



Die Artikel in der Rubrik «Guidelines» geben nicht unbedingt die Ansicht der SANP-Redaktion wieder. Die Inhalte unterstehen der redaktionellen Verantwortung der unterzeichnenden Fachgesellschaft bzw. Arbeitsgruppe; vorliegend handelt es sich um die Schweizerische Interessensgemeinschaft Psychedelika-assistierte Therapie (IG PAT).

Guidelines for Therapeutic Psychedelic Use

Treatment Recommendations for Psychedelic-assisted Therapy

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Introduction

In the early 1970s, psychedelics were strictly regulated or de facto banned worldwide. This also brought medical applications and clinical research to a virtual halt. With the investigation of psilocybin's neurobiological mechanisms of action [1], psychedelic research was revived in the mid-1990s. In 2004, clinical studies with psychedelics and related compounds started in Switzerland with a 3,4-methylenedioxyamphetamine

(MDMA) trial in patients with post-traumatic stress disorder [2], although MDMA is not considered a “classical” psychedelic due to its different acute effects. Various approvals for pioneering human research projects in Switzerland followed [1, 3–12].

Clinical treatment with psychedelics started in 2014 under exceptional licenses issued by the Federal Office for Public Health.

The most common psychedelics, in the broader sense, currently in use are MDMA,

psilocybin, lysergic acid diethylamide (LSD), dimethyltryptamine (DMT) and ketamine. They are used in various study and treatment settings. These range from clinical phase 1, phase 2, and phase 3 studies to limited applications with exceptional medical approval and the comparatively simple use of ketamine. The requirements for those responsible for treatment, as well as those accompanying treatment sessions, vary accordingly.

Abstract

Switzerland's early contributions to the 'psychedelic renaissance', the revival of psychedelic science starting in the early 21st century, might be particularly noteworthy given the growing global interest in using psychedelics for research and therapy. In 2023, the Swiss Interest Group for Psychedelic-assisted Therapy was established to provide a clear and widely accepted framework for work related to psychedelic-assisted therapy. Members of this group created a first draft of treatment recommendations (S1 guidelines). These recommendations will be continuously updated to incorporate new findings in research and therapy.

Keywords: Psychedelics; psychedelic-assisted therapy, S1-guidelines; treatment recommendations; Switzerland

Expert groups for psychedelic-assisted therapy (PAT) are currently being formed in various parts of the world to discuss and develop consensus guidelines for PAT while taking into account the relevant literature [13]. The treatment recommendations presented here aim to demonstrate the current state of the art in working with psychedelics in Switzerland. Experts from across Switzerland, including those from clinical inpatient and outpatient treatment facilities, private practices, and university research settings, collaborated to develop the text through a process of mutual discussion and clarification. The Association of the Scientific Medical Societies in Germany (AWMF) classifies this document as an S1 guideline that summarizes the recommendations of a group of experts (www.awmf.org). It will be revised and updated on a regular basis to reflect new findings. Together with a more defined and structured process for setting guidelines, the goal is to advance the treatment recommendations into guidelines of a more robust level (S2 or S3) within the next few years.

Contributions to the Treatment Recommendations

In summer 2023, the Swiss Interest Group for Psychedelic-assisted Therapy (IG-PAT) was founded as a society of professionals in Switzerland who are either working in the field of PAT or doing research on psychedelics. The group consists of three professional societies: Schweizerische Ärztegesellschaft für Psycholytische Therapie (SÄPT), Association Professionnelle Suisse pour les Psychédéliques en Thérapie (ASPT), and Société Suisse de Médecine Psychédélique (SSMP), as well as Prof. M. Liechti's clinical pharmacology research group at the University Hospital in Basel, the Pharmacy Dr. Hysek in Biel/Bienne, and the PAT working groups in hospitals and institutions. The Fondazione Alaya, a professional

society from the Italian-speaking part of Switzerland, will soon join the IG-PAT.

These guidelines are based on extensive clinical experience, but they also consider the emerging field of empirical research. They address the need for standardized practices that ensure patient safety, therapeutic efficacy, and ethical considerations when administering psychedelics for mental health treatment.

A diverse group of professionals and experts from across Switzerland gathered in the IG-PAT to contribute their insights, professional findings, and experiences. This collaborative effort encompassed psychiatrists, psychologists, psychotherapists and clinical pharmacologists to ensure that the guidelines reflect a wide range of clinical experience and expertise. Pharmaceutical companies such as Compass Pathways (London, United Kingdom) or MindMed (New York, NY, United States of America), which conduct psychedelic research in order to market psychedelic substances, have had no influence on the development of these recommendations, neither through financial contributions to experts or professional societies nor through lobbying.

The Development Process

These guidelines are based on a thorough review of both clinical practices developed over decades of therapeutic work with psychedelics and the growing body of empirical research in the field. Through an iterative process, the contributing experts combined their knowledge and experience to create guidelines that are both practical and informed by the most recent scientific understanding. The current state of development addresses and reflects ongoing discussions such as the role and importance of accompanying psychotherapy [14–16] or the potential applications in indications outside psychiatry in the narrower sense (cluster headache, palliative care, and others).

These guidelines serve as a comprehensive manual for clinicians interested in implementing PAT into their practice. They cover the entire therapeutic process, from patient selection and preparation to the psychedelic experience and subsequent integration, emphasizing the importance of a supportive therapeutic relationship throughout. The recommendations aim to provide a safe, effective, and ethical approach to PAT while encouraging personal growth and the healing or improvement of patients' symptoms. However, the limited medical use approvals restrict the use of psychedelics in the treatment of patients to difficult-to-treat disorders for which other approved treatments have failed.

Potential Limitations and Further Steps

At this point, we decided on a loosely structured, informal clarification process as proposed for S1 guidelines. This approach was chosen because the authors sought a straightforward and feasible method to summarize a pragmatic and widely accepted initial version of the document. In an ongoing consolidation process, the document will be continuously expanded and refined over the next few years.

While these guidelines represent a significant step forward, they also highlight the limitations of the current empirical evidence and the necessity for further research. Future research is essential to validate and refine the outlined clinical practices, ensuring that they remain current with the evolving scientific landscape. Furthermore, the guidelines emphasize the importance of developing individualized treatment plans and incorporating new insights into clinical practice as the field progresses.

Summary of the Recommendations Shortened into 56 Points

The 56 points listed below are also incorporated in the full text of the English version on pages 33ff.

General Information

Compliance with laws and regulations: The use of psychedelics in therapeutic practice complies with applicable legal provisions and ethical guidelines.

1. Limited medical use: The use of psychedelics within the scope of exceptional authorizations is limited to serious illnesses and must be carried out under medical supervision.

2. Use of the acronym PAT: For better international understanding and clarity, the term psychedelic-assisted therapy (PAT) is used in Swiss practice to refer to both psychotherapeutic treatment and non-psychotherapeutic use.

3. Further training and qualifications: Therapists who provide PAT undergo appropriate training to ensure that the treatment is performed professionally and safely.

4. Transparency and documentation: All treatments and their results are documented to track progress, record risks and gain scientific knowledge that can contribute to improving therapy.

Responsibilities

5. Responsible person: The person responsible for the treatment is clearly defined and bears ultimate responsibility. In studies, this is usually the principal investigator; in medically managed institutions, the medical license holder (and above them, clinic management); and in private practices, the medical license holder.

6. Professional qualification: As psychedelics are narcotics, prescription and treatment must be performed by a medical doctor with a valid license to practice and, in most cases, a specialist title in psychiatry and psychotherapy. Doctors with other specialties are also qualified for specific indications.

7. Delegation of tasks: Parts of the treatment can be delegated to qualified personnel, including study staff, non-medical psychotherapists, or specially trained nursing staff.

Indication and Contraindication

8. Exceptional treatment: PAT is considered when psychiatric, psychotherapeutic and psychopharmacological treatments have failed or are ineffective.

9. Primary indications: PAT is primarily used for depression, anxiety and PTSD, for which there is the most evidence (phase 2 and 3 clinical trials).

10. Other indications: Exceptional approvals are not limited to specific diagnoses. In certain cases, they can also be applied for less researched or difficult-to-treat indications such as substance use disorders, obsessive-compulsive disorders, eating disorders, and autism spectrum disorders, as long as the potential effectiveness for the indication in question is convincingly demonstrated. This should be evaluated through suitable accompanying research.

11. Risk of psychosis and psychotic disorders: Individuals at risk of psychosis or with a his-

tory of schizophrenic-psychotic or bipolar episodes, especially bipolar I, should not be referred for PAT until the risks have been scientifically clarified.

12. Adolescents: Adolescent patients require special care because their cognitive development is not yet complete.

13. Consideration of attachment capability: People with insecure and rapidly fluctuating attachment capability require increased caution.

14. Consultation of appropriate specialists in the event of serious physical illnesses: In the event of serious physical illnesses or an unclear initial somatic situation, it is recommended to consult an appropriate specialist.

Therapeutic Process: General

15. Long-term therapeutic process: PAT should be seen as part of a longer psychotherapeutic process that goes beyond the administration of psychedelics.

16. Integration into existing therapy: PAT should be integrated into existing psychotherapeutic frameworks.

17. Preparation, substance experience and aftercare: PAT requires a thorough preparation phase, followed by the actual psychedelic experience and subsequent aftercare.

18. Agreement on therapy goals: It is important to set specific therapy goals in consultation with the patient. These goals may include, but are not limited to, reducing symptoms, improving quality of life, accepting one's personal situation and restoring the ability to work.

19. Ethical consideration: For therapeutic use outside of studies, special consideration should be paid to the potential harm caused by the disease's progressive course, which cannot be sufficiently influenced by conventional means.

Therapeutic Process: Preparation

20. Indication and contraindication: A thorough clarification of the indication and psychological and somatic contraindications is carried out.

21. Informed consent: A comprehensive informed consent process is carried out, during which the effects and potential consequences of the treatment are openly and clearly explained.

22. Social environment: The current family and partnership situation, as well as possible effects on interpersonal relationships, are discussed.

23. Imparting specialist knowledge: Set, setting, substance, dosage, duration, and course of the psychedelic sessions are explained.

24. Individual or group setting: If necessary, clarify whether the substance experience should take place in an individual or group setting.

25. Temporary loss of autonomy: Open communication about the possible temporary loss of physical, psychological, or mental autonomy during treatment and the possible difficulties that may arise as a result.

26. Set: Active engagement with the patients' expectations, doubts, wishes, hopes, and fears.

27. Persistent worsening: Explaining the possibility of persistent worsening of well-being and symptoms due to the PAT, as well as the possibility of emerging from the treatment frustrated and without significant experiences or insights.

Therapeutic Process: Substance Session, Set and Setting

28. Room facilities: The room for the session is well-equipped and pleasantly furnished.

29. Movement options: It is possible to change positions within the room (lying or sitting) and move around to some extent.

30. Monitoring: The patient's vital signs can be monitored.

31. Emergency measures: The therapists are familiar with emergency interventions and related medications.

32. Hospitalization: Knowledge of local somatic and psychiatric emergency structures is available.

Therapeutic Process: Integration

33. Integration: The goal of integration is for patients to enrich their psychedelic experiences through deep understanding and to transfer the knowledge gained into their everyday lives.

34. Difficult experiences: Difficult experiences are given special attention.

35. Promotion of self-reflection: Preparatory and follow-up psychotherapeutic interventions facilitate the process of recapitulation and reflection.

Further Therapeutic Training

36. Further psychotherapeutic training: Since PAT is a psychotherapeutic method, comprehensive further psychotherapeutic training is essential. This includes the development of a therapeutic identity, learning different therapeutic techniques, understanding the therapeutic relationship and the ability to self-reflect.

37. Understanding of psychedelics: Therapists have a thorough understanding of the psychological processes and challenges associ-

ated with the unique experience during PAT, as well as knowledge of psychedelic substances, preparation, and integration.

38. Qualified further training: Further training in PAT is comprehensive and competent. Quality criteria and certifications from recognized institutions are necessary to ensure quality.

39. Transparency and accessibility: Information about training courses and specialist agencies is accessible and transparent for everyone.

40. Quality standards and admission criteria: General quality standards and admission criteria are defined so that different providers can be evaluated based on objective criteria.

41. Cooperation and partnerships: Joint training programs and specialist units will be promoted to use resources more efficiently.

42. Feedback and evaluation: The evaluation of training courses is collected from the participants as a standard in order to tailor courses to the needs of the learners.

43. Conceptual basis: Institutions have a clear conceptual framework for the implementation of PAT, as well as close contact with pre- and post-treatment entities.

44. Exchange and quality assurance: Institutions have regular exchanges with other PAT providers about method development and quality assurance.

45. Personal experience for therapists: Appropriate scientific research will be conducted to assess the relevance of personal experience with psychedelic substances for therapeutic training and its impact on the therapeutic mindset.

46. Participation in specific scientific projects: Wherever possible, therapists are encouraged to participate in such projects.

Ethics, Quality and Safety

47. Compliance with quality standards: The substances used in PAT meet GMP standards to the greatest extent possible and are subject to quality control.

48. Safety in use: The substances are used under safe and controlled conditions.

49. Therapeutic abuse: The prevention of abuse is a top priority in the training and further education of PAT therapists.

50. The discussion of the risk of therapeutic abuse is an integral part of therapeutic quality functions like intervention and supervision.

51. Open dialog: Patients are given the opportunity to openly discuss conflicts and ambiguities in the therapeutic relationship.

52. Ombudsman's office: In the event of conflicts that cannot be resolved in therapy, an arbitration board can be called upon, which

will be available on the SÄPT website (saept.ch).

53. Legal action: In the event of suspected serious therapeutic offenses or unprofessional incidents, the Medical Ethics Committee can be called upon and/or civil or criminal proceedings can be initiated.

54. Emergency preparation: Therapists are trained to deal with emergency situations such as acute suicidal tendencies, severe anxiety, aggression, or impulses to leave the treatment setting.

55. Continuous monitoring and support: The treatment is continuously monitored and supported. During the acute effects of the substance, the therapist or an accompanying person must remain present constantly.

56. Supervision and intervention: Therapists undergo continuous training through intervention and supervision.

Where to Find the Complete Guidelines

This article is a short version of the treatment recommendations. The complete guidelines are available in four languages (English, German, French and Italian) under ADDITIONAL INFORMATION at the beginning of this article and provide an in-depth exploration of PAT. This resource is invaluable for healthcare professionals seeking to incorporate PAT into their practice by ensuring that they are equipped with the latest knowledge and best practices in this emerging field.

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Conflict of Interest Statement

Both authors received small financial support from the Federal Office for Public Health for medical writing (no order or contract, no deadline, no requirements of content).

HDA received consulting fees from Mind Medicine Inc for participating in one single advisory board meeting.

PG received consulting fees from Compass Pathways, MindMed Inc. and the Reconnect Foundation. He participates on the advisory board for a phase 3 LSD study carried out by MindMed Inc. and is the president of the Schweizerische Ärztgesellschaft für Psycholytische Therapie (SÄPT).

Author Contributions

HDA and PG equally contributed to this article. They both established and revised the text and share responsibility for the content. Together, they drafted a first version of the full text version of the treatment recommendations (online only) and led through the implementation and adaptation process and clarification with the experts who co-authored the treatment recommendations. They finalized the treatment recommendations. They share responsibility for the content of the full version of the treatment recommendations with all contributing associations and co-authors.



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