventions ranged from one to 52 weeks.
- Significant effects on existential well-being (g = 0.52) and quality of life (g = 0.21) at post-treatment, on hope at post-treatment (g = 0.43) and after 6 months (g = 0.25). Largest effect sizes for Life Review
- No effects for anxiety, depression, spiritual well-being
- Existential interventions might be suited to improve existential well-being and quality of life in the short term, hope in the short term and at 6 months, and self-efficacy in the short term. Follow-ups in the medium and long term were scarce

Current solutions- psychopharmacological

- SSRIs
- TCAs
- Mirtazapine
- Bzds
- Ketamine

Review > Cochrane Database Syst Rev. 2023 Mar 31;3(3):CD011006.
doi: 10.1002/14651858.CD011006.pub4.

Antidepressants for the treatment of depression in people with cancer

Giovanni Vita [1], Beatrice Compri [1], Faith Matcham [2], Corrado Barbui [3], Giovanni Ostuzzi [3]

Affiliations + expand

PMID: 36999619 PMCID: PMC10065046 (available on 2024-03-31)
DOI: 10.1002/14651858.CD011006.pub4

- 14 RCTs (1364 participants)
- For acute-phase treatment response (six to 12 weeks), antidepressants may reduce depressive symptoms when compared with placebo, even though the evidence is very uncertain
- No studies reported data on follow-up response (more than 12 weeks)
- In head-to-head comparisons, there was no difference between SSRIs, TCAs, or Mirtazapine; However, there was a positive safety profile for SSRIs.
- Intravenous esketamine might be a potential treatment but further studies needed

Classic psychedelics

- Psilocybin
- LSD
- Mescaline
- DMT

Psilocybin

- Found in several mushroom species
- Metabolized to psilocin
- potent agonist at serotonin 5-HT1A/2A/2C receptors, with 5-HT2A receptor activation directly correlated with hallucinogenic activity

Grob CS, Danforth AL, Chopra GS, Hagerty M, McKay CR, Halberstadt AL, Greer GR. Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer. Arch Gen Psychiatry. 2011 Jan;68(1):71-8. doi: 10.1001/archgenpsychiatry.2010.116. Epub 2010 Sep 6. PMID: 20819978.

Randomized Controlled Trial

> Psychopharmacology (Berl). 2006 Aug;187(3):268-83; discussion 284-92.
doi: 10.1007/s00213-006-0457-5. Epub 2006 Jul 7.

Psilocybin can occasion mystical-type experiences having substantial and sustained personal meaning and spiritual significance

R R Griffiths [1], W A Richards, U McCann, R Jesse

Affiliations + expand

PMID: 16826400 DOI: 10.1007/s00213-006-0457-5

- Double-blind RCT
- 30 volunteers received 30mg psilocybin or methylphenidate 40 mg. Volunteers were encouraged to close their eyes and direct their attention inward.
- Questionnaires assessing drug effects and mystical experience immediately after and 2 months after sessions
- Psilocybin produced acute perceptual changes, labile moods including anxiety, and increased measures of mystical experience
- At 2 months- substantial personal meaning and spiritual significance; sustained positive change to attitudes and behaviours

RCTs of psilocybin in palliative care

- Grob CS, Danforth AL, Chopra GS, Hagerty M, McKay CR, Halberstadt AL, Greer GR. Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer. Arch Gen Psychiatry. 2011 Jan;68(1):71-8. doi: 10.1001/archgenpsychiatry.2010.116. Epub 2010 Sep 6. PMID: 20819978.

- Griffiths RR, Johnson MW, Carducci MA, Umbricht A, Richards WA, Richards BD, Cosimano MP, Klinedinst MA. Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. J Psychopharmacol. 2016 Dec;30(12):1181-1197. doi: 10.1177/0269881116675513. PMID: 27909165; PMCID: PMC5367557.

- Ross S, Bossis A, Guss J, Agin-Liebes G, Malone T, Cohen B, Mennenga SE, Belser A, Kalliontzi K, Babb J, Su Z, Corby P, Schmidt BL. Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial. J Psychopharmacol. 2016 Dec;30(12):1165-1180. doi: 10.1177/0269881116675512. PMID: 27909164; PMCID: PMC5367551.

Anderson BT, Danforth A, Daroff PR, Stauffer C, Ekman E, Agin-Liebes G, Trope A, Boden MT, Dilley PJ, Mitchell J, Woolley J. Psilocybin-assisted group therapy for demoralized older long-term AIDS survivor men: An open-label safety and feasibility pilot study. EClinicalMedicine. 2020 Sep 24;27:100538. doi: 10.1016/j.eclinm.2020.100538. PMID: 33150319; PMCID: PMC7599297.

Randomized Controlled Trial > Arch Gen Psychiatry. 2011 Jan;68(1):71-8.
doi: 10.1001/archgenpsychiatry.2010.116. Epub 2010 Sep 6.

Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer

Charles S Grob [1], Alicia L Danforth, Gurpreet S Chopra, Marycie Hagerty, Charles R McKay, Adam L Halberstadt, George R Greer

Affiliations + expand

PMID: 20819978 DOI: 10.1001/archgenpsychiatry.2010.116

- Double-blind, placebo-controlled (niacin 250mg) study
- 12 patients with advanced cancer and anxiety, 67% reported previous psychedelic use
- Moderate dose (0.2 mg/kg) of psilocybin plus psychotherapy
- Exclusion criteria: CNS involvement of cancer, severe CAD, untreated HTN, abnormal hepatic or renal function, DM, lifetime history of schizophrenia, bipolar disease, other psychotic illness, and anxiety or affective disorders within 1 year prior to the onset of cancer. Medication contraindications included active cancer chemotherapy, antiseizure medications, insulin and oral hypoglycemics, and psychotropic medications in the previous 2 weeks.
- Primary outcome- safety: Holter monitoring, hourly BP and HR; adverse psychological effects. Secondary outcomes- Beck Depression Inventory, Profile of Mood States, and State-Trait Anxiety Inventory. Follow-up for 6 months
- Safe; Improved anxiety at 1 and 3 months; improved depression at 6 months.

Clinical Trial > J Psychopharmacol. 2016 Dec;30(12):1181-1197.
doi: 10.1177/0269881116675513.

Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial

Roland R Griffiths [1 2], Matthew W Johnson [3], Michael A Carducci [4], Annie Umbricht [3], William A Richards [3], Brian D Richards [3], Mary P Cosimano [3], Margaret A Klinedinst [3]

Affiliations + expand

PMID: 27909165 PMCID: PMC5367557 DOI: 10.1177/0269881116675513

- Randomized, double-blind, cross-over trial
- Low dose (1 or 3 mg/70 kg) vs. high dose (22 or 30 mg/70 kg) of psilocybin administered in counterbalanced sequence with 5 weeks between sessions and psychotherapy. 6-month follow-up
- N=51; Mean age 56 yrs; 49% F; 94% White; 45% reported past use of hallucinogens; 27% had metastatic ca with prognosis< 2yrs
- At 6 months, >75% of high-dose group showed >50% reduction in depression and anxiety from baseline
- Mystical experience during sessions was a significant mediator of the therapeutic response

Inclusion/Exclusion

- ECOG 0-2
- Patients receiving chemotherapy, hormonal therapy, radiation therapy, biologic therapies may participate while receiving those therapies.
- Non-routine PRN medications for treating breakthrough pain that were taken in the 24 hours before the psilocybin session may result in rescheduling the treatment session
- Exclusion: Cancer with CNS involvement, hepatic or renal dysfunction, BP> 140/90, atrial fibrillation, seizures; currently taking benzodiazepines, ondansetron, dexamethasone, fentanyl etc. Patients with suicidal ideation, psychoses, bipolar disorder

Clinical Trial > J Psychopharmacol. 2016 Dec;30(12):1165-1180.
doi: 10.1177/0269881116675512.

Rapid and sustained symptom reduction following psilocybin treatment for anxiety and depression in patients with life-threatening cancer: a randomized controlled trial

Stephen Ross [1 2 3 4 5 6], Anthony Bossis [7 2 4], Jeffrey Guss [7 2 4], Gabrielle Agin-Liebes [8], Tara Malone [7], Barry Cohen [9], Sarah E Mennenga [7], Alexander Belser [10], Krystallia Kalliontzi [2], James Babb [11], Zhe Su [3], Patricia Corby [2], Brian L Schmidt [2]

Affiliations + expand

PMID: 27909164 PMCID: PMC5367551 DOI: 10.1177/0269881116675512

- Double-blind, placebo-controlled, crossover trial
- Single-dose psilocybin (0.3 mg/kg) or niacin 250mg, both in conjunction with psychotherapy
- Primary outcomes were anxiety and depression assessed between groups prior to the crossover at 7 weeks
- N=29; 62% F; mean age 56; 90% White; 34% stage 4 cancer; 55% previous hallucinogen use
- Immediate and Substantial improvements in anxiety, depression, demoralization, QoL; sustained at 6-month follow-up.
- Mystical experience partially mediated the therapeutic effect

Inclusion/Exclusion

- Projected life expectancy of at least one year
- Medical exclusion criteria included epilepsy, renal disease, diabetes, abnormal liver function, and severe cardiovascular disease (i.e. congestive heart failure, uncontrolled hypertension).
- Psychiatric exclusion criteria included a personal or immediate family history of schizophrenia, bipolar disorder, delusional disorder, paranoid disorder, and schizoaffective disorder.
- Patients with a current substance use disorder were excluded.
- Study participants were free of concomitant psychotropic medications (e.g. anti-depressants) for two weeks prior to randomization and for the duration of the study.

J Psychopharmacol. 2020 Feb;34(2):155-166. doi: 10.1177/0269881119897615.
Epub 2020 Jan 9.

Long-term follow-up of psilocybin-assisted psychotherapy for psychiatric and existential distress in patients with life-threatening cancer

Gabrielle I Agin-Liebes [1 2], Tara Malone [2 3], Matthew M Yalch [1], Sarah E Mennenga [2], K Linnae Ponté [4], Jeffrey Guss [2 3 5], Anthony P Bossis [2 3 5], Jim Grigsby [6 7], Stacy Fischer [6 7], Stephen Ross [2 3 5]

Affiliations + expand

PMID: 31916890 DOI: 10.1177/0269881119897615

- Long-term within-subjects follow-up analysis of self-reported symptomatology involving a subset of participants, n=15
- 3.2 and 4.5 years following dosing session
- 71% of participants in partial or complete cancer remission
- Sustained reduction in anxiety, depression, hopelessness, demoralization, death anxiety. No lasting adverse effects.
- Participants rated it among the most personally meaningful and spiritually significant experiences of their lives
- Possible mechanisms- mystical experience, trait openness, cognitive flexibility

Set

- Each participant met with the two session monitors before (preparation), in-between, and after 8-hr dosing sessions (integration).
- Griffiths 2016: mean of 4 therapy sessions, duration 9 hrs
- Ross 2016: mean of 6 therapy sessions, duration 12 hrs
- Build rapport and trust; review significant life issues in the patient's history, and the nature and status of present relationships and concerns
- Discuss the purpose and intention of participation, the treatment goals, the structure of the sessions, and critical issues to be examined during the treatments.
- Prepare for the range of emotional reactions that might be experienced, including challenging psychological issues that might arise. “Trust, let go, and be open”

Grob CS, Danforth AL, Chopra GS, Hagerty M, McKay CR, Halberstadt AL, Greer GR. Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer. Arch Gen Psychiatry. 2011 Jan;68(1):71-8. doi: 10.1001/archgenpsychiatry.2010.116. Epub 2010 Sep 6. PMID: 20819978.
Griffiths RR, Johnson MW, Carducci MA, Umbricht A, Richards WA, Richards BD, Cosimano MP, Klinedinst MA. Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. J Psychopharmacol. 2016 Dec;30(12):1181-1197. doi: 10.1177/0269881116675513. PMID: 27909165; PMCID: PMC5367557.

Setting

- “Room decorated with fabric wall hangings and fresh flowers to provide a pleasing and comfortable environment” (Grob 2011)
- “Drug sessions were conducted in an aesthetic living-room-like environment with two monitors present” (Griffiths 2016)
- “The room included fresh flowers and fruit. Participants were encouraged to bring in items of personal significance and meaning.” (Ross 2016)
- Subjects were encouraged to lie in bed wearing eye shades and headphones to listen to preselected music and focus their attention inward.
- The study therapists remained with the participant throughout the entire 8-hour session
- Towards the end of the dosing session, participants were encouraged to discuss the entirety of their subjective experience with the treatment team to consolidate the memory of the experience

Adverse effects

- Transient increase in BP (elevated SBP>150mmHg in 34% of high-dose group, Griffiths 2016). Cardiovascular effects peaked at 180-min post-dosing (Ross 2016)
- Nausea/vomiting (15% of high-dose group, Griffiths 2016)
- Headache (28%, Ross 2016)
- Transient psychological distress (32% of high-dose group, Griffiths 2016)
- No instances of persistent perception disorders or psychoses

J Psychoactive Drugs. 2020 Sep-Oct;52(4):289-299. doi: 10.1080/02791072.2020.1769878.
Epub 2020 Jun 12.

A Meta-Analysis of Placebo-Controlled Trials of Psychedelic-Assisted Therapy

Jason B Luoma [1], Christina Chwyl [1], Geoff J Bathje [2], Alan K Davis [3 4], Rafael Lancelotta [5]

Affiliations + expand

PMID: 32529966 PMCID: PMC7736164 DOI: 10.1080/02791072.2020.1769878

- 9 RCTs of psychedelic-assisted therapy using psilocybin, LSD, ayahuasca, and MDMA
- Significant mean between-groups effect size of 1.21, which is larger than the typical effect size found in trials of psychopharmacological or psychotherapy interventions (0.3-0.5)
- Effect size achieved with 1-3 doses vs. daily dosing of psychopharmacological agents
- Partly explained by the combination of psychedelic and psychotherapy

Limitations of current research

- Small sample sizes; clinico-demographic characteristics not generalizable
- Blinding of participants either unsuccessful or not reported
- High % of previous psychedelic experience
- Expectancy effects- enthusiastic participants and disappointed placebo group
- People of color were largely absent from these studies
- Carryover effects in crossover trials
- Private sector funding

Luoma JB, Chwyl C, Bathje GJ, Davis AK, Lancelotta R. A Meta-Analysis of Placebo-Controlled Trials of Psychedelic-Assisted Therapy. J Psychoactive Drugs. 2020 Sep-Oct;52(4):289-299. doi: 10.1080/02791072.2020.1769878. Epub 2020 Jun 12. PMID: 32529966; PMCID: PMC7736164.
Hovmand OR, Poulsen ED, Arnfred S, Storebø OJ. Risk of bias in randomized clinical trials on psychedelic medicine: A systematic review. J Psychopharmacol. 2023 Jul;37(7):649-659. doi: 10.1177/02698811231180276. Epub 2023 Jul 4. PMID: 37403379; PMCID: PMC10350724.

Future directions

- Larger sample sizes
- Parallel group design
- Low dose psychedelic as active placebo
- Psychedelic-naive participants to improve blinding
- Measure success of blinding of participants, therapists, and assessors
- Clinician-reported outcomes
- Fewer exclusion criteria to make findings more generalizable
- Study cost-effectiveness, given that psychedelic-assisted therapy, as currently delivered, may be relatively expensive
- Studies to understand the role of concurrent psychotherapy practices and measure therapeutic fidelity

Overview

- Perspective as a health scientist and clinical trial therapist
- Neurobiological underpinnings
- Ancestral, spiritual and Indigenous histories
- Current legal and regulatory context
- Patient experiences
- Key themes including:
  - Role of spiritual care workers
  - Exquisite sensitivity to context
  - Psilocybin can occasion profound emotional experiences, richly varied and highly personal
  - Palliative care as an already transformative space
- Key Definitions including:
  - Peak psychedelic therapy model
  - Preparation-Session-Integration

Neurobiological Underpinnings

- Psilocybin acutely reduces connectivity in associative networks of the brain including medial and lateral prefrontal cortex, cingulum, temporoparietal junction and insula, but concurrently increases sensory, brain-wide connectivity and induces hyper-connectivity in sensory areas; the integration of functional connectivity in sensory regions and the disintegration in associative regions may underlie the psychedelic effect (Preller et al., 2020). Recent neuroimaging studies have better documented the brain network reintegration dynamics which occur after the widespread, global desynchronization of brain networks and entropic dynamics of acute psilocybin effect (Daws et al., 2022; Doss, Madden, et al., 2021; Mertens et al., 2020). As revised networks form following drug effect, greater connectivity and revised network dynamics have been found between regions of the neocortex and sub-cortical regions including components of the limbic system.
- Source: **Knowledge Synthesis in the Science of Psilocybin: Scoping Reviews of Clinical and Preclinical Research.** July 2023. DOI: 10.13140/RG.2.2.15260.26248

Religious (Entheogenic) and Medicinal Histories

- *Psilocybe* genus mushrooms are pan-global in their distribution
- Evidence of cultural and ritualistic use of psychoactive drugs across multiple cultures, often found in funeral and other ritual settings
- The Eleusinian mysteries of Ancient Greece as a collective psychedelic ritual of Earth worship, death-reckoning, myth and meaning-making
- The Mushroom Stones of Guatemala
- Mazatec Mushroom Rituals
  - Maria Sabina, “one who knows” and can access the book of knowledge
  - The *velada* and the history of *Teonanactl,* the sacred mushroom that paints
  - Role of the healer/guide/ritualist/ceremonialist and the role of spirituality in healing

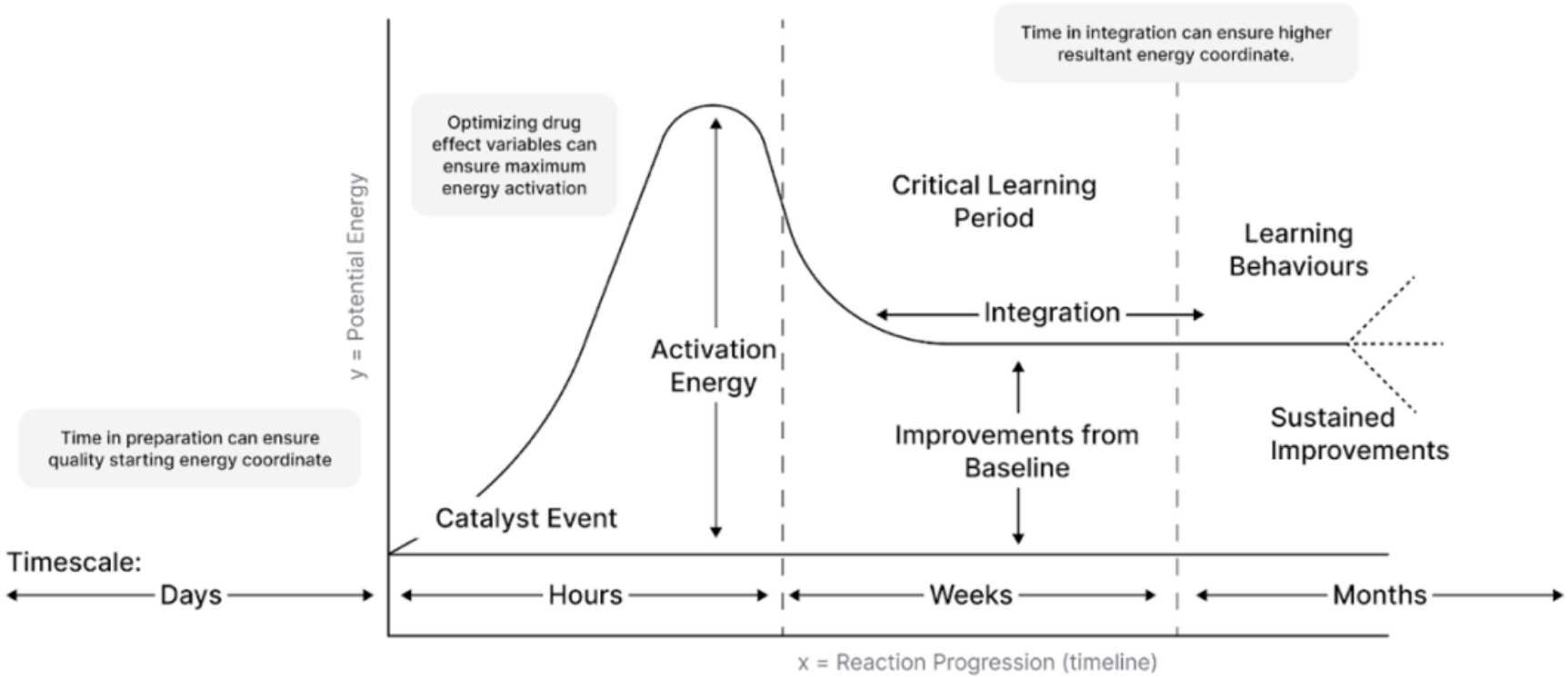
Peak Psychedelic Model

- Emphasis on high, threshold dose levels:
  - 25mg psilocybin (high, but not too high)
  - Curated setting (sensitivity to context)
  - Use of music, eyeshades
  - Mantra: “Let go and surrender”
- Relatively Standardized Preparation-Session-Integration (PSI) Model
- Psychopharmacology: psilocybin used as an adjunctive therapy: catalyst effect
- Psychedelics as “non-specific amplifiers”
- Known predictors of positive outcomes:
  - Emotional tolerance and ability to self-regulate (breathwork, meditation)
  - Trait of absorption
  - Positive language
  - Age, previous experience

The Psychedelic Experience

- 1964 manual based on THE TIBETAN BOOK OF THE DEAD (Bardo Thodol), by Timothy Leary, Ralph Metzner & Richard Alpert
- Marsh Chapel experiment, Good Friday 1962
- The clear light of consciousness, *bardos*, death-and-rebirth as the model of change
- The encountering of wrathful deities
- Psychedelics as a death practice: ego dissolution, liminality (betwixt and between)
- Three stages of the journey:
  - Ego loss
  - Hallucinations
  - Period of Re-entry

Transition State Model of Psychedelic Action: A Reaction Energy Diagram



Current Legal and Regulatory Context

- Psilocybin is classified in Canada as a Schedule 3 controlled substance under the Controlled Drugs and Substances Act of 1996 making the production, possession and sale of psilocybin illegal. While the CDSA largely prohibits access to or use of controlled substances though exemptions for research or humanitarian purposes may be granted under Section 56 of the CDSA or under the Special Access Program of Health Canada. Researchers have suggested that the national and international regulatory restrictions on psychedelic compounds have been barriers to the growth of quality clinical research (Sellers et al., 2018).
- Active training and certification programs including Foundations of Psychedelic-assisted Psychotherapy Program (Michener Institute), Vancouver Island University, U Ottawa plus Therapsil

Special Access Program (Health Canada)

- Psychedelic drugs are subject to the *Food and Drugs Act* (FDA) and its regulations, and most are also controlled under the *Controlled Drugs and Substances Act* (CDSA). Legally, to conduct activities with psychedelic controlled substances in Canada, health care practitioners need appropriate authorizations from Health Canada under both the FDA and the CDSA. Regulatory amendments to the *Food and Drug Regulations* (FDR) made it possible for health care practitioners to request access to restricted drugs through the SAP as of January 2022. Psilocybin and MDMA are both classified as restricted drugs. The decision to authorize a drug through the SAP, whether it is a psychedelic drug or any other class of drug, is based on sufficient evidence to support the requested use, including the drug information available to the SAP at the time of the request, as well as evidence of how it would benefit the patient based on their clinical history. The SAP reviews requests on a case-by-case basis.

https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/requests-special-access-program-psychedelic-assisted-psychotherapy.html

Patient Experiences / Subjective Effects

- Experiences of deep emotionality and spirituality
- Cognitive reappraisal
- Multi-perspectivism
- Forgiveness and Self-compassion
- Alterations to identity and personality are possible
- Experiences of expanded consciousness, of seeing into things (mind-manifesting)
- **Psilocybin sits on the fear response and opens the heart**
- Therapeutic effects mimic biological function and mirror visual effects
  - Interconnection and relationality
  - What is closer in the visual field becomes bigger, and dividing lines soften into unified field

Therapeutic Mechanisms

- Experiences of mysticism and transcendence
- Emotional connectivity and decreased fear response
- Therapeutic rapport is key: safety in order to unfold
- Improved neurological and biological function
- Cognitive flexibility leads to behavioural flexibility and improvements to health behaviours
- Rapid onset anti-depressant effects

- Rescues the deficits of chronic stress
- Gut microbiome and improved HPA function
- Potent anti-inflammatory effects
- Heightened neuroplasticity
- Importance of afterglow period: critical window of improved learning, socially mediated oxytocin-generating activities
- Psilocybin attenuates past conditioning, disrupting habit and potentiating new learning
- Importance of integration key (persisting effects to at least 30 days)

“Many do not realize that
We must here die.
For those who realize this,
Quarrels end.”

Buddha, Dhammapada (5-6)

Q & A

Session Wrap Up

- Thank you for joining us!
- Please fill out the feedback survey following the session—a link has been added into the chat

Thank You

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