Treatment recommendations

Psychedelic-assisted therapy (PAT)

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Summary

Aim and purpose

After decades of stagnation, the research and medical use of mind-altering substances such as psilocybin, MDMA, LSD and others resumed around 20 years ago. Since 2014, psychedelic-assisted therapies (PAT) outside of research projects have also been possible in Switzerland with exceptional approval from the health authorities (Federal Office of Public Health, FOPH). Canada and Australia also provide for treatments in exceptional cases, and other countries will follow. In a few years, psychedelics may be approved drugs. This will require clearly describable treatment standards that can be used as a guide by professionals, authorities, health insurers, politicians and the interested public.

Methodology

The expert knowledge within the SÄPT forms the basis for this document. It has also been compared with the international professional literature. We deliberately chose a narrative style to illustrate the content and important statements without reaching the level of detail of a textbook. In a second editorial round, a working group was formed with the two newly formed specialist associations in French-speaking Switzerland to revise and supplement the text. This group produced the final version.

Outlook

Psychedelic-assisted therapy is currently undergoing dynamic development with many important issues and questions that have not yet been answered or classified. Above all, the treatment cannot yet be carried out on a regular basis, as the substances in question - with the exception of ketamine - are narcotics of the highest level of prohibition. This could change in the foreseeable future. The treatment recommendations should therefore be revised periodically (2-3 years) and supplemented with new findings.

Contents

Summary *2*

Contents *3*

Introduction *4*

Purpose and development of guidelines **4**

Historical background **6**

Current situation - "Psychedelic renaissance" **7**

Therapeutic use of psychedelics in Switzerland **8**

Professional requirements and qualifications *9*

Further education, training, certification, networking **10**

Personal experience **12**

Indication and contraindication *13*

Patient variables, disorders, absolute and relative contraindications **14**

Psychedelic-assisted therapy (PAT) *15*

Psychotherapeutic framework **16**

Embedding in ongoing therapy 16

Preparation 18

Psychedelic experience: substance, set, setting 20

Integration 26

Safety, difficult and emergency situations **27**

Drug information **28**

Ethics, quality assurance, supervision and intervision *28*

Ethics **29**

Quality assurance, supervision and intervision **30**

Self-care **30**

Patient register and questionnaire for quality assurance **31**

Outlook *31*

Guideline recommendations *33*

References *39*

Introduction

In Switzerland, the exceptional possibility of treating patients with psychedelics in a psychotherapeutic outpatient or inpatient setting has existed since 2014. Despite relatively restrictive legislation, this was preceded by various approvals of pioneering human research projects in Switzerland (e.g. Gasser, 2012; Gasser et al, 2014; Hysek et al, 2014; Hysek & Liechti, 2012; Liechti et al, 2000, 2001; Liechti & Vollenweider, 2000; Oehen et al, 2013; Vollenweider et al, 1997, 1998, 1999, 2007 and others).

The various psychedelics mainly in current use - methylenedioxymethamphetamine (MDMA), psilocybin, lysergic acid diethylamide (LSD), ketamine and dimethyltryptamine (DMT) (the latter either parenterally as a monosubstance or orally in combination with a monoamine oxidase (MAO) inhibitor) - are administered in different study and treatment contexts. These range from clinical phase 1, phase 2 and phase 3 studies to restricted applications with exceptional medical approval and the comparatively accessible use of ketamine. The requirements for those responsible for the treatment, as well as those accompanying treatment sessions, are correspondingly variable.

Purpose and development of guidelines

After an initial phase of discovery, new treatment methods undergo development through clinical research, experience, and testing in everyday clinical practice. This is followed by a process of operationalization and structuring to improve observations of the therapeutic processes and results, to make it easier to train people who want to learn this new treatment method, and finally to continuously monitor the quality and improve the procedures. Psychedelic-assisted therapy (PAT) is currently in the early stages of this process. This means that a discussion is opening up for a wide variety of viewpoints, including controversial ones, as there is currently much less scientific evidence concerning the context of this treatment than the acute effects and potential therapeutic impact of these substances in some psychiatric indications.

Johnson and colleagues (2008) have already proposed safety guidelines for conducting studies with psychedelics, and recently the U.S. Food & Drug Administration (FDA) also published a draft guideline for the conduct of clinical trials with psychedelics (FDA, 2023). While the development of study protocols calls for the strictest requirements to be placed on drug safety and risk management, the potential harm to the individual patient due to the progressive course of the disease, which cannot

be adequately influenced by conventional therapy, must be given particular consideration in the ethical assessment of therapeutic use outside of studies.

Expert groups for PAT are currently being formed in various places around the world to discuss and develop consensus guidelines for PAT, taking into account the relevant literature (APPA, 2023). These guidelines - including the treatment recommendations presented here - are a snapshot with limited validity. According to the classification of the German Association of Scientific Medical Societies, this document is an S1 guideline that summarizes the recommendations of a group of experts (awmf.org). They are revised at periodic intervals and adapted to future new findings.

With the founding of two new professional associations - the Association Professionnelle Suisse pour les Psychédéliques en Thérapie (ASPT) and the Société Suisse de Médecine Psychédélique (SSMP) - the French- and Italian-speaking parts of Switzerland are now also organized in specialist groups alongside the Swiss Medical Association for Psycholytic Therapy (SÄPT), which has existed since 1985. These three associations, together with other institutions working in the field, founded the Swiss Interest Group for Psychedelic-Assisted Therapy, IG PAT, in 2023. The IG PAT developed these guidelines in an open consensus process.

To name just a few important points for discussion:

- Is PAT a psychotherapy that uses psychedelics as catalysts to deepen the experience (Grinspoon & Doblin, 2001; Grof, 1980; Grof et al., 2001; Gründer et al., 2023), or is it essentially a pharmacotherapy that requires specific personal supervision for reasons of safe use (Goodwin et al., 2023)?
- Is the subjective psychedelic-induced experience an important part of PAT (Mithoefer et al., 2016; Yaden & Griffiths, 2021) or is it not necessary or even potentially harmful (Olson, 2021)?
- Is physical contact (e.g. holding a hand) between therapist and patient a helpful or even necessary intervention in certain PAT situations (Calder & Hasler, 2023; Mithoefer, 2015), or is physical contact an unnecessary, ethically questionable reminiscence, and / or is it reserved for people trained in body psychotherapy?
- Is personal experience with the effects of psychedelics a necessary part of the training of a PAT therapist, analogous to the self-awareness of other psychotherapy methods (Mueller, 2022; Nielson & Guss, 2018), or is self-experience dispensable or even undesirable due to the therapist's bias or lack of neutrality?

These and other central controversies have been and must continue to be discussed. Both empirical research and the many years of sound experience of PAT therapists serve as the basis for this discussion.

The majority of the authors of these recommendations are psychotherapeutically oriented and some have many years of experience with PAT in research and practice. These recommendations are intended as a guide for embedding the psychedelic experience in a longer psychotherapeutic process that is not limited to the one-off administration of psychedelics. They show the relevant methods and overarching issues and are intended to provide orientation for working with psychedelics without reaching the depth of a textbook or training course. However, these guidelines are also intended to help authorities, politicians, health insurance representatives and professionals who are not directly involved to gain an in-depth overview of the topic. The Federal Office of Public Health (FOPH) has expressly encouraged the development of these guidelines as an aid in the assessment of applications for restricted medical use of the narcotics in question.

Historical background

The treatment of physical and mental disorders with the help of mind-altering substances has been part of human medicine since prehistoric times (George et al., 2021). In the modern Western world, a psychedelic was scientifically researched for the first time towards the end of the 19th century with the chemical description of mescaline, which was phenomenologically described in a monograph by the psychiatrist Kurt Beringer (Beringer, 1927). The idea of therapeutic use was not yet included in this work.

In 1943, a new era of consciousness research began with the discovery of the psychoactive effect of LSD by Albert Hofmann. Among other things, this raised the hope of being able to research the development of psychoses using a model psychosis induced by this substance, thus making mental illnesses easier to understand and cure. The systematic treatment of mentally ill people with psychedelics began in the clinical context of scientifically oriented medicine in the mid-1940s with the work of Werner A. Stoll (Stoll, 1947) at the Psychiatric University Clinic in Zurich.

The treatment recommendations presented here follow the principles of evidence-based, conventional medicine.

Current situation - "Psychedelic renaissance"

At the beginning of the 1970s, psychedelics (LSD, psilocybin, DMT, mescaline, etc.) were strictly regulated or de facto banned worldwide. This also brought medical use and clinical research to a virtual standstill. With the investigation of the neurobiological mechanisms of action of psilocybin (e.g. Vollenweider et al., 1997 and others) psychedelic research was revived starting around the mid-1990s. Somewhat later, Griffiths and colleagues in Baltimore initially began researching psychological effects in healthy test subjects (Griffiths et al., 2006 and others). This was followed by clinical studies investigating the effects of psilocybin on anxiety symptoms in cancer patients (Griffiths et al., 2016).
In the early 2000s, the *Multidisciplinary Association for Psychedelic Studies* (MAPS) in the USA launched research projects on MDMA in post-traumatic stress disorder (PTSD) (Gu et al., 2021; Oehen et al., 2013). MDMA was the last of the mind-altering substances used therapeutically in a Western context to be banned in 1985. In 2007, a Swiss project (Gasser et al., 2014) also investigated LSD for the first time in a clinical research project after an interruption of more than 35 years. In 2012, the book "The Psychedelic Renaissance" was published (Sessa, 2012) by the English psychiatrist Ben Sessa, whose title coined the term that subsequently came to be used to label the renewed interest in mind-altering substances in research and clinical application. In the course of this revival of psychedelic research, the anesthetic ketamine (Ketalar®), an atypical, short-acting psychedelic that had been on the market since the 1960s, also found a new use as a treatment for treatment-resistant depression. Psychedelics are not yet approved substances (as of fall 2023), but are being tested in clinical trials for various indications (including PTSD, depression, anxiety disorders, and alcohol dependence, among others) (Bogenschutz et al., 2022; Goodwin et al., 2022; Holze et al., 2023; Mitchell et al., 2021).
In these guidelines, we use the term "psychedelics" as a generic term for the mind-altering substances used in therapy. In particular, we focus on the substances MDMA (not a classic psychedelic in the narrower sense), LSD, and psilocybin, which are currently used within the scope of the FOPH's exceptional authorizations. Other classic psychedelics such as mescaline or DMT could be used in a similar way in the coming years based on the current state of research. In addition, ketamine is also currently being used to some extent in a psychotherapeutic context, and the relevant professional training programs are also being held in Switzerland.

Therapeutic use of psychedelics in Switzerland

Between 1988 and 1993, some doctors - all members of the SÄPT - were authorized by the FOPH to treat patients with LSD and MDMA (Gasser, 1996). After a longer break, in 2014 Switzerland became the only country in the world to allow the national health authority (Federal Office of Public Health, FOPH) to provide treatment with LSD and MDMA on a case-by-case basis, and psilocybin was added in 2021.

The basis for this is an exemption article in the Narcotics Act (Article 8, paragraph 5 of the NarcA), according to which a permit can be issued in exceptional cases for the substances in the highest prohibition level (list d) if it is for the "limited medical use" of treating serious illnesses. PAT is not a *first-choice treatment*, but is only considered for people who have already undergone several other psychotherapeutic or psychopharmacological therapies without lasting success.

In some cases, the term "compassionate use" was also used for these treatments, as they are only used after the usual methods have been exhausted and are often used in patients with life-threatening/terminal illnesses. In regulatory terms, however, the term *compassionate use* refers to the temporary use of a medicinal product that has not yet been approved in patients outside of a parallel approval study. For such a treatment, the study sponsor (the pharmaceutical company) would have to submit the application for use to Swissmedic. However, the restricted medical use of psychedelics does not generally take place in parallel with a licensing study (in Switzerland),it is not carried out at the request of a sponsor, and it is approved by the FOPH.

In regulatory terms, PAT in Switzerland is a "restricted medical use" of an otherwise prohibited substance based on an exceptional authorization from the FOPH. From a therapeutic perspective, we use the term "psychedelic-assisted therapy" (PAT). In addition to its suitability in terms of content, PAT has the advantage that this term is gaining international acceptance.

Currently (fall 2023), legal PAT outside of approved studies is only possible worldwide in Switzerland, Australia (since July 1, 2023, selected therapists, use of MDMA for PTSD and psilocybin for depression), and Canada (selected therapists, use of psilocybin for palliative treatments for cancer patients). There are also clinics in Mexico and Canada that specialize in the use of the atypical psychedelic ibogaine for the treatment of opioid addiction, and in some South American countries, centers have also been established that combine the shamanic-indigenous or syncretic legal use of ayahuasca with psychotherapeutic approaches.

In Switzerland, more than 1000 licenses for restricted medical use have been issued to around 60 doctors since 2014. It is estimated that around 2000 to 3000 psychedelic treatments with MDMA, LSD and psilocybin have taken place. Concrete figures are currently available for the years 2016 up to and including November 2023: During this period, there were a total of 1051 authorizations (initial authorizations and continuations), of which 351 were for MDMA, 338 for LSD and in the years 2021 - 2023 362 were for psilocybin (information from the FOPH, as of December 2023).
The authorizations are valid for one patient for one specific substance for a period of one year with the possibility of extension if the therapeutic process requires it and a new authorization is granted. The decision on the dosage of the substance, the frequency of psychedelic sessions, the setting, and the form and intensity of accompanying psychotherapy lies with the holder of the exceptional authorization and their individual therapy design.
For almost ten years, the FOPH has made it possible for psychedelic-assisted treatments to be carried out in Switzerland on a not insignificant scale. In 2019, the FOPH commissioned an expert report that provides information on the status and development scenarios of treatment with psychedelics (Liechti, 2019).

Professional requirements and qualifications

In order to obtain an individual license for the use of psychedelics in a patient, a medical license is required. When using esketamine (Spravato®), training is provided by the pharmaceutical distribution company. PAT with racemic ketamine (Ketalar®) is subject to the rules of *off-label use* and is therefore also more the responsibility of the doctor administering it. However, a FOPH authorization is not required for this, as ketamine is not classified as a narcotic. A permit from the Federal Office of Public Health (FOPH) is required to obtain, store and use psychedelics (LSD, MDMA, psilocybin). The application to the FOPH must be submitted by the treating doctor with a license to practice in Switzerland and is only valid for patients residing in Switzerland.
The person responsible for the treatment is a) in the case of a study, the principal investigator, b) in a medically managed institution, the medical licensee (in the case of ultimate medical responsibility, the medical director) or c) in a private practice, the medical licensee. They can delegate parts of the treatment to study staff, non-medical psychotherapists or specifically trained nursing staff, among others (Ljuslin & Schaller, 2017). However, the licensee or, in a medically run institution, the medical

director, remains the person ultimately responsible for the treatment in question. The licensee's liability insurance covers the risks of a PAT within the scope of its obligation to indemnify.

Further education, training, certification, networking

In addition to the requirement of a medical license set by the FOPH, in most cases we consider a mostly completed advanced training in a psychotherapeutic technique to be a prerequisite, at least for the implementation of PAT with pre- and aftercare for primarily psychiatric indications. In addition to comprehensive knowledge of the diagnosis and treatment of mental illness in general, this also includes the advanced development of an identity as a therapist and a basic therapeutic mindset, the acquisition of suitable therapeutic techniques, knowledge of the nature and characteristics of the therapeutic relationship, the ability to engage in professional self-reflection, and the willingness to critically and comprehensively examine one's own personality and accordingly develop it further. As in other specialist areas, the ability to engage in professional exchange, collegial cooperation, and the ability to take criticism are of central importance. We consider the currently practiced broad professional background of PAT therapists to be a valuable resource for our patients, but also for the further development of the service and the method. Depending on the treatment indication, the requirements for one’s psychotherapeutic background may vary. For example, the embedding of PAT into psychotherapy in the treatment of pain disorders such as cluster headaches, MS, post-viral fatigue, palliative care, or the use of microdosing in ADHD (Mind Medicine, Inc., 2021; Schindler, 2022, 2023; Schindler et al., 2021, 2022) may be relevant, but less so than in PAT for depression or anxiety disorders. Accordingly, there are also permit holders in other specialties (e.g. general medicine, internal medicine, neurology, palliative medicine or anaesthesia). In some cases in which pre- and post-treatment is provided by a psychotherapist, the patient may be accompanied on the substance treatment day in whole or in part by a person who is familiar with PAT but not specifically trained in psychotherapy, e.g. particularly in an inpatient setting.

Psychedelic-assisted psychotherapy as a method enables an experience that lies beyond the usual psychological experiences. This singular experience requires therapists to have a deep understanding of the psychological processes and the particular challenges involved. Additional knowledge about psychedelic substances, as well as the proper preparation and integration of these experiences, is therefore essential to ensure that the method is carried out successfully and responsibly. Accordingly, we consider formalized continuing education or additional training to be a fundamentally sensible

option for learning PAT in the medium term[1] (Aicher & Gasser, accepted). The training courses, some of which last several years, are resource-intensive. At present, there are not yet enough lecturers with the relevant expertise to put together such comprehensive training. Interested parties often have to put themselves on waiting lists, look for courses a long way away or make do with online formats. It is often difficult to assess the quality in advance. For example, there are online offers for courses of short duration with questionable certification promises. In addition, the target groups of various offers differ, some with the aim of doing justice to psychotherapeutic work, others with a focus on supporting primarily healthy people outside of a therapeutic setting. Guidelines with quality criteria for continuing education programs - such as those developed by Phelps (2017) - should provide orientation. Certification by recognized institutions will also need to be implemented. Existing certification structures can be used for this purpose. Information on training courses and specialist bodies should be accessible and transparent for everyone. General quality standards and accreditation criteria for training courses and specialist centers must be defined. Collaboration and partnerships should be encouraged to create joint training programs or specialist units. Feedback and evaluation of participants should also be standardized in order to adapt the training courses to the needs of the learners. The training offers to be developed should be built on a solid foundation that takes into account both the available scientific evidence and the established professional expertise of therapists already working in the field.

In addition, the training offers to be developed should be integrated into the existing continuing education landscape. This makes it possible to utilize synergies, which in turn supports the professional development of therapists and contributes to the continuous improvement of their qualifications.

There is currently no certification to become a PAT therapist. Even if this becomes possible in the foreseeable future and there are accredited certifications in Switzerland, the problem of demand from colleagues and patients exceeding supply will not be solved in the short term. This situation is likely to be further exacerbated if psychedelics become registered medications available on prescription.

In this situation, the already important networking in intervision and support through supervision, as well as the opportunity to take advantage of high-quality training opportunities, are becoming

[1] The SÄPT is offering a three-year further training course in its third program, and the waiting lists are long. Demand for further training in PAT currently far exceeds supply.

increasingly important. For several years now, the Swiss Medical Association for Psycholytic Therapy (SÄPT) has been organizing one-day training seminars in Switzerland that are specifically aimed at PAT therapists. The SÄPT also conducts quarterly online training courses. There is now a wide-ranging international program of other online events that impart and discuss knowledge about psychedelics. Until a sufficient number of certified continuing education courses are offered, the continuous updating of a continuing education portfolio, in which participation in qualified continuing education events is documented, could be a means of documenting one's own interest and the acquisition of skills. This is comparable to the FMH continuing education certificate, which includes continuing education, supervision and intervision. Such a continuing education portfolio would still need to be outlined and defined. Other conditions, such as minimum time or content requirements and recognized continuing education formats and content, would have to be clarified. As with other medical treatments, it is fundamentally the responsibility of the medical practitioner to undergo further training and education.

The requirements of employees who provide PAT as part of an institutional service are basically the same as those described above. In the case of treatments within a clinic, the clinic management has an additional responsibility to ensure the quality and safety of the service. They are responsible for ensuring that the individual employees have the qualifications described above and that the necessary knowledge is maintained and transferred within the institution. In addition, there should be a conceptual basis for the institution that regulates the course of therapy within the institution and contact with the pre- and post-treatment authorities, such as in the treatment guidelines of the UPK Basel (Müller, 2023). Institutions should be involved in a regular exchange on method development and quality assurance with other institutional PAT providers (e.g. in a quality circle).

Personal experience

Another important question is the necessity of personal experience with psychedelic substances. Practically all psychotherapy training courses require candidates to have a certain amount of personal experience with the method they are learning. In Switzerland, personal experience is mandatory for the federally accredited psychotherapy training programs and also for the FMH training in psychiatry and psychotherapy, as well as for the state-recognized training to become a psychological psychotherapist in Germany. It is reasonable to assume that with psychedelic substances, due to the

very specific mind-altering experience which is often outside of what is known through everyday experience, it could be all the more important for therapists to be able to understand the nature of patients' experiences during treatment, as these can differ fundamentally from those in regular waking consciousness in practically all areas of perception.
However, the requirement for prospective therapists to have a psychedelic experience also raises ethical questions regarding autonomy and potential contraindications (Emmerich & Humphries, 2023). The PAT training currently underway at the SÄPT is being accompanied by a scientific study on this topic (Mueller, 2022). As part of the study, participants have the opportunity to have substance-induced personal experiences with MDMA, LSD and psilocybin. The question of the relevance of such experiences and possible effects on the therapeutic mindset will be investigated. The scientific data and findings of this study will contribute to the current discourse. For legal reasons, psychedelic experiences with the substances mentioned here are currently not feasible for therapists outside of scientific studies in most countries. However, there are alternative methods, such as holotropic breathwork or the off-label use of ketamine, which can give an impression of related altered states of consciousness, although the experiences induced by the various methods differ phenomenologically in terms of dynamics and also in terms of physical sensations. As with other methods, personal experience of psychedelics is no guarantee of therapeutic competence. Even in psychedelic experiences on the part of the therapist, the set, setting and substance can vary so greatly in their interaction that one only becomes acquainted with particular facets and subdomains of experience in the course of training. It is helpful to be aware of this fundamental limitation in one’s own clinical work.

Indication and contraindication

PAT, which can currently be carried out in Switzerland thanks to exceptional permits, is in any case a treatment reserved for people who have already undergone several psychiatric, psychotherapeutic and/or psychopharmacological treatments with no or no lasting success. The following criteria must be met: The patient is suffering from an illness that is difficult to treat, their suffering can be alleviated by taking the prohibited narcotic, existing treatment options have largely been exhausted, and the dispensing of the prohibited narcotic enables the patient to lead a more independent lifestyle (Federal Council report Kessler, 2018). This is a prerequisite for granting a license. It must be stated

by the applicant and is checked by the FOPH as an entry criterion. A large number of research projects, such as MDMA for PTSD or psilocybin for so-called "treatment-resistant depression" (TRD), also focus on mental disorders which underlie suffering that is difficult to treat. The only exception to the FOPH's exceptional authorizations in this regard is the treatment of cancer patients who are struggling with (existential) anxiety in the context of severe physical illness. The reason for this is there is often little remaining time for psycho-oncological treatments and treatment should quickly lead to the essential therapeutic aspects. This is often possible with psychedelics, as a relatively large number of study results already show (e.g. Gasser et al., 2014; Griffiths et al., 2016; Holze et al., 2023; Ross et al., 2016).

The law does not define any specific indications for the prescription of psychedelics. As a rule, however, exceptional authorizations are only granted for the most extensively researched indications such as depression, PTSD and anxiety disorders (phase 2 and 3 clinical trials). However, subject to convincing justification and compliance with the criteria for limited medical use, the FOPH may also grant authorizations for additional indications in individual cases (e.g. substance use disorders, obsessive-compulsive disorders, eating disorders or autism spectrum disorders). There must be no contraindications and the criterion of lack of response to alternative, suitable forms of therapy must be met.

Treatment is also conceivable for applications that do not have a psychotherapeutic focus in the narrower sense, for example the treatment of pain disorders such as cluster headaches, MS, post-viral fatigue, palliative care or microdosing in ADHD, and the FOPH has already approved a small number of such treatments.

Patient variables, disorders, absolute and relative contraindications

In somewhat simplified terms, it can be said that psychedelics can be used successfully for illnesses where there are clear psychodynamic causes and where psychotherapy is also effective. Although the triggering of chronic psychotic illnesses that go beyond the acute effect of psychedelics has not yet been scientifically proven, the precautionary principle dictates that people at risk of psychosis or with a history of schizophrenic-psychotic and bipolar (especially bipolar I, i.e. manic-depressive in the narrow sense) episodes should be excluded from PAT. In addition, increased caution is required in

adolescents whose cognitive development is not yet complete. Increased caution is also required for people with insecure and strongly fluctuating attachment skills (e.g. emotionally unstable personality disorders or antisocial personality disorder), as the therapeutic relationship is an essential protective factor against self-harm and/or harm to others. Therefore, in the case of serious disorders of the ability to interact and relate (e.g. early attachment and developmental disorders in the sense of complex traumatization or narcissistic personality disorders), there are special requirements for cultivating a long-term, goal-directed and sustainable therapeutic relationship.

In older people, the question of drug interactions and also the physical burden of a psychedelic experience arises more frequently, although the classic psychedelics have a good somatic risk profile overall. For people in less socially integrated circumstances with insecure or absent close relationships, including pronounced social isolation, financial difficulties, involuntary unemployment or inability to work, the question of how a psychedelic experience can be meaningfully integrated in the face of meager resources must also be carefully examined. The indication for "extended" forms of social or psychiatric assistance should definitely be examined in these cases: Visits from housing assistance, psychiatric home care, or social work support can substantially support PAT, stabilize its results or make it possible in the first place.

In addition, there are a number of serious physical illnesses (especially cardiovascular or neurological) or physiological conditions (pregnancy, breastfeeding) for which the risk profile of the substances used cannot yet be conclusively assessed and for which an individualized, careful risk-benefit assessment must be made. If a more serious somatic illness is present or if the initial somatic situation is unclear, it is advisable to consult an appropriate specialist.

Psychedelic-assisted therapy (PAT)

In the older works of the 1950s to 1970s, PAT was quite naturally understood as a psychotherapy. Even during this first period of development of psychedelic-assisted psychotherapy, two distinct methods were developed: On the one hand, the "psycholytic" method, based on a depth psychological approach with resistance analysis and transference interpretation (Leuner, 1971, 1981) and on the other hand the "psychedelic" method, more in line with the emerging humanistic currents, with a stronger focus on so-called spiritual *peak experiences* and their presumed transformative effect (Grof et al., 2001).

Only recently has the question been raised as to whether the therapeutic effects of these substances could be based on purely pharmacological-biological mechanisms (e.g. Grieco et al., 2022). For example, efforts are being made to develop new substances with 5-HT-2A receptor affinity that do not have a psychoactive, psychedelic effect. The intention behind this is to find a substance that has the positive effects of psychedelics without their subjective effects and corresponding potential limitations (Olson, 2021; Taylor, 2022).

From a bio-psycho-social perspective, most mental illnesses can be understood as an expression of unfavorable interactions between biological, psychological and social factors. Many psychological difficulties can also be interpreted as a reaction to overstraining or traumatizing relationship experiences and the associated problematic attachment patterns and developmental disorders.

Embedding psychedelic experiences in a psychotherapeutic context serves to ensure the safety of the psychedelic session, and we also consider the experience of a trusting therapeutic relationship to be a possible efficacy factor (Grawe, 2004; Murphy et al., 2022). Therefore, according to the current state of knowledge, a good, safe, effective and protective psychotherapeutic framework must be defined and further developed.

Psychotherapeutic framework

Embedding in ongoing therapy

The treatment of mental disorders requires a suitable treatment framework in which the therapeutic interventions take place, usually in a conversational form or with a partially non-verbal method (body psychotherapy, music therapy, art therapy, etc.). Drug treatments (e.g. antidepressants) can also be introduced and accompanied therapeutically. This also applies to PAT, especially as it is a treatment for serious, long-standing psychological, psychosomatic or somatic problems, sometimes with psychological comorbidity (e.g. cluster headaches). Potentially successful PAT pursues the perspective of a holistic, long-term therapeutic process. Agreeing on specific therapeutic goals with the patient is an essential stage in this process. These goals can include, for example, a significant reduction in symptoms, an increase in the quality of life or way of living, acceptance of one's personal situation, restoration of the ability to work, and similar.

As the demand for PAT in Switzerland currently far exceeds the supply, many patients now come to treatment with a direct request for psychedelic therapy. However, it is quite possible that a therapist

will be the one to suggest the option of PAT with the patient after a longer period of psychotherapeutic treatment and either carry it out themselves or refer them to a colleague in cooperation.

Depending on the severity and type of illness, inpatient treatment can offer advantages in terms of safety and effectiveness. For example, inpatient treatment may be necessary for a severely depressed patient during which PAT is integrated into the inpatient treatment.

In most cases, however, outpatient treatment is therapeutically sufficient and more economically viable. The experience from two therapeutic LSD studies (Gasser et al., 2014; Holze et al., 2023) suggest that overnight accommodation should be provided at the treatment location (psychiatric practice) for protracted LSD sessions. An overnight on-call service can be set up for this purpose. Patients can be discharged home the next morning after an integration session with the study therapist. The respective session frequency for the psychedelic experiences and the specific procedure depend on the patient's individual problems and the therapist's basic training and methodology. In a follow-up survey (Gasser, 1996), it was found that patients who received outpatient psychotherapy with PAT were treated psychotherapeutically for an average of three years. During this time, they attended an average of 70 counseling therapy sessions and had seven psychedelic experiences with substances such as MDMA and/or LSD. In a recent retrospective study (Schmid et al., 2020), it was shown that patients participated in a substance session with LSD or MDMA on average every three and a half months. The average and standard deviation of days between these substance sessions was 105 ± 51 days, with a range of 35 to 343 days. This occurred after three to ten psychotherapy sessions without substances.

In our experience, PAT can be seen as fundamentally compatible with other psychotherapeutic approaches and can be usefully combined with various psychotherapeutic approaches and techniques. Despite the therapeutic principles in common, there are significant differences between psychotherapy in general and PAT modalities. It is necessary for PAT therapists to have an openness to a larger frame of reference and a specific understanding of the sometimes intense substance-induced states and the possible levels of experience of these altered states of consciousness. PAT therapists must also understand the corresponding requirements of the therapeutic setting.

Psychedelics seem to have a transdiagnostic potential (Kočárová et al., 2021; Pouyan et al., 2023). Furthermore, it is known from psychotherapy research that psychotherapy is effective to a considerable extent through general factors not specific to psychotherapeutic orientation (Grawe, 2004; Rogers, 1949; Wampold, 2015). Accordingly, the quality of the therapeutic relationship, the

patient's trust in the therapist and in the treatment, and the therapist's mindset characterized by empathy, appreciation, coherence, integrity and authenticity, etc. are decisive factors. This likely also applies analogously to PAT. As in all psychotherapies, the main effective factors are problem actualization and resource activation (see Grawe, 2004). This also applies to psychedelic-assisted treatment. In addition, psychedelic treatments sometimes facilitate spontaneous experiences of unity and connectedness or experiences of deep spirituality, meaning or comprehensive trust. This can result in resources of great therapeutic effectiveness.

It has been postulated that psychedelics are not used to treat specific categorical diagnoses, but rather the common pathomechanisms underlying mental disorders, such as loss of confidence, cognitive constriction, emotional blockage, feelings of alienation from oneself and others, social withdrawal, isolation, etc., in the sense of a transdiagnostic perspective. (e.g. Watts et al., 2017). However, due to methodological standards in drug development, research with a view to approval as a drug currently requires a focus on defined disorders or indications. This could change in the future if categorical diagnoses are possibly replaced by multidimensional models, as is being discussed, for example, as part of the Research Domain Criteria (RDoC) initiative (Kelly et al., 2021).

Due to the use of psychedelics in the context of therapy, there are specific points that should be considered and addressed in every PAT.

Preparation

An essential part of the preparation, and actually the prerequisite for the psychedelic session is establishing a relationship of mutual trust. This can coincide with the start of psychotherapy, which begins professionally with the development of a working therapeutic alliance. As described above, a sustainable therapeutic relationship is one of the most important factors in any psychotherapy. In the context of PAT, it is even more important due to the often long periods of non-verbal contact in perhaps regressive as well as transpersonal psychological processes, the long total duration of the treatment sessions (6 to 10 hours depending on the substance used), and the usually very intense substance-induced experience. During PAT sessions, patients regularly experience difficult emotions and stressful issues that need to be made accessible for therapeutic treatment. In the preparation phase, expectations, hopes, wishes, but also fears and doubts are clarified and, if necessary, an intention is made visible and formulated. The procedure, the setting, the substance and dose, and other parameters of the psychedelic session are discussed and questions can be clarified. It is also

discussed whether the experience with the substance will take place in an individual or group setting. Preparation also includes discussing current medications (adjustment, tapering or pausing if necessary).

During the preparation phase, it is advisable for the patient to develop an inner mindset that is conducive to the psychedelic experience. Methods of self-regulation and expression can be used here, such as mindfulness, breathing or physical exercises. Arrangements regarding possible physical contact during the psychedelic session should also be discussed. Figure 1 shows key aspects of the initial phase of a PAT (preparation phase).

Preparing and building a trusting relationship for the PAT

- Clarification of the indication and contraindications (psychological and somatic), discussion of current medications
- Declaration of consent, information about possible consequences of the treatment
- Get to know the patient's current situation and history
- Discuss the current family and partnership situation and possible consequences of treatment for relationships
- Show empathy, be a witness
- Offer specialist knowledge regarding set, setting, substance, dosage
- Decision for an individual or group setting
- Explain the course of the psychedelic session, clarify specific questions about the design of the room and the placement in it, introduce other caregivers (co-therapists) if necessary
- Addressing and respecting boundaries, addressing and practicing physical contact (need for closeness vs. appropriate distance and opportunity to withdraw in the presence of the other person, principle of non-violence, personal responsibility and mutual respectful interaction even in challenging situations)
- The possible temporary loss of physical or mental autonomy during PAT is discussed. Conflicts associated with this are addressed.
- Talk about expectations, goals, doubts, wishes, hopes, intentions and fears

- Clear mention of the possibility of a sometimes persistent deterioration in well-being and symptoms as a result of PAT. The possibility of coming out of treatment frustrated and without significant experiences or insights is also addressed.
- Answering all contextual questions
- Practicing helpful tools such as directing attention through mindfulness, self-regulation through breathing exercises, etc.
- Both sides must feel safe

Fig. 1 Elements of preparation for a psychedelic session

Psychedelic experience: substance, set, setting

The choice of substance is discussed with the patient in advance and must also be specified in the application (LSD, MDMA or psilocybin). Usual dose ranges are between 75 and 200 micrograms for LSD (often with an initial dose of 100 mcg), between 75 and 150 milligrams for MDMA (effect dependent on weight, among other things, often with an initial dose of 100 mg for women and 125 mg for men) and between 15 and 30 milligrams for psilocybin (often with an initial dose of 20 mg). In current treatment practice, there is leeway for the dose. The decision lies with the license holder and is usually discussed individually with the patient.

In the above-mentioned initial work by Stoll (1947), no particular attention was paid to the inner state of the patient or the external framework in which the treatment took place. It was not until the work of S. Grof (Grof, 1980) and T. Leary (1964) that a widespread concept emerged which, in addition to the substance, also paid attention to contextual factors and is often characterized by the triad "set, setting, substance" first described by Leary and adopted by others (e.g. Eisner, 1997; Hartogsohn, 2016). "Set" refers to the mental state of the patient, i.e. motivational aspects, intentions, expectations, fears, wishes, hopes, doubts, the current mood in general, but also previous experience, world view and values. "Setting" refers to the physical and socio-cultural context of the treatment. Today, for example, a specially equipped and supervised room is generally recommended in order to carry out psychedelic treatment safely and effectively. The constant attendence of the therapists with their presence and therapeutic mindset are also an important part of the setting. Experience has shown that it can be helpful, especially in regressive states and also for safety reasons, if therapists of both sexes are present. In group therapies, the presence of several therapists is

necessary in order to ensure attention to the whole group as well as temporary care for an individual patient. Figure 2 provides a brief description of this framework.

However, the prerequisites for carrying out PAT must first be clarified, in particular the indication and the question of whether a sustainable relationship seems possible. A supportive social environment and, above all, supportive, meaningful and close relationships can be essential for successful integration. If the patient's partner shows an explicitly fearful, negative or even hostile attitude towards PAT, it can be difficult for a patient to give a psychedelic experience the necessary significance in their everyday life or to integrate the insights gained into their reality. If the patient is undergoing ongoing psychotherapy with another practitioner in addition to PAT, this person's attitude towards PAT should also be open and not hostile. Clarification of the collaboration before, during and after the PAT is highly recommended and valuable.

Setting

- A pleasantly furnished room with little disturbance, usually with the option of playing music. Usually no bright light during the session, but it should also be possible to create good, clear lighting.
- Patients should be able to move around, lie down, sit and take a few steps
- Constant presence of the therapist
- Co-therapists are desirable for individual therapy, necessary for group therapy (preferably of the opposite sex)
- Knowledge of emergency interventions (including medication: blood pressure crisis, nausea, severe pain) and availability of the necessary equipment
- Possibility of monitoring vital parameters (blood pressure, pulse, temperature)
- Knowledge of the local somatic and psychiatric emergency structures

Fig. 2 Setting the PAT

The majority of treatments are still carried out in individual settings with one or sometimes two people accompanying the patient. Increasingly, however, treatments are also being carried out in group settings within the framework of exceptional permits in Switzerland. This has the advantage

that other people are present during the psychedelic session in addition to the therapeutic companions, with whom the psychedelic experience can be shared. Patients regularly mention the presence of peers as helpful, especially during debriefings. They can be experienced as role models, examples, or support. For some patients, however, the group setting can also be overwhelming. Whether a group setting is an option is clarified with the patients in advance.

To ensure the best possible setting for the PAT, the room in which the treatment takes place is set up comfortably. The majority of patients lie down during substance use, which is why the room is furnished with a mattress (or several mattresses for groups), a bed or a sofa bed. The toilet should be easily accessible, ideally without stairs, and should be able to be opened from the outside in an emergency. Similar to sacred spaces, facilities fluctuate between the poles of sobriety and meditative simplicity and an inviting atmosphere with flowers, candles and cultural or spiritual symbolism. Pushing patients too suggestively in a certain direction of experience is problematic, as are overly sparse, cold furnishings that do not allow them to "let go" inwardly. The light in the room tends to be dimmed to encourage inward attention. Simple aesthetic elements such as flowers or pictures on the walls also make it possible to turn calmly outwards. Noise from outside is reduced where possible. If music is played, it serves the purpose of structuring the experience, providing support or centering, possibly widening attention and opening up experiential spaces. This takes into account the increased general sensitivity of patients under the influence of substances. Silence can help the patient to get back in touch with themselves and their own inner process. Trying to trigger specific contents of consciousness or emotions through music can be perceived as inappropriate or even manipulative. Both silence and music can also have an overwhelming effect or trigger unpleasant states. As sensory perceptions can generally be heightened under the influence of psychedelics, a pleasant smell and good ventilation in the room should also be ensured.

The setting and also the therapeutic work are not designed in a defined ritual, as is practiced in shamanic rituals with psilocybin or religious ceremonies with ayahuasca (e.g. Santo Daime). However, the psychedelic experience also has a ritual or ritual-like structure to some extent in the Western psychotherapeutic context due to repetitive processes and specially prepared room furnishings. Jungaberle and colleagues (2006) have investigated the protective effect of rituals in various – contexts, including psychedelic ones.

The therapist finds themselves in an unusual situation compared to the usual psychotherapeutic work. A psychedelic session lasts a long time, around 6 to 8 hours for MDMA and psilocybin and 8 to 10 hours for LSD. During this time, there are no regular breaks in which the therapist can withdraw.

Constant attention to the patient's process is required. However, it can be very quiet over longer phases, in which the patient lies quietly, keeps their eyes closed and does not speak. According to the established practice, the therapist generally has no active task over longer periods of time, except to be quietly present in the basic therapeutic mindset with open attention, acceptance and empathy. Longer conversations and frequent questions during the main effect of the substance are usually perceived by the patient as a burden or disruption of the process. Sometimes patients request a short or longer conversation. In most cases, however, verbal interaction during the main effect of the substance is limited to an exchange of a few words. Support is provided more through the choice of music and through non-verbal intervention, e.g. turning towards or moving closer to the patient or holding a hand when the patient is seeking support and reassurance, or through the basic position and orientation in the room in which the therapist is sitting, etc. Towards the end of the substance effect, somewhat longer conversations, questions, clarifications etc. may follow. This marks the beginning of a certain integration of the extraordinary experience. The therapist needs in-depth knowledge of the effects of the substance and knowledge of the nature and content of a psychedelic experience and the psychological processes that result from it. In addition, an intuition based on knowledge and experience is required. Not every therapeutic intervention can be discussed in advance in the silence and inwardness of the processes, because the patient is not always able to give a clear answer to questions. However, the patient's reaction to an intervention can often be used to decide whether the intervention should be continued or ended again with as little disruption as possible. As the inner process of perception initiated by the effect of the substance often lasts for a long time without external intervention, the therapist is also present in a calm, attentive therapeutic mindset and is ready to react at any time if necessary. The support is "unconditional" in the sense that the therapist must accompany a session - once it has started - to the end without reservation. In emergency situations, there is the option of interruption or sedation with ketanserin (which, however, has a latency of around one hour), benzodiazepines or neuroleptics. As verbal intervention is often impractical or even impossible because the internal process completely absorbs the patient, and the substance itself can also lead to transient impairments of cognitive and motor processes with limited verbal communication ability, depending on the dose, a range of other skills or options are needed to support the therapeutic process and/or ensure safety in the experience (see Figure 3). For example, it may be necessary to accompany the patient to the toilet as their sense of direction, balance and motor coordination may be impaired.

Finally, the therapist needs to be aware of possible therapeutically challenging or clinically relevant psychiatric emergency situations and have the necessary equipment (emergency medication, telephone numbers, on-call arrangements, etc.). In patients who have undergone careful somatic assessment, critical somatic situations will not occur more frequently than in general therapeutic practice. Basic knowledge, equipment and checklists for, for example, sudden symptomatic hypertension, vomiting, headaches/migraines, or an epileptic seizure should be available, although more serious incidents have also very rarely been described as of this writing. It can be clinically difficult to distinguish somatic complaints requiring treatment from mental processes with partly somatic manifestations, which is a differential diagnostic challenge.

Therapeutic mindset

- Outwardly and inwardly attentive, calm support and engagement
- Knowledge and intuition
- Undirected / silent attention
- Ability to be still / not always actively intervene
- Acceptance and openness
- Appreciation
- Empathy
- Authenticity / Congruence / Integrity
- Humor
- Flexibility (willingness to adapt the setting to the needs of the respective patient)

Therapeutic tools

- Exercises for self-awareness
- Various forms of verbal intervention or interaction
- Transference and countertransference as a diagnostic tool and, above all, orientation; also in the context of closeness, distance and boundaries
- Music and silence
- Body therapeutic interventions
- Emergency interventions (pharmacological and non-pharmacological)

Fig. 3: Aspects of therapeutic support for a PAT

Eating on the day of the substance experience: It is recommended that patients have a *light* breakfast that is not hard on the stomach with potential to cause nausea under the effects of the substance, but gives energy for the day so that patients are not preoccupied with hunger during the experience. Eating is not usually done during the main effect of the substance. As the effects wear off towards the end, light snacks such as fruit, nuts or similar are often brought into the room. Depending on the room and setting, a warm soup or similar can be eaten together afterwards.

Integration

The integration of psychedelic experiences has only received a great deal of attention in recent years, and in some cases the relevant knowledge is taught in specially created seminars. Essentially, the aim is to harness a psychedelic experience by deepening understanding and transferring it to everyday life. Especially difficult experiences (sometimes referred to as "bad trips" in colloquial language), unfinished emotional processes, intensification of fears, despair, frustration, intense grief, anger or similar need therapeutic work to understand and classify. Integration can also be understood as a process of change over time, which can sometimes occur unconsciously. Integration and processing already begin during the psychedelic experience when, towards the end of the acute effect, rational, analytical and categorical thinking comes to the fore again compared to the previously predominant associative, creative and intuitive thinking. Patients begin to recapitulate and reflect on what they have experienced. There may also be an increase in short or longer conversations with the therapist or other participants in a group.

This process can be supported and made conscious, at least in part, by the accompanying psychotherapy and various centering and calming methods such as meditation, time in nature, or any creative processes (such as painting, journaling, making music). Patients can also be encouraged to write a diary-like, descriptive summary promptly after the psychedelic experience, which can be discussed in therapy.

Integration topics

- "Collecting the pearls"
- Expressing, symbolizing or verbalizing the numinous and ineffable
- Biographical understanding
- Processing traumatic experiences: Acknowledging the facts, validating one's own experience and reactions at the time, recognizing the effects of traumatization on psychological development that has since been arrested or misdirected
- Accepting difficult life circumstances
- Discussing existential topics (meaning, suffering, illness, death)

- Rethinking values and attitudes to life
- Facilitating a change of perspective or broadening the context of understanding in which the problem takes place
- Identify, activate and maintain resources
- Implementing insights
- Understanding relationships and social life and reshaping them if necessary
- Being and staying connected to oneself
- Complete and normalize body schema and body image

Fig. 4 Themes of integration after the psychedelic experience

Figure 4 lists frequent topics mentioned in integration sessions. After a long experience within oneself, which has largely taken place without words and, depending on the case, also without concrete thoughts, the verbalization and cognitive apprehension, recapitulation and classification of the experience is of particular importance. "Collecting the pearls" refers to paying attention to important moments during the substance experience. For depressed patients in particular, moments of joy, happiness and unity are important treasures of experience that remind them that something like this can still be experienced within themselves. Their unavailability in the rest of everyday life can trigger a problem actualization that is as painful as it is therapeutically valuable.

Experiences can also be numinous (experiences of the absolute, the divine) and at the same time sub-symbolic and nonverbal. As with all mystical experiences, words and language must first be found in order to come close to telling oneself and/or others something of what has been experienced. Sometimes integration is also about a deeper biographical understanding or the re-experiencing of a traumatizing situation, whose split-off meaning takes on a more tangible, more complete form through expression. The aim of integration is to transfer the experience into normal everyday life and thus perhaps also to experience a desired change.

Safety, difficult and emergency situations

On the one hand, safety concerns the safety of using the substances themselves. The substances that are available for PAT in Switzerland are provided by the Department of Clinical Pharmacology at the University Hospital Basel in collaboration with a GMP (Good Manufacturing Practice) producer and

undergo the necessary quality tests. They correspond as far as possible to medicines manufactured under GMP conditions.

On the other hand, safety also means reliability, support and competence in the therapeutic relationship, trust in the integrity of the therapist, respect and appreciation on the part of the therapist, with the knowledge of the possibility of being able to discuss conflicts and ambiguities. The therapist also offers themselves as a projection surface for transference and is able to classify and accept this, as well as recognize counter-transference without acting it out.

The therapist must be ready at all times for challenging therapeutic situations, such as great agitation, difficult feelings, disorientation, or fainting. The therapist must also be trained and mentally prepared for emergency situations such as acute suicidal tendencies, severe prolonged anxiety, impulsive or persistent aggression, or impulses to leave the treatment setting.

Drug information

The use of the substances by the license holder (doctor) is carried out in accordance with the legal requirements for the use of prescription drugs by a doctor. Because of narcotics laws, the substances cannot be given to patients, but are administered/applied directly under supervision. The indications and contraindications of the treatment must be checked in advance and patients must be informed about the effects, including adverse effects. Interactions with existing medication must be taken into account and existing medication may need to be paused briefly. The substances do not currently have an approved published drug information as a legal basis for the indication. However, published study data is available on the most important pharmacological aspects. The practitioner must take this evidence into account, analogous to the use of a drug in the *off-label* area. There are also recommendations on interactions (Clinical Pharmacology, University Hospital Basel). If you have any questions, please contact Prof. M. E. Liechti (matthias.liechti@usb.ch) or Dr. med. Y. Schmid (yasmin.schmid@usb.ch).

Ethics, quality assurance, supervision and intervision

In principle, all ethical guidelines for medicine and psychotherapy also apply to PAT. This also includes a differentiated discussion of medical ethical issues (safeguarding autonomy, duties of care of healthcare professionals, weighing risks and benefits, specifics of information, etc.), taking into

account the specific circumstances of a PAT, e.g. in the context of inter- and supervision. Part of an ethical approach is involving patients in treatment planning and providing them with detailed information. Accordingly, a declaration of consent (informed consent) from the patient is required for the PAT.

Ethics

In recent years, several patients worldwide have publicized physical and psychological assaults during PAT sessions, some of which have also been widely discussed at congresses and on social media. Therapeutic boundary violations have a considerable negative impact and scope and can have a traumatizing effect on people who are often already burdened by trauma. The code of conduct of the Swiss Medical Association (FMH), like that of the FSP and ASP (associations of psychotherapists), clearly states that a relationship of dependency arising from medical or psychotherapeutic activity must not be abused (FMH, 2023). The Swiss Society of Psychiatry and Psychotherapy (SGPP) further states that abuse begins where doctors "*satisfy their own personal, sexual, economic, social or other interests. It is the psychiatrists who are responsible for maintaining professional boundaries, even if patients wish to have sexual contact, for example*". These guidelines also apply in PAT. The particular vulnerability in the altered state of consciousness requires special sensitization compared to therapy in everyday consciousness.

There are mediation options (ombudsman's office) for serious errors, malpractice, therapeutic assaults, and also unjustified accusations by patients that cannot be clarified therapeutically. A PAT-specific ombudsman service will be made available on the saept.ch website at the beginning of 2024. Violations can be punished by expulsion from the professional association and withdrawal of the license to practice by the authorities. There is also the possibility of criminal and civil proceedings. It is our job to point this out to patients and to advise our colleagues. The prevention of such incidents must be given the highest priority in the further education and training of PAT therapists.

Processing and broadly discussing assaults that have already occurred is of great importance to therapists for their own work. In addition to talking to victims and perpetrators, therapeutic quality events such as intervision and supervision meetings should attempt to understand the dynamics and circumstances surrounding such assaults and other therapeutic integrity violations in order to further reduce the risk of such incidents. A sincere error culture is essential.

Existential vulnerability, identity crises and the like can be preconditions for therapeutic assaults. Education and dialogue should sensitize *all* therapists involved in PAT (Dickeson et al., 2020).

Quality assurance, supervision and intervision

Ethical aspects are very often dilemmas and questions about the hierarchy of values for which there is no clear right or wrong answer. Regular self-reflection in peer-led intervision groups or in supervision with experienced colleagues is a very effective way of ensuring good therapeutic quality. The continuous discussion of one's own therapeutic processes or those of others, whether successful or problematic, serves to further professional training and the further development of therapeutic competence. Especially in the case of mistakes, therapeutic uncertainty, personal lack of understanding, or inability, it is helpful to have a place in supervision to gain perspective on these impasses. An open error culture is essential for this. It has also been shown that working transparently in teams can minimize the risks of overstepping boundaries compared to individuals assuming responsibility. The professional associations should encourage regular collegial exchange and networking, and further training and conferences on practice-relevant topics should also be held.

Self-care

PAT sessions take a long time and accompanying psychedelic experiences can be both psychologically and physiologically challenging. Therapists are sometimes heavily involved in the psychological processes of patients. Self-care is therefore of crucial importance. This includes regular exchange with colleagues and supervisors in the context of inter- and supervision and one's own psychotherapy or teaching analysis, but also awareness and setting one's own boundaries as well as relaxing and regenerative practices such as meditation, sport or yoga. During PAT sessions, therapists take care to adopt a comfortable position that allows them to accompany patients in a relaxed manner. This is particularly important for the sometimes long outwardly quiet phases, during which the therapist has no active task but still needs to be present and attentive. Self-care is therefore important for the therapist's long-term physical and mental health. It also has a direct influence on the treatment, especially as therapists are better able to provide the presence, safety and support needed to accompany the patient. Self-care is therefore not only crucial for the therapists themselves, but also for the treatment and the well-being of the patients.

Patient register and questionnaire for quality assurance

Authorization holders are encouraged to carry out accompanying quality assurance measures on safety and efficacy, coordinated by the University Hospital Basel (Schmid et al., 2021). The PAT treatments should be documented with a set of questionnaires by the therapists in the sense of quality control, but also with a view to a future overall evaluation. All practitioners are encouraged to participate in quality assurance. The questionnaires can be downloaded here (saept.ch/begrenzte-medizinische-anwendung/). There are also instructions on when to use which questionnaire. If you have any questions, please contact Dr. med. Y. Schmid, University Hospital Basel (yasmin.schmid@usb.ch).

In the case of new applications and special indications, authorizations may be subject to conditions such as inclusion in patient registries or indication-specific outcome analyses (e.g. LSD microdosing for ADHD).

Outlook

After an initial period of intensive use and research from the 1950s to the early 1970s and a subsequent "ice age" (or time in the psychedelic underground) due to worldwide prohibition, psychedelic-assisted therapy has once again become the focus of increased attention since the 2000s. Interest in psychedelics has reached a broad public, at least in the Western world, with far too often exaggerated "healing expectations" regarding their potential.

Nevertheless, there is a steadily growing number of scientific studies investigating the possibilities and risks of PAT. Much is still in flux and it is not yet certain whether one of the psychedelic substances will make it to approval as a drug and thus enable widespread use for the treatment of mental disorders.

However, this would only be one milestone. The ongoing debates, for example regarding the design of this form of therapy or basic principles of medical ethics (respect for the patient's autonomy, avoidance of harm, care, and justice) should continue to be heeded. In addition, further questions need to be answered and problems solved:

- How can a sufficient number of therapists be trained and a good quality of treatment be achieved in the long term? The numerous requests for therapy places and further training

opportunities show that both patients' and therapists' interest in this approach has increased significantly in recent years and that supply is lagging behind demand. It is therefore essential to create high-quality further training opportunities.

- How can the new treatment be affordable for the general population and not just reserved for the wealthy? How can therapists receive appropriate compensation for their time-consuming work? PAT is not covered by the current insurance system. Regular and cost-based financing of PAT is required, and solution-oriented negotiations must be conducted with health insurance providers.
- How sustainable is the effect of PAT and under what circumstances? The long-term benefits and risks of PAT treatments should be evaluated.

These and many other relevant questions need to be asked and discussed. Answering them is a continuous process and so we also see this document as one snapshot in time, the further development of which we see as an ongoing task to which we invite you to contribute.

Guideline recommendations

General information

Compliance with laws and regulations: The use of psychedelics in therapeutic practice complies with the 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 is 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 cover use both within psychotherapeutic treatment and outside of it.
3. Further training and qualifications: Therapists who carry out psychedelic-assisted therapy undergo appropriate training to ensure that the treatment is carried out professionally and safely.
4. Transparency and documentation: All treatments and their results are documented in order to track progress, record risks and gain scientific knowledge that can contribute to improving the 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 is performed by a medical doctor with a license to practice and, in most cases, a specialist title in psychiatry and psychotherapy. Doctors from 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 if psychiatric, psychotherapeutic and psychopharmacological treatments have already been unsuccessful or ineffective.
9. Primary indications: PAT is mainly 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, but can also be applied for in certain cases for less researched and difficult-to-treat indications such as substance use disorders, obsessive-compulsive disorders, eating disorders and autism spectrum disorders, provided that 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 history of schizophrenic-psychotic or bipolar episodes, especially bipolar I, should not be referred for PAT until the risk has been scientifically clarified.
12. Adolescents: Special care should be taken with adolescent patients whose cognitive development is not yet complete.
13. Consideration of attachment capability: People with insecure and strongly 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 advisable to consult an appropriate specialist.

Therapeutic process: General

15. Long-term therapeutic process: Psychedelic-assisted therapy (PAT) should be seen as part of a longer psychotherapeutic process that goes beyond the one-off 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 can include reducing symptoms, improving quality of life, accepting one's personal situation, restoring the ability to work, etc.
19. Ethical consideration: For therapeutic use outside of studies, special consideration should be given to the potential harm caused by the progressive course of the disease which cannot be sufficiently influenced by conventional means.

Therapeutic process: Preparation

20. Indication and contraindication: a thorough clarification of the indication and psychological as well as somatic contraindications is carried out.
21. Informed consent: A comprehensive *informed consent process is* carried out in which the effects and possible consequences of the treatment are explained openly and clearly.
22. Social environment: Discussion of the current family and partnership situation, as well as possible effects of the treatment on interpersonal relationships.
23. Imparting specialist knowledge: set, setting, substance, dosage and course of the psychedelic session 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 or psychological/mental autonomy during treatment and the possible difficulties associated with this.
26. Set: Active engagement with patients' expectations, doubts, wishes, hopes and fears.
27. Persistent worsening: Explaining the possibility of sometimes persistent worsening of well-being and symptoms due to PAT, as well as the possibility of emerging from 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 places in the room (lying or sitting) and move around to a small 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 emergency structures, both somatic and psychiatric, is available.

Therapeutic process: Integration

33. Integration: The aim of integration is for patients to enrich their psychedelic experiences through deep understanding and to transfer the knowledge gained into their personal everyday lives.
34. Difficult experiences: Special attention is paid to difficult experiences.
35. Promotion of self-reflection: The process of recapitulation and reflection is promoted by preparatory and follow-up psychotherapeutic interventions.

Further therapeutic training

36. Further psychotherapeutic training: As psychedelic-assisted therapy (PAT) is a psychotherapeutic method, comprehensive further training in a psychotherapeutic method is essential. This includes the development of a therapeutic identity, therapeutic techniques, an understanding of the therapeutic relationship, and the ability to self-reflect.
37. Understanding of psychedelics: Therapists have an in-depth understanding of the psychological processes and particular challenges associated with the unique experience of PAT, and additional 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 in order to evaluate different providers on the basis of objective criteria.
41. Cooperation and partnerships: Joint training programs and specialist units will be promoted in order 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 adapt the training courses to the needs of the learners.
43. Conceptual basis: Institutions have a clear conceptual basis for the implementation of therapy, as well as contact with pre- and post-treatment entities.
44. Exchange and quality assurance: Institutions are involved in a regular exchange with other PAT providers on 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 the impact on the therapeutic mindset.
46. Participation in specific scientific projects: Where possible, therapists are recruited to participate in such projects.

Ethics, quality and safety

47. Compliance with quality standards: The substances used in the PAT comply with GMP standards as far as possible and are provided under 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 such as intervision and supervision.
51. Open dialog: Patients have 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 from 2024 (saept.ch).
53. Legal action: in the event of suspected serious therapeutic offenses and 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 therapy is continuously monitored and supported. The constant presence of the therapist or accompanying person is required during the acute effects of the substance.
56. Supervision and intervision: Therapists undergo continuous training in intervision and supervision.

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