Rural Rounds: Psychedelic-Assisted Therapy in the Rural Setting

Dr. Pamela Kryskow, MD, CCFP, FCFP Dr. Gordon Horner (moderator)

November 2, 2023 | 0800-0900 PST





LAND ACKNOWLEDGMENT

I work, live, and play on the traditional, ancestral and unceded territory of the Snuneymuxw, Klahoose, Tla'amin and Homalco Nations





PRESENTER DISCLOSURES

- Medical Lead Roots To Thrive Non Profit
- Founding board member Psychedelic Association of Canada Non Profit
- Medical Chair Vancouver Island Post Graduate Certificate in Psychedelic Assisted Therapy (Adjunct Professor)
- UBC Department of Family Medicine Clinical Instructor
- Interim Medical Director QI Wellness
- Unpaid advisor Nectara (General Advisor), Synaptic (Oregon Psilocybin Services), University of Washington Center for Novel Therapeutics in Addiction
- Future Warrants Numinus clinical protocol advisor
- Scientific Advisor Mycomedica Life Sciences Public Benefit Corporation
- Roots to Thrive receives research grants I am on the team & receive no compensation





MITIGATION OF BIAS

- All content developed as part of this program was reviewed for potential bias by the members of the program planning committee.
- Financial relationships are unrelated to presentation.
- I will speak about generic & naturally occurring medications.
- I will use my clinical experience in my opinions and will try to clearly point out any bias.



LEARNING OBJECTIVES

- Review the current regulatory landscape for psychedelic-assisted therapy
- Identify how psychedelic medicines are currently accessed for Canadians
- Examine research evidence for treatment of PTSD, depression, end of life distress and other mental health challenges
- Describe how rural practitioners can prepare to work with psychedelic medicines in service to their patients





CASE EXAMPLE

Jane is a 32-year-old woman identifying (she/her) has been diagnosed with treatment-resistant depression since the age of 20, she had tried various conventional treatments with limited success including 3 SSRIs, a SNRI, herbs, acupuncture and meditation. She has been working with a therapist who she has a good therapeutic alliance with and has suggested that psilocybin might be an option. She has done some research on it and sees it frequently mentioned in the media. She wants to discuss this option with you





The current regulatory landscape for psychedelic-assisted therapy





Identify how psychedelic medicines are currently accessed for Canadians





A bit of history first...



HISTORIC CONTEXT



Weyburn Mental Hospital - Saskatchewan 2012-2017

740 North Rings & Los Angeles &0 Box 1056. WEIghnen. My deak Aldous, farsh \$74b 205 To fation Hell OR go angeliz Just take a pinch of PSYCHEDELIC (Delos te manifest) I like phonenchymnes . I suggest one discuss which to pash for before the engagement. I have booked at the Backingham. I kust successfully a should see you on the night of Wednesday 11th. I should call you prevailed I don't get in too late. We night decide to lunan my whole address into Rhyming complets. It would be askeering. I hope to get archive colour a clocem sint the one we bought tegethere was a great success. Ver phonen thym - subtanting Phone rothy mic - asjective To make this trivid word sublime Take half a framme of To plumb by deals Just take a prich of psychedolog Aldous Huxley's letter to Humphry Osmond, with Osmond's note showing his first use of the term "psychedelic," 30 March 1956.

Psychedelic Prophets - The Letters of Aldous Huxley and Humphrey Osmond







Humphry Osmond - 1956

HISTORIC CONTEXT

Controlled Substance Act US (1970)

MDMA - Schedule – 1985

"No medical use"

"High potential for abuse"





UBC CPD Medicine CONTINUING PROFESSIONAL DEVELOPMENT



PUBLIC ENEMY NUMBER ONE

IS DRUG ABUSE

NIXON

in the United States

HISTORIC CONTEXT

"We knew we couldn't make it illegal to be either against the war or black, 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 Nixon policy advisor





REGULATORY LANDSCAPE

Canadian Schedules Controlled Drugs and Substances Act (CDSA)

- Schedule I
 - MDMA
 - Ketamine
- Schedule III -
 - DMT/Ayahuasca
 - Psilocybin
 - LSD
- Ibogaine regulated prescription drug but not authorized for medical use



REGULATORY LANDSCAPE

- 2012 Moved into Schedule J making them ineligible for Special Access Program (SAP)
- Section 56(1) exemptions case by case application Dr. Bruce Tobin (2017)
- Section 56.1 exemptions clinical trials (2013)
- Special Access Program (SAP) January 2021



REGULATORY LANDSCAPE

Special Access Program (SAP)

Psilocybin ~ 125 granted End of Life Distress & Treatment Resistant Depression

MDMA ~ 25 granted PTSD





DECRIMINILIZATION

- Psilocybin Vancouver, Kingston, Toronto
- MDMA British Columbia



CHURCHES SECTION 56 EXEMPTIONS

Sante Daime – Ayahuasca

- Céu do Montréal
- Beneficient Spiritist Center União do Vegetal
- Ceu da Divina Luz do Montreal
- Église Santo Daime Céu do Vale de Vida
- Ceu de Toronto





Examine research evidence for treatment of PTSD, depression, end of life distress and other mental health challenges



REGISTERED TRIALS

- 1000's of ketamine trials PTSD, depression, chronic pain, eating disorders, neurological conditions, OCD, anxiety
- 156 Psilocybin PTSD, depression, anxiety, migraines, eating disorders, PD, OCD, grief, fibromyalgia, SUD, Burnout (Professional, Caregiver), Alcohol Use, Cancer, Palliative, Well-being, OUD, Borderline personality
- 142 MDMA PTSD, anxiety, alcohol use, combat stress, cognition, SUD, autism, chronic pain, exposure therapy
- 5 LSD cluster headaches, anxiety, ADHD, palliative care, depression,
- Iboga, Peyote, Huachuma, 5MEO DMT, MEAI, Ayahuasca and more



- Psilocybin alcohol use disorder, tobacco cessation, eating disorders, PTSD, violence reduction
- MDMA PTSD, disordered eating, chronic pain
- LSD substance use disorders, anxiety, depression, alcohol use disorder
- Ketamine depression, OCD, disordered eating, substance use challenges, chronic pain, suicidality
- DMT/Ayahuasca substance use challenges, anxiety, depression, trauma



John Hopkins -Psilocybin & End of Life Distress (2000)

- Regulatory approval 2000
- Published 2006
- Lab synthesized psilocybin
- Top 5 significant experiences of their lives



Photo credit: John Hopkins





Depression & Anxiety in Patients with Life Threatening Cancer

- 2 sessions 5 weeks apart
- 1 or 3mg/70kg vs 22 or 30mg/70kg
- 92% in high dose vs 32 in low dose clinically significant response
- Anxiety remission 52%(high dose) vs 12% (low dose)
- Depression remission 60% (high dose) vs 16% (low dose)

Griffiths RR, Johnson MW, Carducci MA, et al. Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. *J Psychopharmacol.* 2016;30(12):1181-1197.





RESEARCH







JAMA Psychiatry | Original Investigation

Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder A Randomized Clinical Trial

Alan K. Davis, PhD; Frederick S. Barrett, PhD; Darrick G. May, MD; Mary P. Cosimano, MSW; Nathan D. Sepeda, BS; Matthew W. Johnson, PhD; Patrick H. Finan, PhD; Roland R. Griffiths, PhD

2 psilocybin sessions (20mg/70kg & 30mg/70kg)

Supportive psychotherapy

71% had clinically significant results at 4 weeks:

- > 50% reduction in GRID-HAMD score
- 54% in remission

(waitlist control)



Clinical Trial > N Engl J Med. 2021 Apr 15;384(15):1402-1411. doi: 10.1056/NEJMoa2032994.

Trial of Psilocybin versus Escitalopram for Depression

Robin Carhart-Harris ¹, Bruna Giribaldi ¹, Rosalind Watts ¹, Michelle Baker-Jones ¹, Ashleigh Murphy-Beiner ¹, Roberta Murphy ¹, Jonny Martell ¹, Allan Blemings ¹, David Erritzoe ¹, David J Nutt ¹

2 Psilocybin doses 25mg at 3 and 6 weeks and daily 1mg psilocybin for 6 weeks

2 Psilocybin doses 1mg at 3 and 6 weeks and daily escitalopram

Psychological support



Clinical Trial > N Engl J Med. 2021 Apr 15;384(15):1402-1411. doi: 10.1056/NEJMoa2032994.

Trial of Psilocybin versus Escitalopram for Depression

Robin Carhart-Harris ¹, Bruna Giribaldi ¹, Rosalind Watts ¹, Michelle Baker-Jones ¹, Ashleigh Murphy-Beiner ¹, Roberta Murphy ¹, Jonny Martell ¹, Allan Blemings ¹, David Erritzoe ¹, David J Nutt ¹

Psilocybin demonstrated non-inferior efficacy in depression at 6 weeks (QIDS-SR-16)

Secondary endpoints favored psilocybin: Well-being, pleasure or loss of anhedonia, flourishing



Tobacco Cessation (n=15)

Mean age 51 years

19 cigarettes a day

31 year smoking history

Johnson MW, Garcia-Romeu A, Griffiths RR. Long-term follow-up of psilocybin-facilitated smoking cessation. The American Journal of Drug and Alcohol Abuse. 2017;43(1):55-60.



Tobacco Cessation (n=15)

2-3 high dose sessions (20-30mg) (5 & 7 weeks, 13 week optional)

4 weeks preparation, CBT, mindfulness, guided imagery

67% abstinent at 12 months (n=10)

86.7% (n=13) "most personally meaningful and spiritually significant experiences of their lives"

Johnson MW, Garcia-Romeu A, Griffiths RR. Long-term follow-up of psilocybin-facilitated smoking cessation. *The American Journal of Drug and Alcohol Abuse*. 2017;43(1):55-60.



Alcohol Use - Binge Drinking (n = 93)

2 sessions (4 and 8 weeks) optional open label 38 week

Psychotherapy - 4 pre session, 4 between session 1 & 2, 4 post 2nd session (CBT and motivational interviewing)

25mg/70kg - 30mg/70kg - 40mg/70kg

Percentage of heavy drinking days 50% than at screening and 41% lower than diphenhydramine group

Johnson MW, Garcia-Romeu A, Griffiths RR. Long-term follow-up of psilocybin-facilitated smoking cessation. *The American Journal of Drug and Alcohol Abuse*. 2017;43(1):55-60.



RESEARCH



MDMA

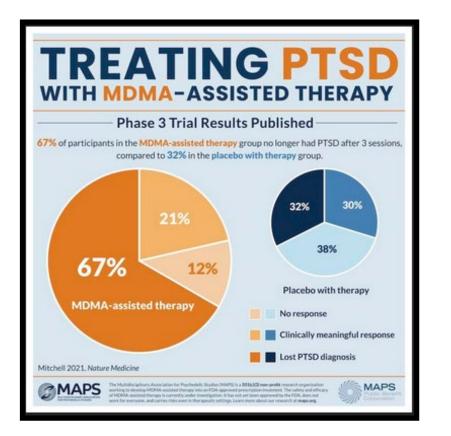


Clinical Trial > Nat Med. 2021 Jun;27(6):1025-1033. doi: 10.1038/s41591-021-01336-3. Epub 2021 May 10.

MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study

Jennifer M Mitchell ¹ ², Michael Bogenschutz ³, Alia Lilienstein ⁴, Charlotte Harrison ⁵,

- Average of 15 years of PTSD (highest 50 years)
- 84% developmental trauma
- Average of 13 medications



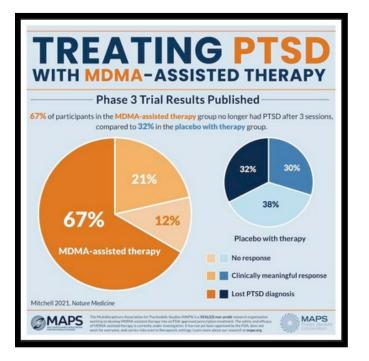


Clinical Trial > Nat Med. 2021 Jun;27(6):1025-1033. doi: 10.1038/s41591-021-01336-3. Epub 2021 May 10.

MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study

Jennifer M Mitchell ¹², Michael Bogenschutz ³, Alia Lilienstein ⁴, Charlotte Harrison ⁵,

- 3 MDMA Sessions with 2 therapists 8 hour sessions
- Supportive Therapy 42 hours
- 67% of patients with PTSD no longer qualified for the diagnosis (@ 12 months)
- 88% clinically meaningful reduction in symptoms
- Sept 2023 confirmatory Phase 3







RESEARCH

LSD



UBC CPD Medicine Continuing PROFESSIONAL DEVELOPMENT

LSD & Alcohol Use Disorder Significant and beneficial effects on alcohol use to 3 months, lost significance at 6 months

Krebs TS, Johansen PØ. J Psychopharmacol. 2012 Jul;26(7):994-1002

LSD & Anxiety Decreased state and trait anxiety that was sustained at 12 months

Gasser P, et al. J Nerv Ment Dis. 2014 Jul;202(7):513-20.



RESEARCH



Ketamine



Intranasal - treatment resistant depression - on label (esketamine)

- at 4 weeks not clinically significant reduction in MADRS scores (<12 for 3 weeks)
- \$2500-\$7500/month

Intravenous - acute suicidality (0.2mg/kg)

Maguire, L., Bullard, T., & Papa, L. (2021). Ketamine for acute suicidality in the emergency department: A systematic review. The American Journal of Emergency Medicine, 43, 54-58.

Intravenous - depression (0.5mg/kg)

Marcantoni, W. S., Akoumba, B. S., Wassef, M., Mayrand, J., Lai, H., Richard-Devantoy, S., & Beauchamp, S. (2020). A systematic review and meta-analysis of the efficacy of intravenous ketamine infusion for treatment resistant depression: January 2009–January 2019. Journal of Affective Disorders, 277, 831-841.



Adjunctive Ketamine With Relapse Prevention–Based Psychological Therapy in the Treatment of Alcohol Use Disorder

Meryem Grabski, Ph.D., Amy McAndrew, Ph.D., Will Lawn, Ph.D., Beth Marsh, B.Sc., Laura Raymen, M.Sc., Tobias Stevens, Ph.D., Lorna Hardy, Ph.D., Fiona Warren, Ph.D., Michael Bloomfield, ... See all authors

Published Online: 11 Jan 2022 | https://doi.org/10.1176/appi.ajp.2021.21030277

3 weekly ketamine infusions

Supportive psychotherapy

86% abstinent from alcohol at 6 months Relapse rates 2.7 times less than placebo



CASE REPORT article

Front. Psychiatry, 12 January 2022 Sec. Psychopharmacology https://doi.org/10.3389/fpsyt.2021.803279 This article is part of the Research Topic Therapeutic Use of Ketamine in Psychiatric Disorders View all 12 Articles >

A Cohort-Based Case Report: The Impact of Ketamine-Assisted Therapy Embedded in a Community of Practice Framework for Healthcare Providers With PTSD and Depression

Shannon Dames^{1*}, Pamela Kryskow¹ and Crosbie Watler²

91% saw improvements in generalized anxiety

79% saw improvements in depression

86% of those who screened positive for PTSD now screen negative

92% had significant life/work functionality improvements



ACCESSIBILITY



Describe how rural practitioners can prepare to work with psychedelic medicines in service to their patients



ACADEMIC PSYCHEDLIC PROGRAMS

- Vancouver Island University Fall 2022
- University of Ottawa 3 course Summer 2020
- Trinity Western University one course
- Justice Institute of BC one course



ACADEMIC PSYCHEDLIC PROGRAMS

- CIIS Center for Psychedelic Therapies and Research
- John Hopkins Center for Psychedelic & Consciousness Research
- UC Berkeley Center for Psychedelic Science
- UCSF Neuroscape Psychedelic Division
- Naropa



CAVEATS

- NOT another biological model
- Skill & mentorship is needed BEYOND training
- Multidisciplinary teams are needed
- Payment model is needed
- Safe access is needed



REFERENCES AND RESOURCES

Psychedelic Prophets The Letters of Aldous Huxley and Humphry Osmond Edited by Cynthia Carson Bisbee, Paul Bisbee, Erika Dyck, Patrick Farrell, James Sexton and James W. Spisak

Griffiths RR, Johnson MW, Carducci MA, et al. Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial. J Psychopharmacol. 2016;30(12):1181-1197.

Grob CS, Danforth AL, Chopra GS, et al. Pilot study of psilocybin treatment for anxiety in patients with advanced-stage cancer. Arch Gen Psychiatry. 2011;68(1):71-78.

Ross S, Bossis A, Guss J, et al. 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;30(12):1165-1180.

Carhart-Harris R, Bolstridge M, Day C, et al. Psilocybin with psychological support for treatment-resistant depression: Six-month follow-up. Psychopharmacology (Berl). 2018;235(2):399-408.

Carhart-Harris RL, Bolstridge M, Rucker J, et al. Psilocybin with psychological support for treatment-resistant depression: an open-label feasibility study. Lancet Psychiatry. 2016;3(7):619-627.

Johnson MW, Garcia-Romeu A, Cosimano MP, Griffiths RR. Pilot study of the 5-HT2AR agonist psilocybin in the treatment of tobacco addiction. J Psychopharmacol. 2014;28(11):983-992.





REFERENCES AND RESOURCES

Johnson MW, Garcia-Romeu A, Griffiths RR. Long-term follow-up of psilocybin-facilitated smoking cessation. The American Journal of Drug and Alcohol Abuse. 2017;43(1):55-60.

Bogenschutz MP, Forcehimes AA, Pommy JA, Wilcox CE, Barbosa P, Strassman RJ. Psilocybin-assisted treatment for alcohol dependence: a proof-of-concept study. Journal of psychopharmacology (oxford, england). 2015;29(3):289-299.

Moreno FA, Wiegand CB, Taitano E, Delgado PL. Safety, tolerability, and efficacy of psilocybin in 9 patients with obsessive-compulsive disorder. The Journal of Clinical Psychiatry. 2006;67(11):1735-1740.

Goldberg SB, Pace BT, Nicholas CR, Raison CL, Hutson PR. The experimental effects of psilocybin on symptoms of anxiety and depression: A meta-analysis. Psychiatry Res. 2020;284:112749.

Anderson BT, Danforth A, Daroff PR, et al. Psilocybin-assisted group therapy for demoralized older long-term AIDS survivor men: An open-label safety and feasibility pilot study. EClinicalMedicine. 2020;27:100538.

Davis AK, Barrett FS, May DG, et al. Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial. JAMA Psychiatry. 2021;78(5):481-489.

Carhart-Harris R, Giribaldi B, Watts R, et al. Trial of Psilocybin versus Escitalopram for Depression. N Engl J Med. 2021;384(15):1402-1411.



REFERENCES AND RESOURCES

Matthew W. Johnson , Albert Garcia-Romeu & Roland R. Griffiths (2017) Long-term follow-up of psilocybin-facilitated smoking cessation, The American Journal of Drug and Alcohol Abuse, 43:1, 55-60, DOI: 10.3109/00952990.2016.1170135



