

Psychedelic treatments; questions from clinical research and implementation

Robert Schoevers
Dept. of Psychiatry
University Medical Center Groningen

EMA Multi Stakeholder Workshop



ER GAAT NIETS BOVEN 
GRONINGEN

city
of
talent

Conflict of interest

Research funding	Netherlands Organisation Health Research & Development, EU Horizon 2020, NIMH (USA), EU Horizon 2023, UMCG, Stichting tot Steun, Nationaal programma Groningen, Healthcare insurers innovation funds, Janssen Pharmaceuticals, Novartis, Compass Pathways, Clexio Biosciences, GH research
Speakers fee	
Scientific advisory	
Clinical trials	
Shareholder	None
Other	None

How to maintain initial positive effects?



THE LANCET
Psychiatry

Maintenance ketamine treatment for depression: a systematic review of efficacy, safety, and tolerability

Sanne Y Smith-Apeldoorn, Jolien KE Veraart, Jan Spijker, Jeanine Kamphuis, Robert A Schoevers

Can we combine with other medications?

Pharmacodynamic Interactions Between Ketamine and Psychiatric Medications Used in the Treatment of Depression: A Systematic Review

Jolien K. E. Veraart^a, Sanne Y. Smith-Apeldoorn, Iris M. Bakker, Berber A. E. Visser, Jeanine Kamphuis, Robert A. Schoevers, Daan J. Touw



Safety of Ketamine Augmentation to Monoamine Oxidase Inhibitors in Treatment-Resistant Depression: A Systematic Literature Review and Case Series

Jolien K. E. Veraart, MD^{a,b,c}; Sanne Y. Smith-Apeldoorn, MD^a; Mats Kutscher, MSc^a; Maurice Vischjager, MSc^a; Annemarie van der Meij, MD^c; Jeanine Kamphuis, MD, PhD^a; and Robert A. Schoevers, MD, PhD^{a,d}

Can we prescribe in patients with comorbidities?

Ketamine Treatment for Depression in Patients With a History of Psychosis or Current Psychotic Symptoms: A Systematic Review

Jolien K. E. Veraart, MD^{a,b,c}; Sanne Y. Smith-Apeldoorn, MD^a; Jan Spijker, MD, PhD^{c,d}; Jeanine Kamphuis, MD, PhD^a, and Robert A. Schoevers, MD, PhD^{a,e}

NEWS FEATURE

Schizophrenia

Bipolar disorder

On the spectrum

BY DAVID ADAM




Pyromania

Social phobia

Research suggests that mental illnesses lie along a spectrum – but the field's latest diagnostic manual still splits them apart.

What is optimal support?

Patient perspectives and experiences with psilocybin treatment for treatment-resistant depression: a qualitative study

Joost J. Breeksema ^{1,2}✉, Alistair Niemeijer³, Erwin Krediet⁴, Tilman Karsten⁵,
Jeanine Kamphuis¹, Eric Vermetten ⁴, Wim van den Brink^{6,7} & Robert Schoevers ¹


scientific reports



What are adverse effects of classic psychedelics and how often do they occur?

Review

Adverse events in clinical treatments with serotonergic psychedelics and MDMA: A mixed-methods systematic review

Joost J Breeksema^{1,2,3} , Bouwe W Kuin¹, Jeanine Kamphuis¹, Wim van den Brink⁴, Eric Vermetten²  and Robert A Schoevers¹



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- AE's are poorly defined and remain underreported;
 - lack of systematic assessment of AEs
 - sample selection
- Acute challenging experiences may be therapeutically meaningful
- Systematic and detailed assessment & reporting required in all future studies

Who
participated
in published
studies?



Similar effects across psychedelics & diagnoses?

Psychedelic Treatments for Psychiatric Disorders: A Systematic Review and Thematic Synthesis of Patient Experiences in Qualitative Studies

CNS Drugs
<https://doi.org/10.1007/s40263-020-00748-y>

SYSTEMATIC REVIEW

Joost J. Breeksema^{1,2} · Alistair R. Niemeijer³ · Erwin Krediet^{2,5} · Eric Vermetten^{2,4,5}  · Robert A. Schoevers¹

Therapeutic processes

1. Insight (e.g. illness, causes, own role)
2. Changing perspective of self
3. Connectedness self/others
4. Transcendent experiences
5. More access to emotions

Patient outcomes

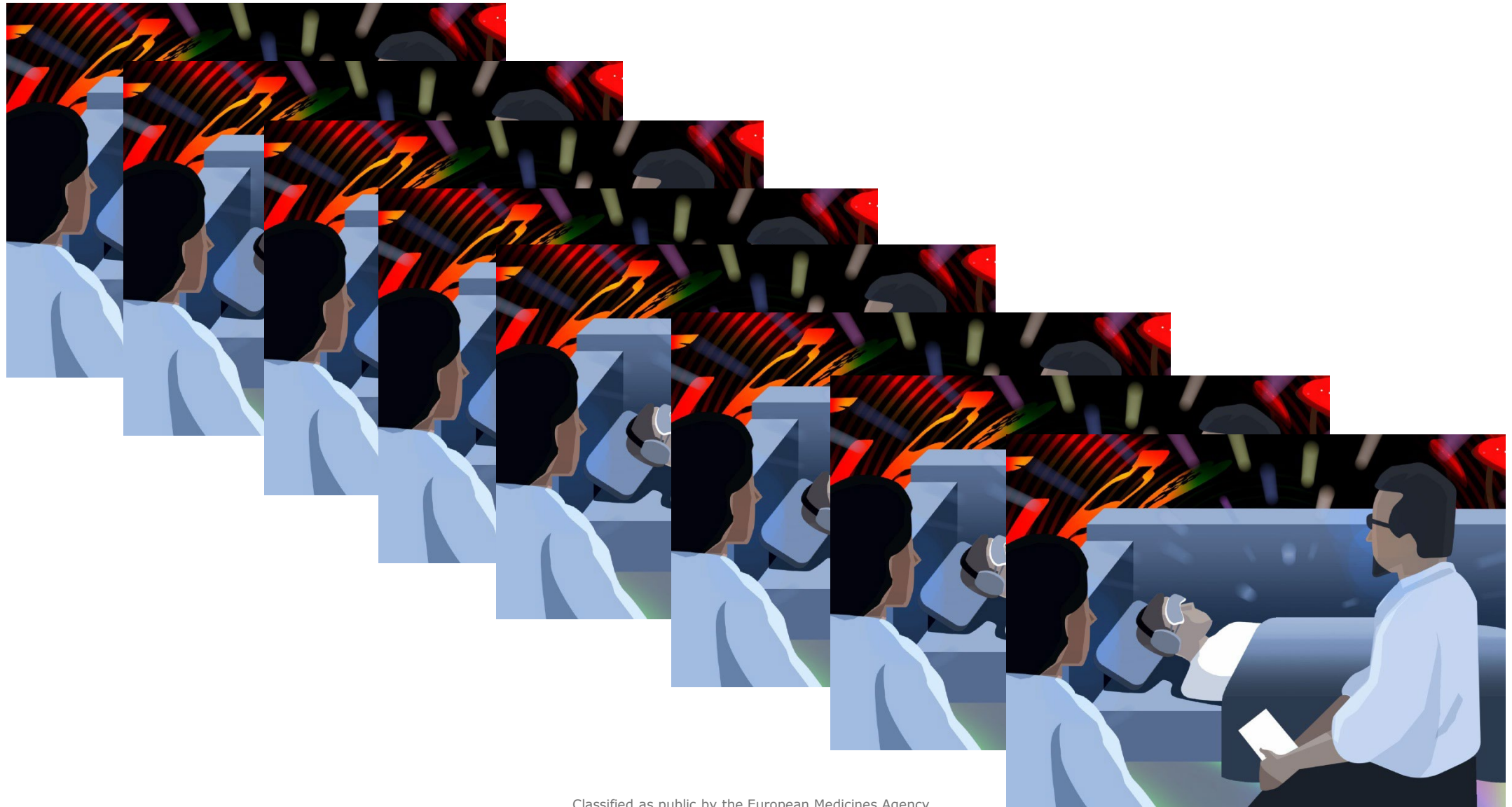
1. Symptom decrease
2. Self image change
3. Connected
4. Larger emotional repertoire
5. Quality of life

What form of psychotherapy works best?

Psychedelic assisted & ketamine assisted psychotherapies; *two reviews in progress*;

- Wide range of psychotherapeutic approaches
- Form of psychotherapy represents prevailing interests of each era
- Studies mostly descriptive, low methodological quality
- Massive heterogeneity in:
 - Drug formulation and dosing regimens
 - Patient populations
 - Description of specific psychotherapeutic interventions
 - Proposed mechanisms: treatment adherence, cognitive flexibility, reduced defensiveness, access to traumatic memories, transformational experiences
 - Psychotherapy provided during or after administration
 - Psycholytic, psychedelic?

How many sessions are needed?





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Questions from research & implementation

- Knowledge gaps
- **Upcoming projects**
- Next steps



PRESS RELEASE



European Union funds groundbreaking research into psychedelic therapy



Funded by the
European Union

A European consortium of 19 partners has been awarded over €6.5M by the European Union to study psilocybin to treat psychological distress in people with progressive incurable illnesses requiring palliative care. This is the first time the EU has funded a multi-site clinical study into psychedelic-assisted therapy.

Psilocybin therapy for psychological distress in palliative care patients

Being confronted with a terminal illness

- **Psychological and existential distress**
 - Profound changes in physical, emotional, social and spiritual well-being
 - Depression and anxiety (up to 80%)
 - Demoralization
 - Decreases in quality of life
- **Poor treatment outcome**
 - Evidence for psychotherapy and antidepressants remains inconclusive

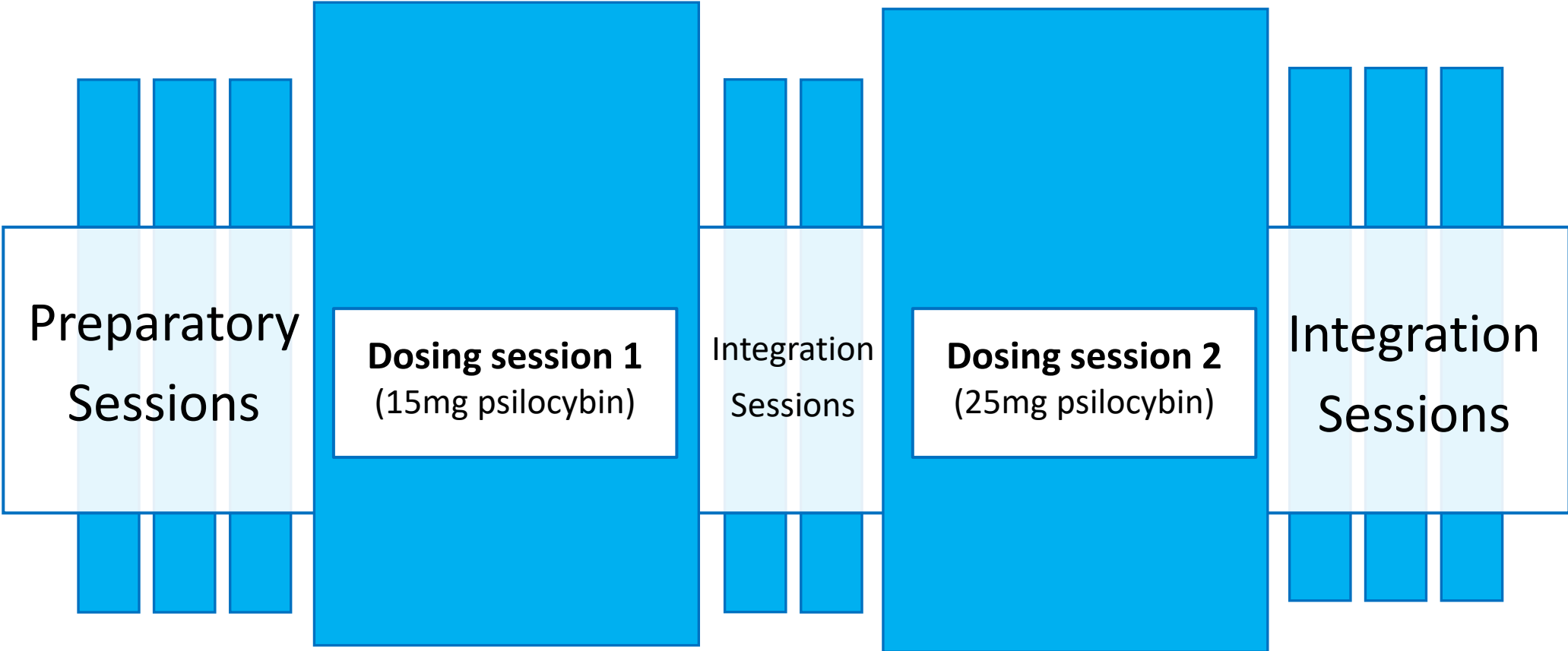


Multi-site double-blind placebo-controlled clinical trial

- **Four medical conditions**
 1. Chronic obstructive pulmonary disorder (COPD) in Groningen
 2. Amyotrophic lateral sclerosis (ALS) in Copenhagen
 3. Multiple sclerosis (MS) in Prague
 4. Atypical Parkinson disorder (APD) in Lisbon
- **Inclusion screening**
 - 100+ patients
 - Age > 18
 - Current depressive episode (ICD-10)
 - Life expectancy of at least 6 months
- **Randomisation and blinding** (2:1 active vs placebo)



Psilocybin Therapy



~3 months

PsyPal key elements

All participants receive psilocybin

Ascending dose (2x)

Therapy manual and training standardized

Mixed methods - including spiritual, existential

Explore phenomena eg 'End of life Distress'

Different chronic deteriorating medical conditions

Combinations with other medications

Continued Care and Public and Patient Involvement

- 1) Peer support networks
- 2) Digital Care platform





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Signalement

Therapeutische toepassingen van psychedelica


RIE




Kansen,
voor beh
psychiat



 TWITTER


 MEEST GELEZEN ARTIKELN

 Seksomnia tijdens behandeling met ee...


a worldwide point of reference for
**research, innovation and
 implementation** of novel treatments in
 mental health care



Improve the health and well-being of patients suffering from mental disorders by establishing a country-wide research and implementation infrastructure

 25% of the general population faces a mental health problem

€ 22 billion economic costs per year in the Netherlands alone

 highest population disease burden and cause the greatest loss of productivity

30% of patients develop a serious 'treatment-resistant' mental disorder

- addiction
- OCD
- chronic pain
- eating disorders
- depression
- post-traumatic stress disorder
- existential distress



1

Nationwide coordination and collaboration of R&D&I efforts.

Patient-centred approach
 Follow-up care to monitor long-term effects

2

Large-scale research answering the gaps

Controlled, sustainable, ethical, safe

3

Translation to clinical practice

Development of specific therapeutic skills

4

High-quality training and certification for health care professionals

Creating clear guidelines



Thank you for your attention!

Research group: [Psychedelic Treatment and Mechanisms \(umcgresearch.org\)](https://umcgresearch.org)

Contact: r.a.schoevers@umcg.nl