



Psychedelic Therapy for End-of-Life Distress: Potentials and Pitfalls

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- CIIS presentations by
 - Dr. Brian Anderson
 - Dr. Anthony Bossis
 - Dick Simon
- I am presenting to you from the traditional, unceded lands of the Muckleshoot, Duwamish, and Stillaguamish peoples

Disclosures

- The views presented in this talk are my own, and do not necessarily reflect the views of the Department of Veterans Affairs or the U.S. Government
- No financial or other conflicts of interest to disclose

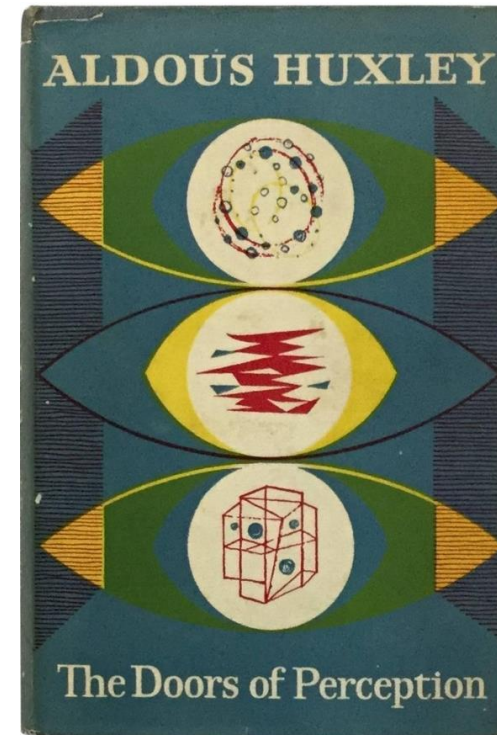
Objectives

- Describe elements of psychedelic-assisted therapy (PAT), including set and setting, preparation, administration, and integration
- Identify rationale for potential use of PAT in people with end-of-life distress
- Discuss potential benefits and risks of PAT near the end of life, including limitations of existing data
- Compare and contrast psilocybin- and MDMA-assisted therapy
- Describe expected competencies for psychedelic therapists



Introduction

- Traditional use of psychedelic compounds
- 1950s-1960s: research into medical applications
- 1970s and later: “War on Drugs”, Schedule I designation
- 2000s: resurgence of interest, research on psychedelic-assisted therapy
- 2017-2019: FDA grants “breakthrough therapy” designation to psilocybin for TRD, MDD; and to MDMA for PTSD



Schedule I



ORIGINAL ARTICLE

ONLINE FIRST

Pilot Study of Psilocybin Treatment for Anxiety in Patients With Advanced-Stage Cancer

Charles S. Grob, MD; Alicia L. Danforth, MA; Gurpreet S. Chopra, MD; Marycie Hagerty, RN, BSN, MA; Charles R. McKay, MD; Adam L. Halberstadt, PhD; George R. Greer, MD

Psychedelics and Palliative Care: Why Consider Their Potential Role?

- Persistent, even refractory suffering is sometimes encountered in specialty palliative care
- Not all suffering is solely physical: anxiety, depression, demoralization, moral injury, PTSD, suicidality, loss of meaning and purpose
- Currently available approaches may be ineffective, unavailable, take too long, have associated problems or ethical concerns
 - Meds/psychotherapy for mental health issues
 - “Last-resort options”: palliative sedation, voluntarily stopping eating and drinking, medical aid-in-dying
- Most patient seeking medical aid-in-dying motivated by non-physical suffering

Psychedelic-Assisted Therapy

- Psychedelic agents thought to act synergistically with psychotherapy to enhance treatment outcomes
- Therapeutic effect thought to be due to interaction of drug, participant's mindset ("set"), external conditions ("setting"), and therapist
 - Set: personality, preparation, expectations, intentions of person having the experience
 - Setting: physical, social, cultural environment in which the experience occurs

Hartogsohn I. Drug Sci Policy Law 3:1, 2017

Johnson MW et al. J Psychopharmacol. 22:603, 2008

Davis J, Lampert J. 2022; BrainFutures monograph, "Psychedelic Medicine"

Penn AD et al. J Humanistic Psychol 2021, <https://doi.org/10.1177/00221678211011013>

Reiff CM et al. Am J Psychiatry 177:391, 2020

Mithoefer M. "MDMA-Assisted Psychotherapy: How Different is it from Other Psychotherapy?" MAPS Bulletin Special Edition, Spring 2013



Psychedelic-Assisted Therapy Structure

- Common structure for psychedelic-assisted psychotherapy has largely been followed by all studies in modern era
- Pre-treatment assessment
 - Screening (e.g., for psychotic disorders or borderline PD)
 - Purpose in seeking a psychedelic experience
 - Begin discussion of what will happen during PAT
 - Pre-treatment agreements

Penn AD et al. J Humanistic Psychol 2021, <https://doi.org/10.1177/00221678211011013>

Davis J, Lampert J, 2022; BrainFutures monograph, "Psychedelic Medicine"

Johnson MW et al. J Psychopharmacol. 22:603, 2008





Preparation Sessions

- Trust-building, explore issues that may emerge during PAT
 - Two therapists meet with participant for several hours
 - Goal: build "safe container" for treatment
 - Physical: safe, comfortable, non-medicalized environment
 - Interpersonal: same therapists remain with participant through medication and integration sessions
 - Psychological: develop trust, rapport; begin to understand material likely to emerge during psychotherapy

Penn AD et al. J Humanistic Psychol 2021, <https://doi.org/10.1177/00221678211011013>

Davis J, Lampert J, 2022; BrainFutures monograph, "Psychedelic Medicine"

Johnson MW et al. J Psychopharmacol. 22:603, 2008

Medication Session(s)

- Setting: comfortable, aesthetically pleasing, culturally appropriate
- Therapeutic role: supervised observation, non-directive, collaborative inquiry – “trust, let go, be open”, encouraged to direct thoughts to inner experience
- "Inner healing intelligence"

Davis J, Lampert J, 2022; BrainFutures monograph, "Psychedelic Medicine"

Johnson MW et al. J Psychopharmacol. 22:603, 2008





Pre-recorded Music Playlist

- Designed to support experience of a "non-ordinary state of consciousness"*, may follow arc of medication effect
- Culturally appropriate for participant
- Eyeshades and headphones encouraged, to reduce distractions and potential pressure to interact with therapists

Mithoefer M. (2016). A manual for MDMA-assisted psychotherapy in the treatment of posttraumatic stress disorder

Two Paradigms for Medication Sessions

- *Psycholytic therapy*: a form of talk therapy; repeated low-moderate doses of medication thought to increase access to material in the unconscious mind
- *Psychedelic therapy*: moderate to high dose medication to induce a transcendent experience to be processed during integration therapy

Most recent psilocybin studies involve psychedelic therapy, while recent MDMA studies have used hybrid of psycholytic and psychedelic therapy approaches

Reiff CM et al. Am J Psychiatry 177:391, 2020



Psychedelic-Assisted Therapy Paradigms

Psychedelic Therapy Paradigm (Most Psilocybin Studies)

- Therapists provide supportive, non-directive presence
- "[During the medication session] therapists typically interact minimally with the patient/participant unless they have needs such as going to the restroom, or they signal a need to interact."

Johnson MW et al. J Psychopharmacol. 22:603, 2008

Psycholytic + Psychedelic Therapy Hybrid (MDMA Studies)

- "The therapists act as empathic listeners, trustworthy guides, facilitators of deep emotional expression and catharsis, and supporters of the participant's own inner healing intelligence. . . . The therapists' role is often to follow, rather than guide, the participant, as [they explore] new and unexpected perceptions and realizations. At other times it may be helpful for the therapists to remind the participant that facing painful experiences is actually a path toward healing."

Mithoefer M. (2016). A manual for MDMA-assisted psychotherapy in the treatment of posttraumatic stress disorder





Integration Psychotherapy

- Variable number of sessions, may begin very soon after administration session(s) and continue for weeks
- Goal: work with participant to interpret content of psychedelic session into meaningful long-term change by identifying insights or interpreting thoughts/ideas that arose during session
 - Not only mystical states but also difficulties
 - Working through painful experiences: important part of therapeutic process, as important as “peak mystical experiences”
 - Should not be considered an adverse event
- Comprehensive suite of interventions necessary for large magnitude of benefit and to minimize adverse effects

Davis J, Lampert J, 2022; BrainFutures monograph, "Psychedelic Medicine"

Penn AD et al. J Humanistic Psychol 2021, epub

Psychotherapy Modalities

- May use elements of various approaches (examples in Table)
- Specific modality largely driven by needs, interest of the participant and skills of the therapist in a given modality, rather than by a specific therapy protocol

Penn AD et al. J Humanistic Psychol 2021, epub

Modality	Reference
Holotropic Breathwork Therapy	Grof & Grof, 2010
Internal Family Systems	Schwartz & Sweezy, 2019
Somatic Experiencing Therapy	Levine, 1997
Acceptance and Commitment Therapy	Carhart-Harris et al., 2018; Watts & Luoma, 2020
Exposure Therapy	Young et al., 2017

Therapist Competencies

Empathetic abiding
presence

Trust enhancement

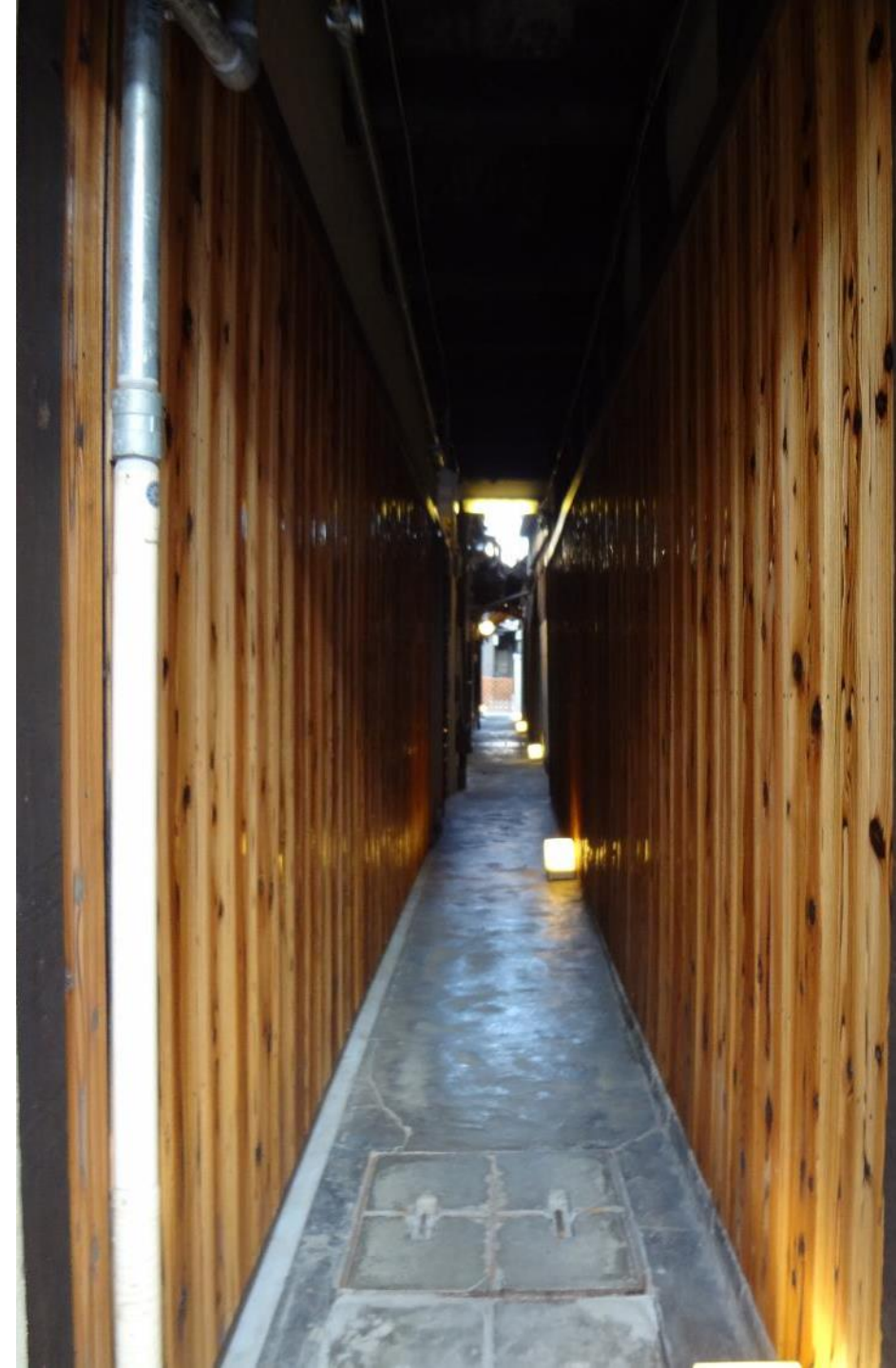
Spiritual intelligence

Knowledge of
physical and
psychological effects
of psychedelics

Therapist self-
awareness and
ethical integrity

Proficiency in
complementary
techniques

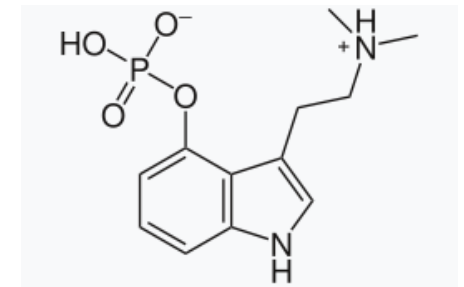
Phelps J. J Humanistic Psychol 57:450, 2017



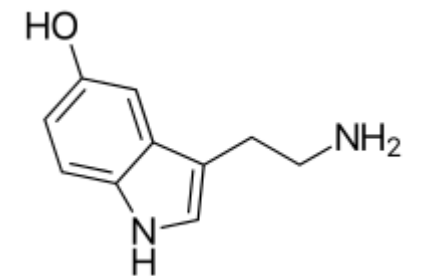


What are the Effects of Psilocybin Itself?

- Psilocybin is part of a family of compounds called tryptamines, which share a core structure with serotonin (5-HT)
 - High affinity for 5-HT_{2a}, 5-HT_{2c} and 5-HT_{1a} receptors
- Effects of high doses 0.3-0.6 mg/kg (20-40mg/70 kg) last 3-6 hrs
 - Alterations in visual and auditory perception
 - Hallucinations and illusions
 - Cognitive effects range from increases in cognitive flexibility, creative thinking and insightfulness to distractibility and disorganized behavior
 - Affective changes range from euphoria and blissful states to paranoia and extreme anxiety
 - Effects variable, can change rapidly during a single episode of use
 - Ross S et al. Chap. 9, Psilocybin, in Grob CS, Grigsby J (eds) Handbook of Medical Hallucinogens, 2021
 - Reiff CM et al. Am J Psychiatry 177:391, 2020



Psilocybin



Serotonin

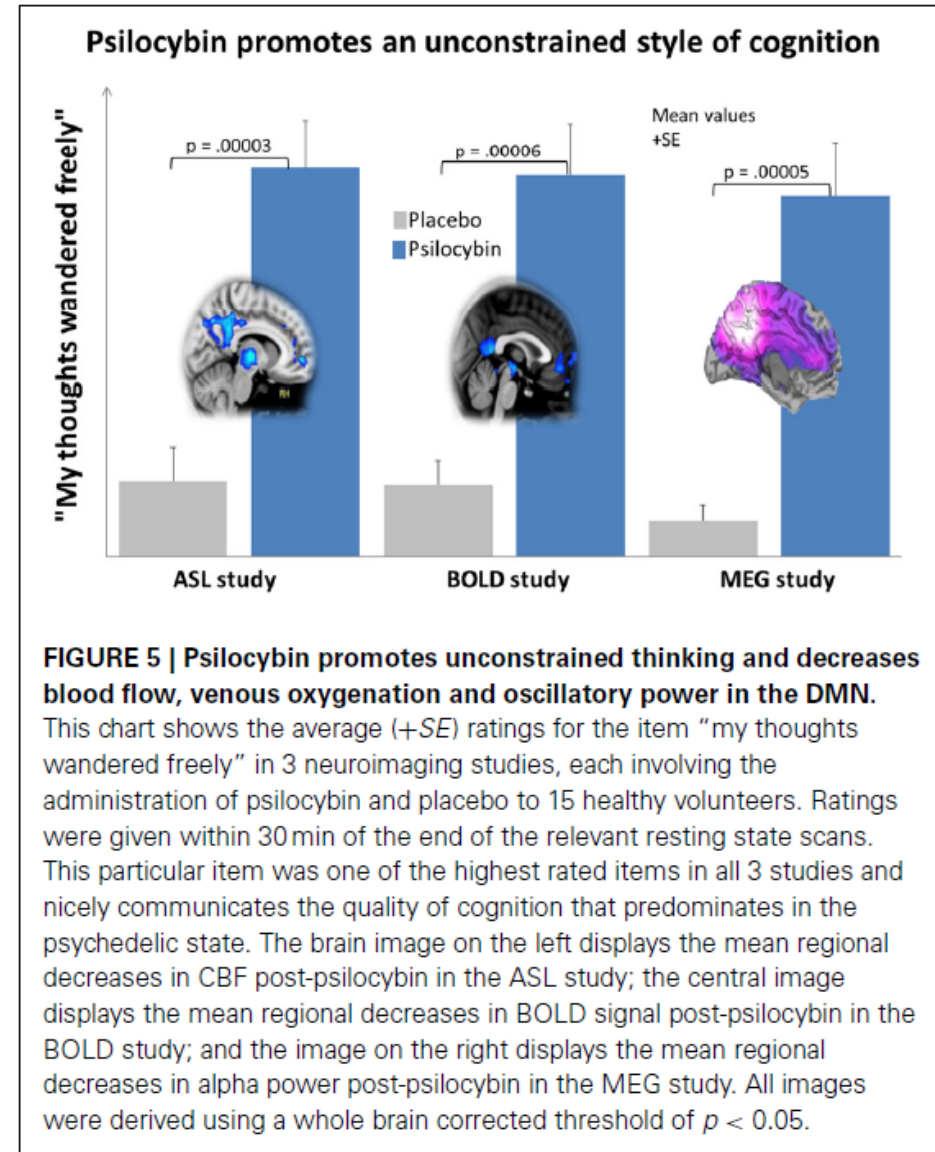
Effects of Psilocybin (cont'd)

fMRI studies:

- Default Mode Network (DMN) – a cortical network with increased activity, connectivity during self-reflection and in depression
- Psilocybin acutely disrupts DMN activity/connectivity → allows disruption of established patterns of thought, behavior →
- Increased ability to develop new perspectives and receptivity to change when psilocybin is co-administered with non-directive supportive psychotherapy

Carhart-Harris RL, et al: Front Hum Neurosci 8:20, 2014

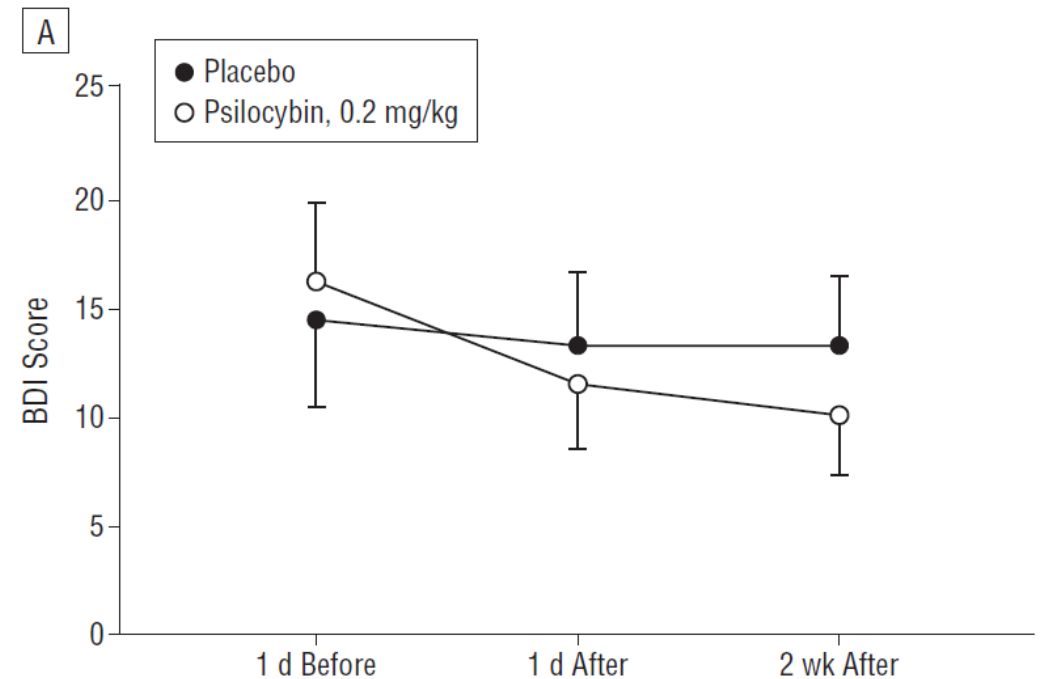
Reiff CM et al. Am J Psychiatry 177:391, 2020



Evidence from 3 Key Studies of Psilocybin in End-of-Life Distress

1. Grob et al. 2011

- Pilot double-blind RCT for anxiety and depression in pts with various advanced cancers (n=12)
- Subjects acted as own controls; 2 sessions in random order, psilocybin moderate dose 0.2mg/kg vs niacin placebo
- BDI scores dropped by almost 30% at 1 month (p=0.05) and remained significantly different at 6 months (p=0.03).



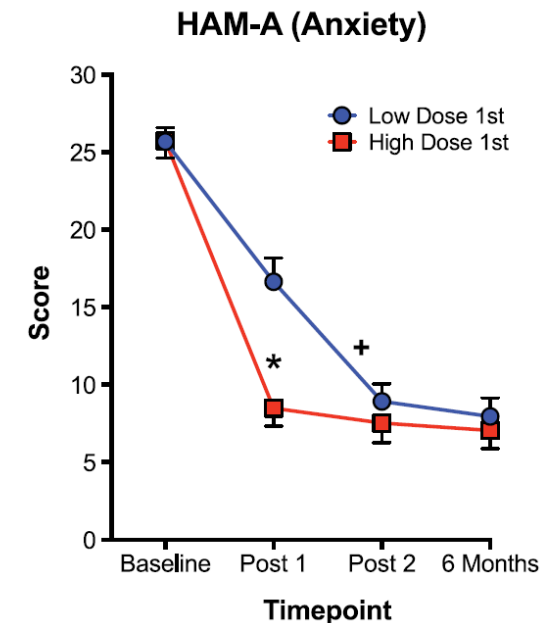
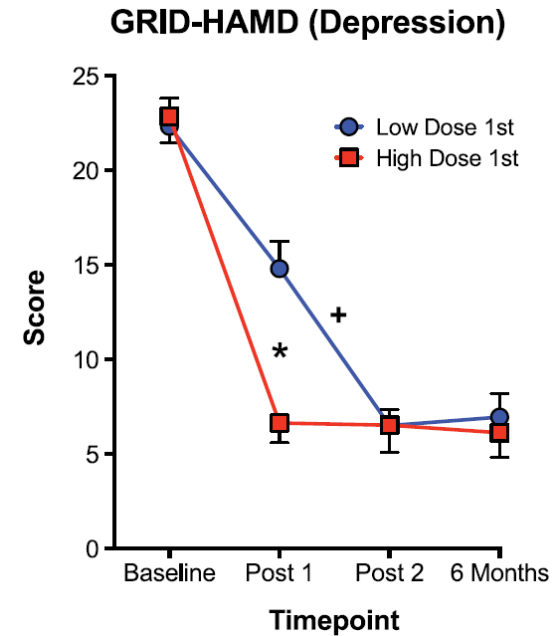
Grob CS et al. Arch Gen Psychiatry 68:71, 2011

Evidence from 3 Key Studies of Psilocybin in EoL Distress

2. Griffiths et al. 2016

- Double-blind crossover RCT, 2 sessions psilocybin for anxiety, depression in various advanced cancers (n=51)
- High dose (22 or 30mg/70kg) vs low dose (1 or 3mg/70kg) as active control
- Overall response rate at 6 months: 78% on HAM-D, 83% on HAM-A, with symptom remission of 65% (HAM-D), 57% (HAM-A)

Griffiths RR et al. J Psychopharmacol 30:1181, 2016

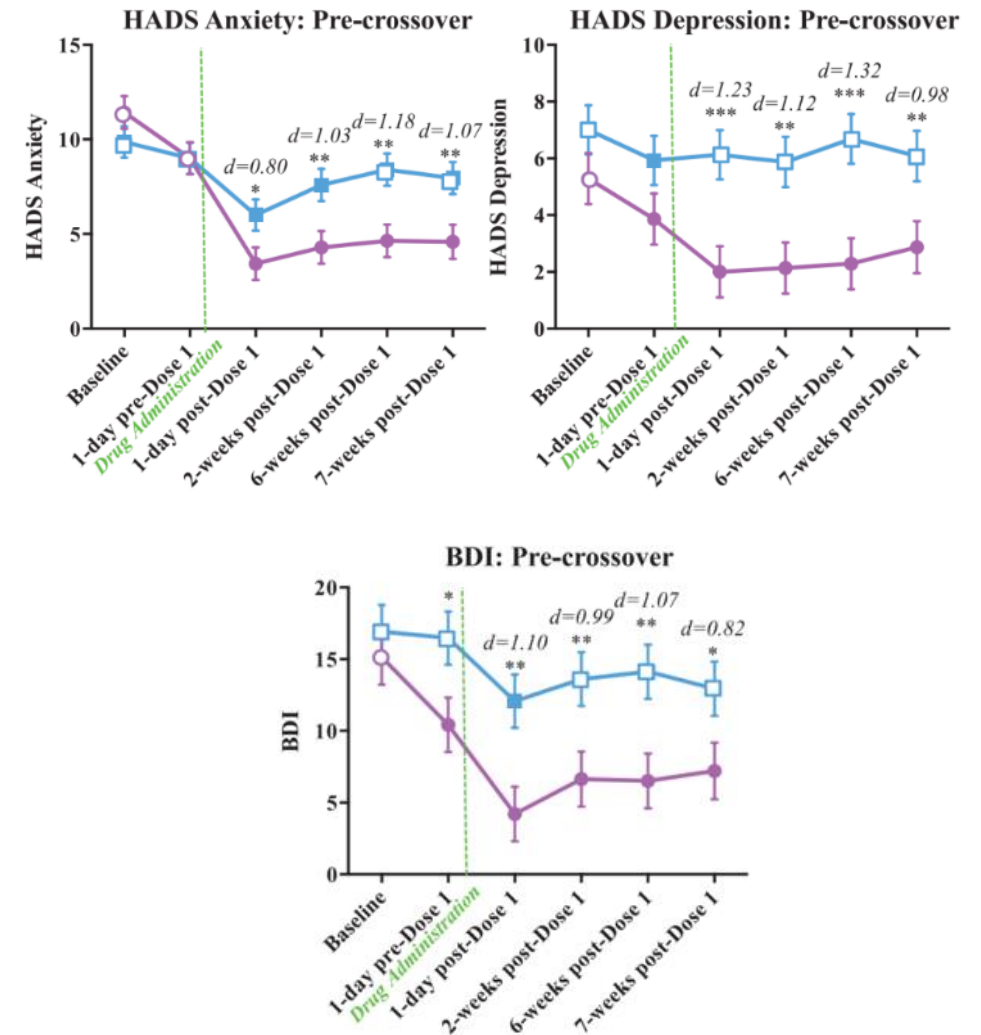


Evidence from 3 Key Studies of Psilocybin in EoL Distress

3. Ross et al. 2016

- Double-blind crossover RCT, psilocybin for anxiety, depression in various cancers (~2/3 advanced CA, n=29)
- High dose (21mg/70kg) vs niacin placebo
- 6.5 months after psilocybin, 60%-80% had clinically significant sustained reductions ($\geq 50\%$ vs baseline) in depression or anxiety, benefits in existential distress/quality of life, improved attitudes toward death

Ross S. et al. J Psychopharmacol 30:1165, 2016

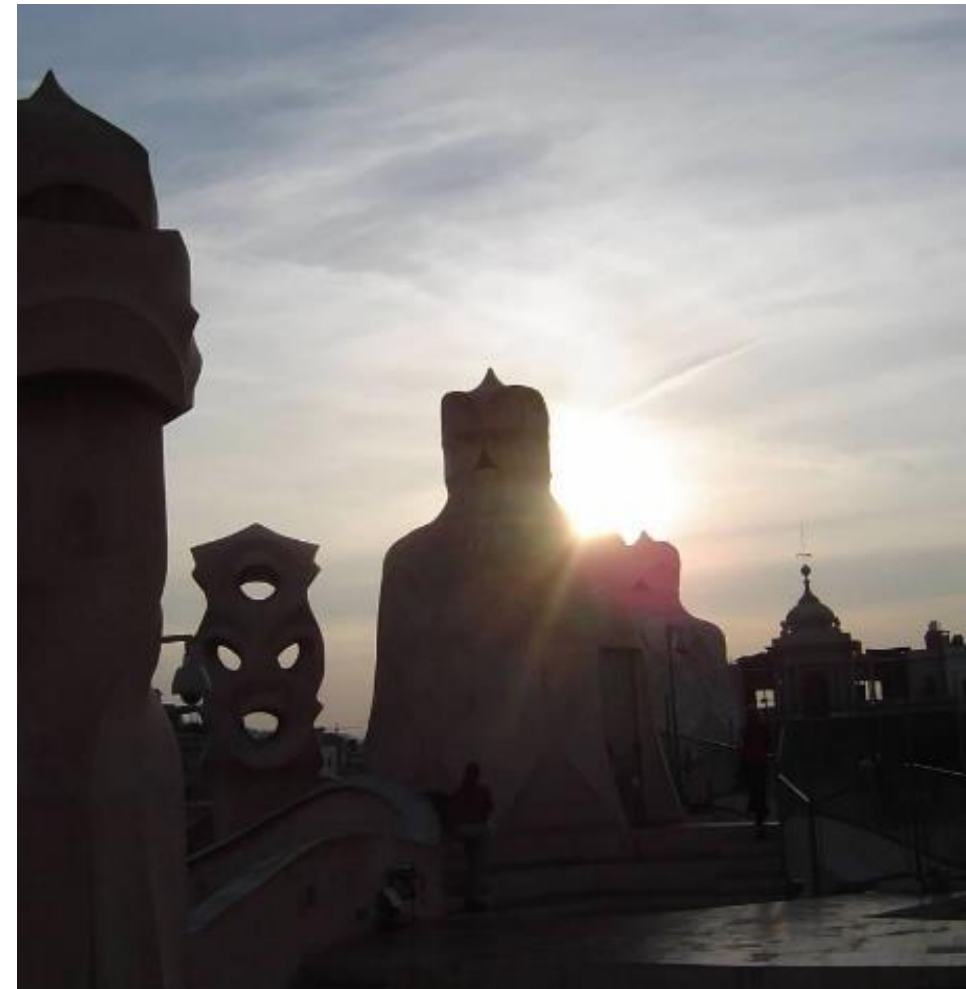


Psilocybin and Mystical Experiences

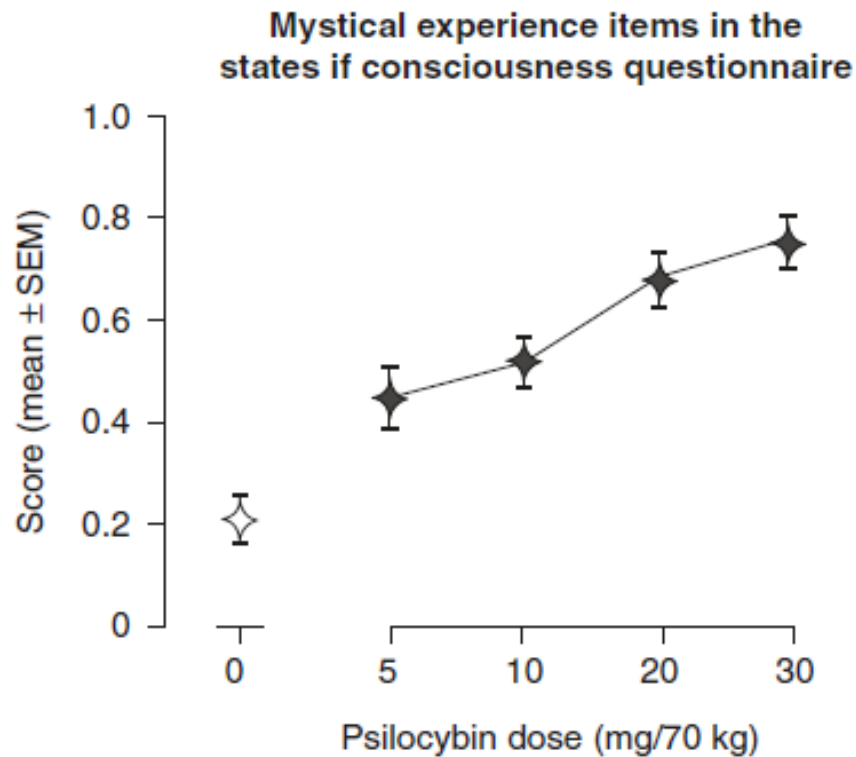
- Beneficial clinical effects correlate with occurrence of a mystical experience, suggesting that mystical state may mediate benefits
- Subjective Features of Mystical Experience (partial list):
 - *Unity*: Sense of oneness or self-transcendence, interconnectedness of all people, all things
 - *Transcendence of time and space*: Sense of timelessness, being part of an infinite realm, with no space boundaries.
 - *Deeply felt positive mood*: Joy, blessedness, peace, and love.
 - *Sense of sacredness*: Awe, wonder, humility, reverence.
 - *Noetic quality*: A feeling of insight, certainty you are experiencing Ultimate Reality
 - *Ineffability*: the experience is felt to be impossible to describe in words

Pahnke W, Richards W, J Religion Health 1966;5:175

Bossis A. Alternative Complementary Ther 21:14, 2021



Psilocybin Dose-Response Effect on Mystical Experience



Griffiths RR et al. Psychopharmacol 218:649, 2011

Grob CS et al., Chap. 5, in Psychological Aspects of Cancer, 2022



Mystical Experiences and Symptom Reduction (EOL Studies)

- Correlations noted between symptom reduction and scores on MEQ-30 (reliable, validated measure of mystical experience)
- MEQ-30 scores positively predict psilocybin-related changes in attitudes, behavior, well-being

Griffiths RR et al. J Psychopharmacol 30:1181, 2016

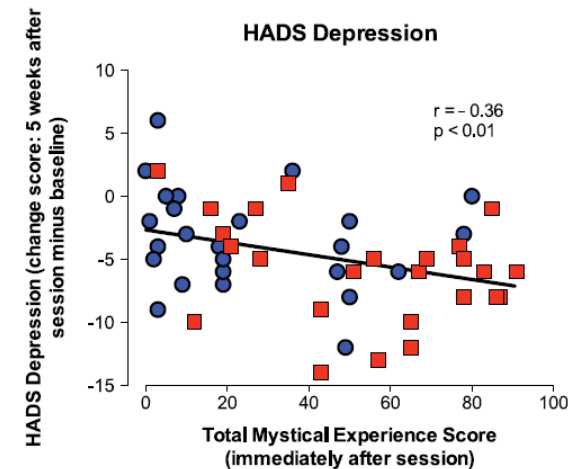
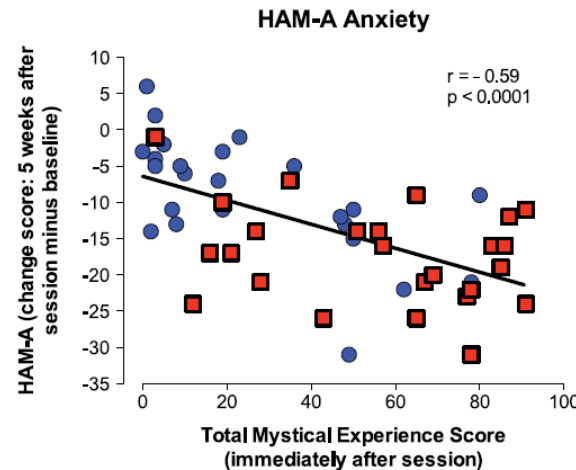
Ross S. et al. J Psychopharmacol 30:1165, 2016

Barrett FS et al. J Psychopharmacol 29:1182, 2015

Maclean KA et al. J Sci Study Relig 51:721, 2012

Reiff CM et al. Am J Psychiatry 177:391, 2020

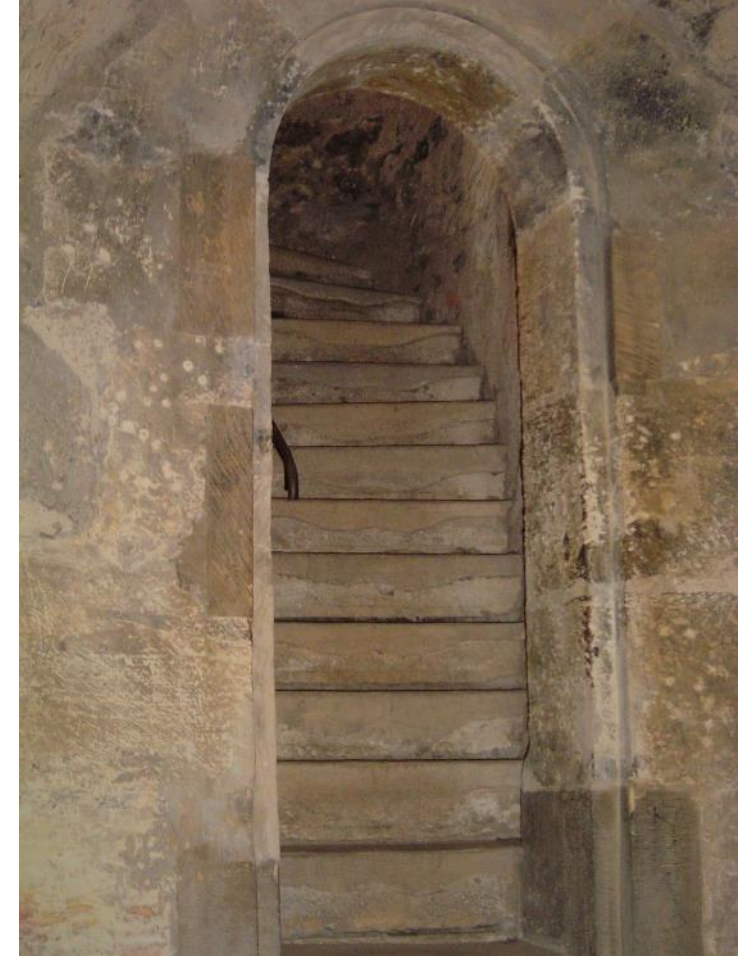
Example data from
Griffiths et al. 2016



Relevance of Mystical Experience to EOL Distress

- Meaning, transcendence identified as key factors in overcoming EOL suffering
- Eric Cassell: “Transcendence is probably the most powerful way in which one is restored to wholeness after an injury to personhood. When experienced, transcendence locates the person in a far larger landscape. The suffering is not isolated by pain but is brought closer to a transpersonal source of meaning and to the human community that shares those meanings.”

Cassell EJ: The Nature of Suffering and the Goals of Medicine. N Engl J Med 306:639, 1982



SPECIAL ARTICLE

THE NATURE OF SUFFERING AND THE GOALS OF MEDICINE

ERIC J. CASSELL, M.D.

Abstract. The question of suffering and its relation to organic illness has rarely been addressed in the medical literature. This article offers a description of the nature and causes of suffering in patients undergoing medical treatment. A distinction based on clinical observations is made between suffering and physical distress. Suffering is experienced by persons, not merely by bodies, and has its source in challenges that threaten the intactness of the person as a complex social and psychological enti-

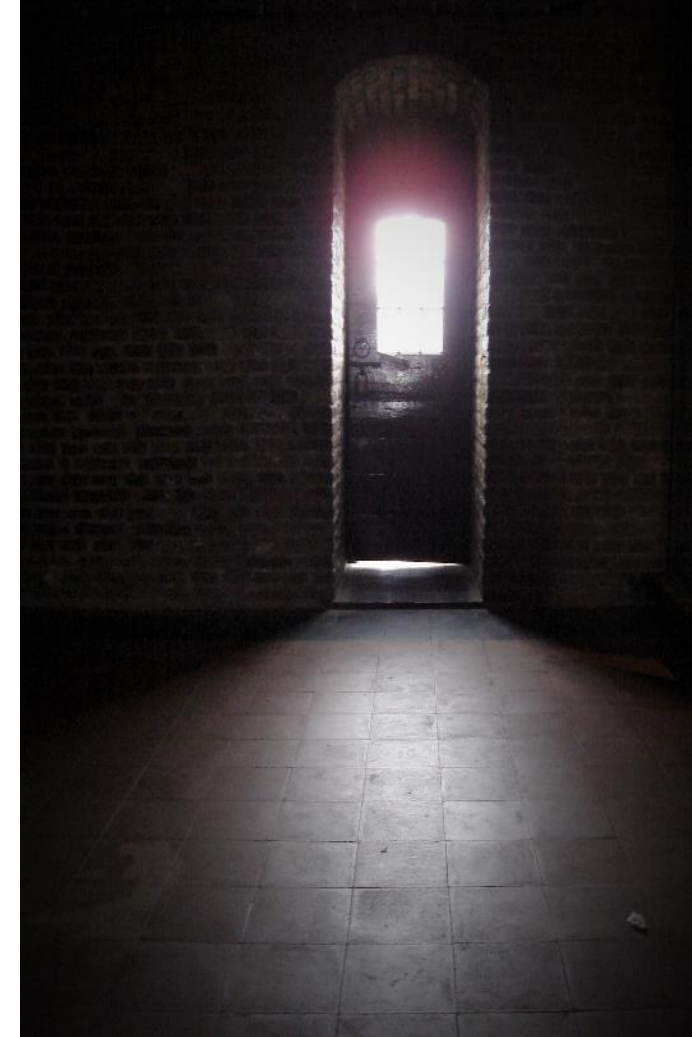
ty. Suffering can include physical pain but is by no means limited to it. The relief of suffering and the cure of disease must be seen as twin obligations of a medical profession that is truly dedicated to the care of the sick. Physicians' failure to understand the nature of suffering can result in medical intervention that (though technically adequate) not only fails to relieve suffering but becomes a source of suffering itself. (N Engl J Med. 1982; 306:639-45.)



Initial Studies for Anxiety, Depression: Large Effect Size but Small "n"

- 2020 meta-analysis of studies of psilocybin-assisted therapy for anxiety and depression (1 uncontrolled, 3 placebo-controlled RCT, n=117)
- Large, statistically significant within-group pre-post effect sizes (>1.1) and large placebo-controlled effect sizes (>0.8 , in 3 trials)
 - (Small effect size = 0.2, medium = 0.5, large = 0.8)
- No serious adverse effects reported

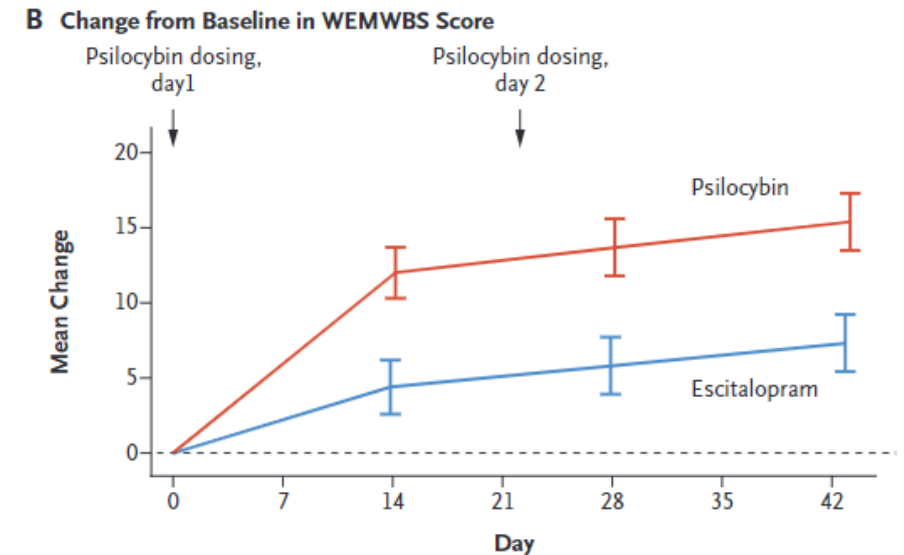
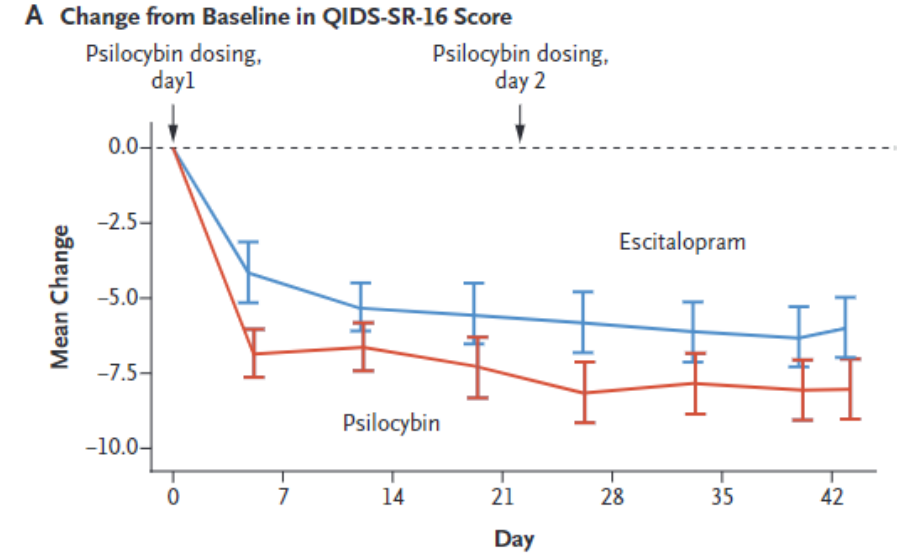
Goldberg SB et al. Psychiatry Res 284:112749, 2020



Psilocybin vs. SSRI in Major Depression

- Double-blind RCT of 2 doses psilocybin 25mg 3 wks apart + 6 wks daily placebo vs. 2 doses psilocybin 1mg 3 wks apart + 6 wks daily escitalopram, n=59
- Primary outcome: Change from baseline depression score at 6 wks
- No significant difference in QIDS-SR-16 scores at 6 wks
- Secondary outcomes (like well-being score) generally favored psilocybin over escitalopram, but analyses lacked correction for multiple comparisons

Carhart-Harris R et al. N Engl J Med 384:1402, 2021



Larger Study of Psilocybin for Treatment-Resistant Depression (TRD)

- Multi-site RCT of single-dose psilocybin-assisted therapy (n=233)
 - 25mg, 10mg, 1mg (control) groups
 - Single dose of 25mg but not 10mg improved depressive symptoms after 3 weeks more than 1mg dose
 - At 25mg, 37% responded at 3 wks (decrease in depression score of $\geq 50\%$)
 - Adverse effects (mainly nausea, headache) in 72% (1mg dose) to 84% (25mg dose)
 - No mystical experience measure obtained

Goodwin GM et al. N Engl J Med 387:1637, 2022

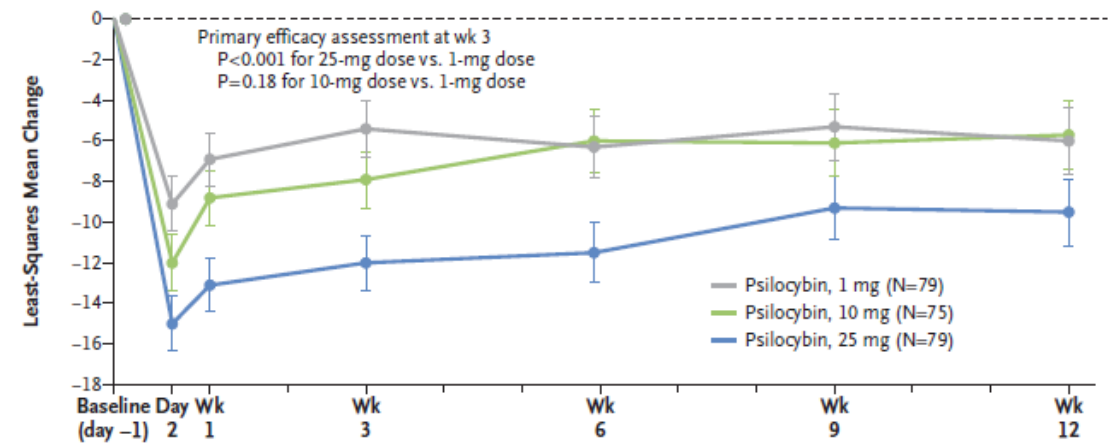


Figure 2. Change from Baseline in MADRS Total Score (Modified Intention-to-Treat Population).

Total scores on the Montgomery-Åsberg Depression Rating Scale (MADRS) range from 0 to 60, with higher scores indicating greater severity of depression. I bars represent standard errors.

Psilocybin Safety Record

- Not thought to precipitate a new psychotic illness, but concerns raised that psychedelic agents may unmask a psychotic disorder in susceptible people
- No short- or long-term evidence of prolonged psychosis, perceptual disorders, or functional impairment in studies of healthy volunteers
- Many studies of longer-term effects of psychedelic agents screened participants for history of psychiatric problems
- Supervision during psychedelic experiences strongly recommended for safety

Byock I. J Palliat Med 21:417, 2018

Geyer MA, Vollenweider FX. Trends Pharmacol Sci 29:445, 2008

Ross S, Peselow E. Clin Neuropharmacol 35:235, 2012

Studerus E et al. J Psychopharmacol 25:1434, 2011



Potential Safety Concerns with Unsupported Use

- Online survey of users of psilocybin (n=1993) asked to describe their worst “bad trip” after mushroom ingestion:
 - 39% rated it as among the most challenging experiences of their lifetime
 - 11% put self or others at risk of physical harm
 - In those whose ingestion was >1 year prior, 7.6% sought treatment for psychological symptoms related to the experience
 - Despite difficulties, 84% endorsed benefiting from the experience, and 76% reported increased well-being or life satisfaction

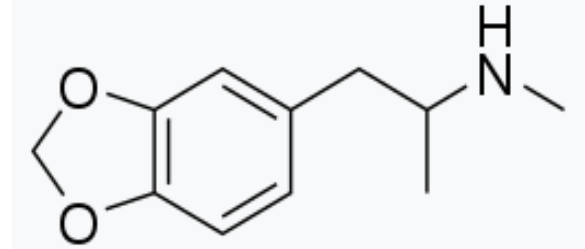


MDMA

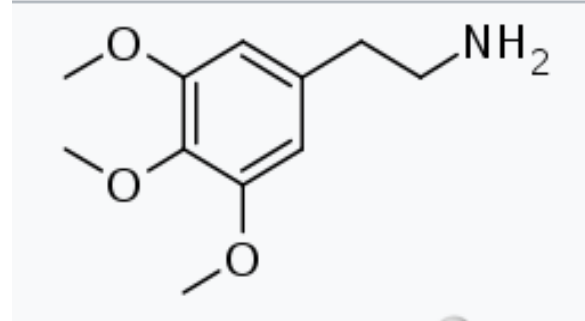
- Only 1 study in people near end of life, but potentially useful in PTSD treatment
- Not a classic psychedelic; MDMA is classified as an "empathogen" or "entactogen"; effects partially overlap with psychostimulants and serotonergic psychedelic agents (LSD, psilocybin, ayahuasca)
- Structurally similar to mescaline
- Main mechanisms of action:
 - Serotonin 5-HT_{2a} agonist; mixed serotonin, norepinephrine, dopamine reuptake inhibition and release

Reiff CM et al. Am J Psychiatry 177:391, 2020

MDMA



Mescaline





MDMA

- Used by some psychotherapists in late 1970s-early 1980s to enhance effectiveness of psychotherapy
- Non-clinical use of MDMA became increasingly popular under the names “ecstasy” or “molly” (*often contains adulterants)
 - Concern for abuse potential led to DEA designation as schedule I drug in 1985
- Study in primates in 2002 reported neurotoxicity at moderate doses, but subjects were given methamphetamine (not MDMA) and the study was retracted

Reiff CM et al. Am J Psychiatry 177:391, 2020

Sessa B, Chap. 3 in “Advances in Psychedelic Medicine”, 2019

MDMA Effects

- Healthy volunteers:
 - Euphoria, empathy, well-being, insightfulness, extraversion, positive mood, gregariousness
 - Increased access to emotionally intense material
 - Increased interpersonal trust, compassion for self and others
- Cognitive/perceptual effects:
 - Transient deficits in spatial/verbal memory, concentration; mild psychomotor impairment; slight visual and auditory alterations; rarely hallucinations

Reiff CM et al. Am J Psychiatry 177:391, 2020

Sessa B, Chap. 3 in "Advances in Psychedelic Medicine", 2019

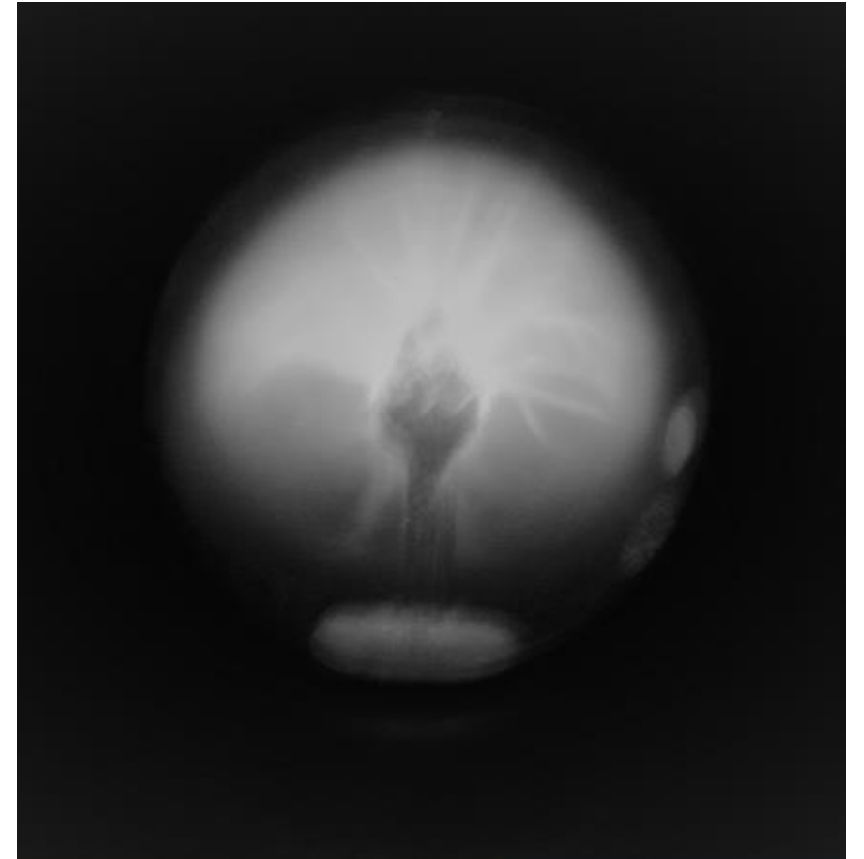


MDMA Effects

- Unpleasant affective symptoms:
 - Anxiety common in study participants
 - Grief, fear, rage relatively common in PTSD studies (*should not be considered adverse effects of MDMA)
- Autonomic, cardiovascular effects: increased energy; transient, mild increases in heart rate and blood pressure; tachypnea
- Other: muscle tightness, bruxism, reduced appetite
- “Mild abuse potential”, though illicit use of ecstasy after MDMA use in clinical studies is rarely observed

Reiff CM et al. Am J Psychiatry 177:391, 2020

Sessa B, Chap. 3 in “Advances in Psychedelic Medicine”, 2019





MDMA-Assisted Psychotherapy in PTSD

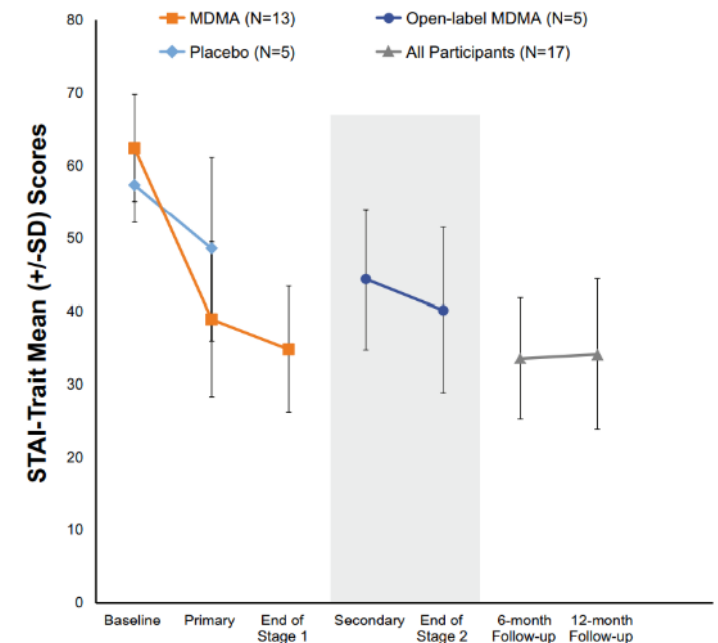
- MDMA effects do not appear to be mediated by mystical experience
 - In Phase 2 studies, mystical experience scores not correlated with PTSD symptom reduction
- Reduced fear of traumatic memories, increased feelings of trust/compassion toward others without "sensory distortions" or inhibiting access to difficult emotions →
- MDMA can increase effectiveness of psychotherapy by making traumatic memories more accessible and strengthening therapeutic alliance

Rick Doblin, MAPS data on file

Williams MT et al. J Psychedelic Studies 4:40, 2020

MDMA for Anxiety in Serious Illness

- Pilot double-blind RCT of two 8-hour sessions with MDMA 125mg (n=13) or placebo (n=5) + integration psychotherapy (additional open-label MDMA sessions after unblinding)
- Participants with various cancers or non-dementing neuro illness and moderate/severe anxiety
- Outcome: Anxiety symptoms at baseline vs 1 month after last medication session
- MDMA group tended to have greater reduction in anxiety than placebo, but not significant (p=0.056)
 - Large effect size of 1.03



MDMA Phase 3 Study in Severe PTSD

- Participants: multi-site double-blind RCT (n=90), avg PTSD duration 14 years, 77% white
- History of suicidal ideation in >90%, and suicidal behavior in 30-35%
- Psychotherapy with MDMA or placebo (3 sessions 4 wks apart, 80-180mg MDMA in divided dose vs. placebo)
- Outcomes: PTSD symptoms and functional impairment at baseline vs 2 months after last medication session

Mitchell JM et al. Nature Med 27:1025, 2021

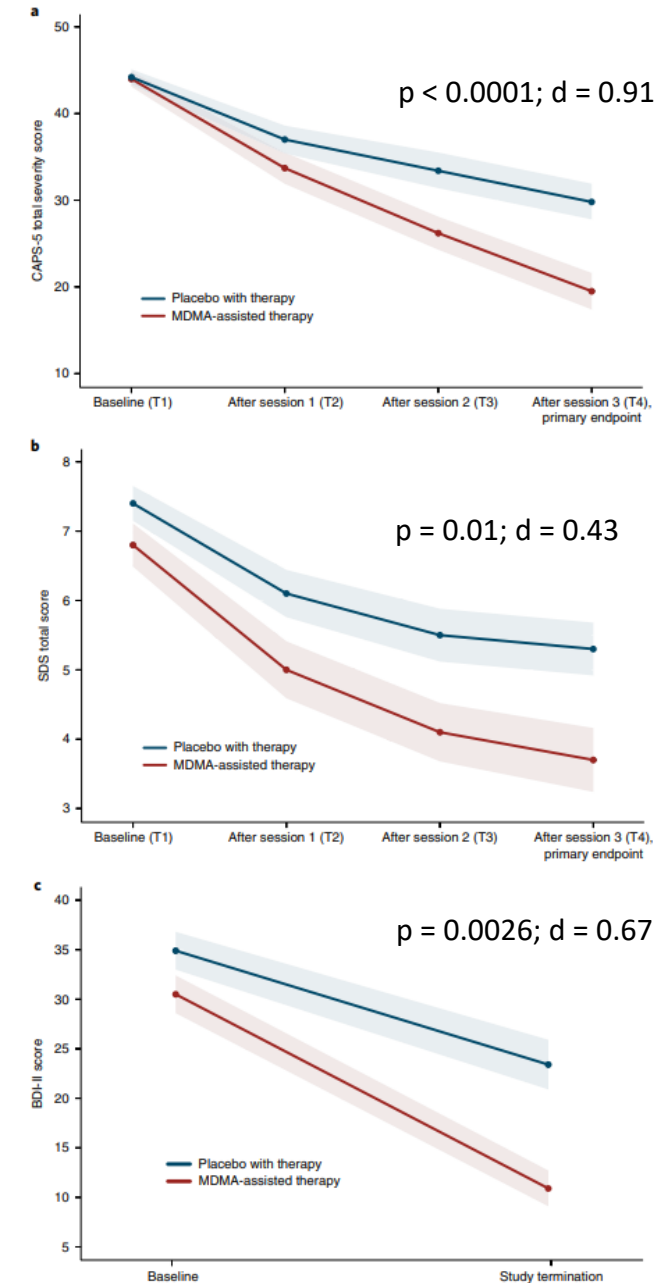


Improvement in PTSD Symptoms at 2 Months

- 67% of MDMA + Therapy group no longer qualified for a PTSD diagnosis after 3 MDMA sessions, vs 32% of Placebo + Therapy
- PTSD symptom effect size 0.91 (vs 0.31 to 0.56 with sertraline, paroxetine in other studies)
- MDMA-assisted therapy can reduce functional impairment and depression

Mitchell JM et al. Nature Med 27:1025, 2021

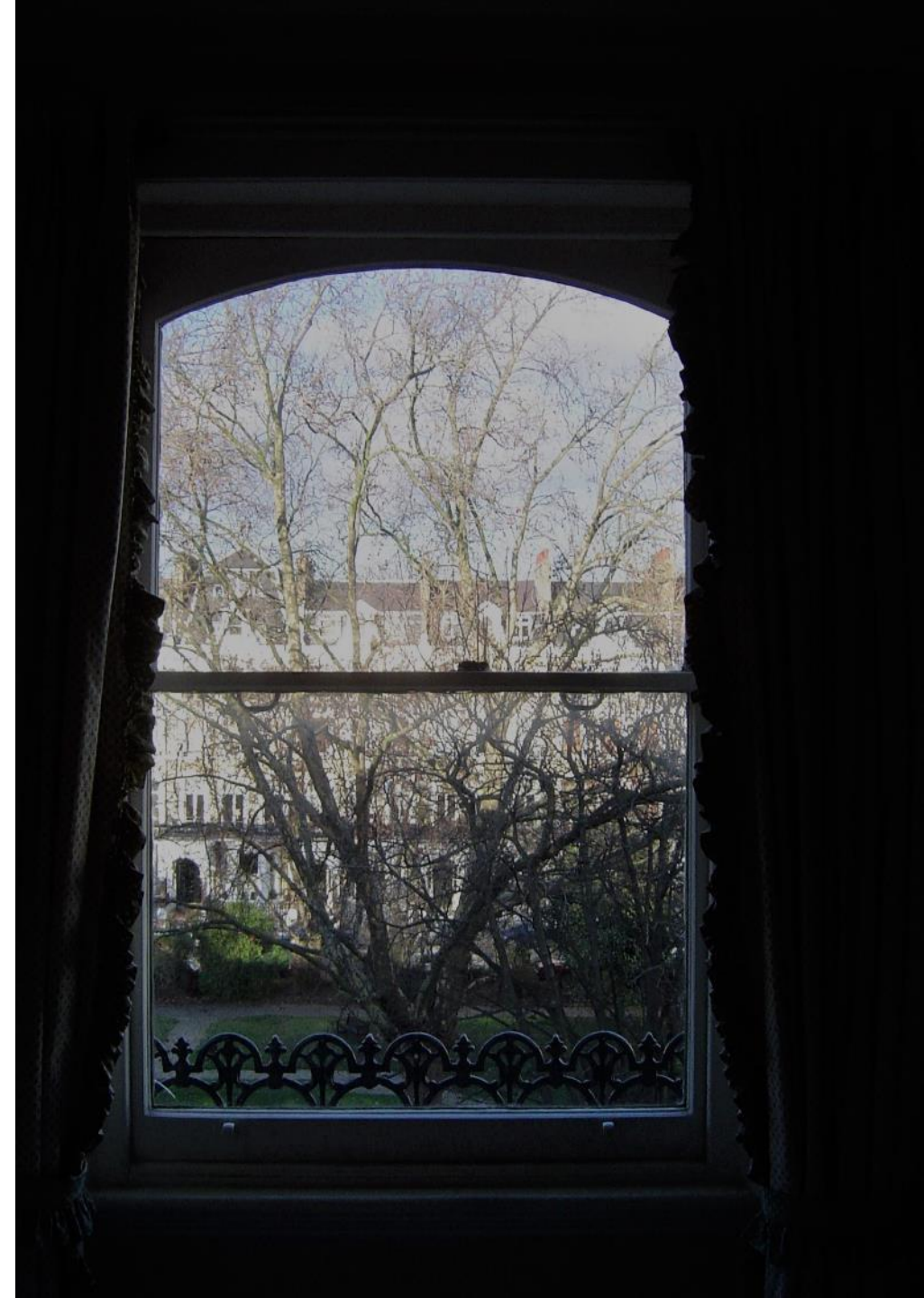
Feduccia AA et al. Front Psychiatry 10:1, 2019



Status of Availability of Psychedelic-Assisted Therapy

- Psilocybin, MDMA, other psychedelic agents still Schedule 1
- Oregon: facilitated use of psilocybin legal starting in 2023
- Colorado: approved measure creates framework for psilocybin use in mental healthcare and therapeutic settings
- In both states, regulatory framework is under development
- Licensed centers in OR, CO will be proving grounds for safety and efficacy of broader access to psilocybin-assisted therapy

- Medscape.com, "Cancer Patients Struggle to Access Psilocybin Before They Die", Dec. 13, 2022



Potential for Tension Between “Mainstream” Entities and Advocates

- American Psychiatric Association opposed Oregon Measure 109, describing it as unsafe and making misleading promises to Oregonians struggling with mental illness
- Veterans asking for and receiving psychedelic treatments through available avenues, e.g., ayahuasca sessions in Peru for Veterans with PTSD
- Advocates suing DEA on behalf of terminally ill cancer patients for access to psilocybin therapy under “Right To Try” Act

Seattle Times, “Have a safe trip: Oregon trains magic mushroom facilitators”, Dec. 22, 2022

Medscape.com, “Cancer Patients Struggle to Access Psilocybin Before They Die”, Dec. 13, 2022





Concerns with Approval of PAT in Medical Settings

- Overall medical and non-medical use may outpace the science
 - Limited generalizability of existing studies (little representation of BIPOC, minoritized sexual groups, other marginalized groups; exclusion of comorbid mental and physical illness)
 - Small number of study subjects even in most widely studied conditions (depression, AUD, anxiety/depression in cancer, PTSD)
 - Potential for significant medical and psychiatric sequelae in vulnerable populations
 - Potential for substance use disorder needs further study

Penn AD et al. J Humanistic Psychol 2021 epub
Reiff CM et al. Am J Psychiatry 177:391, 2020

Concerns with Approval of PAT in Medical Settings

Risk Evaluation and Mitigation Strategies | REMS



U.S. FOOD & DRUG
ADMINISTRATION

- Post-approval issues:
 - Risk Evaluation and Mitigation Strategies (REMS) requirements may be restrictive to the extent that unregulated and possibly unsafe off-label treatments will proliferate, as with ketamine treatment clinics
 - Payors will try to limit costs, reducing psychotherapy hours
 - Benefit/risk of stand-alone psychedelic administration without psychotherapy has not been studied
 - Commercialization may bring PAT into medical settings more quickly, but may exacerbate inequities in access

Penn AD et al. J Humanistic Psychol 2021 epub

Reiff CM et al. Am J Psychiatry 177:391, 2020

Culturally-Informed Adaptations



- Inclusion of Indigenous and culturally diverse leaders in all aspects of PAT work
- Outreach, diversification of study participants and care recipients
- Study compensation (and ultimately, equity in access)
- Diversification of treatment teams
- Culturally appropriate, personalized setting/environment (artwork, music, reading material, décor)
- Trauma informed care (with care to avoid microaggressions)
 - Strong effort to ensure safety, transparency, trustworthiness, mutuality/power sharing; ask permission; offer choices
- Ongoing consent throughout PAT process
- Cultural humility training for PAT team members

Williams MT et al. J Psychedelic Studies 4:40, 2020

[Trauma-Informed Care Resources Guide
\(crisisprevention.com\)](https://crisisprevention.com/)



Estimated Need for Psychedelic Therapy Clinician Specialists

Assuming FDA approval is granted for 1 or more agents/indications, in next few years we will need

- Trained practitioners in psychiatry, behavioral health, nursing, spiritual care, other disciplines
- Estimated need: 25,000+ providers

Dr. Brian Richards, Psy.D.

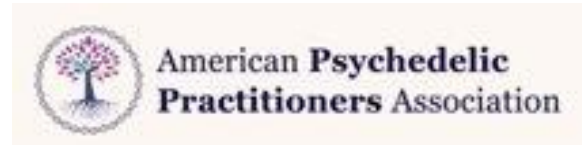
Presentation, "The Psychedelic Medicine Clinic of the Near Future"

California Institute of Integral Studies, October 2022

Need for Established Standards, Competencies

- American Psychedelic Practitioners Association
 - New organization focused on advocating for safe, effective, and accessible care for all who can benefit from psychedelic medicine
 - Mission includes development of standards for care and training

[American Psychedelic Practitioners Association \(thepsychedelicassociation.org\)](https://thepsychedelicassociation.org)



- Board of Psychedelic Medicine and Therapies
 - "a non-profit public benefit corporation dedicated to creating board certification for psychedelic medicine practitioners and educating practitioners, the health care system, and potential consumers about the inherent value of the certification process"

[Board of Psychedelic Medicine and Therapies \(BPMT\) \(psychedelicsboard.org\)](https://psychedelicsboard.org)

Davis J, Lampert J. 2022; BrainFutures monograph, "Psychedelic Medicine"





Summary



- Psychedelic-assisted therapy is a suite of interventions including attention to set and setting, preparation, medication sessions, and integration
- These therapies have significant potential to improve EoL care
- Breakthrough therapy designations accorded to psilocybin for MDD and TRD, and to MDMA for PTSD
- Benefits/risks need to be studied in larger, more diverse study populations
- Licensed centers in OR, CO will soon become initial testing grounds for safety and efficacy of broader access to psilocybin-assisted therapy
- Concerns about safety, access, scalability, culturally informed care will continue
- Rapidly evolving field will need more well-trained clinicians, professional standards for clinical care and training

*Thank you –
from VA Puget Sound
Health Care System
Seattle, Washington*



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