MIND FOUNDATION

Kick-off for a game with extra time: The EPIsoDE scientific symposium with an outlook on psychedelics in medical care

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On Friday, September 6, and Saturday, September 7, 2024, the first scientific double symposium to conclude the EPIsoDE study took place at the Central Institute of Mental Health (ZI) in Mannheim. It was the kick-off for a multi-year publication series on one of the most remarkable data sets in the field of medical psychedelic research.

The two symposia took place in the beautiful rooms of the “Alte Brauerei” in Mannheim. They marked the first highlight of a research program led by Prof. Dr. med. Gerhard Gründer, psychiatrist, Head of the Department of Molecular Neuroimaging at the ZI and chief physician at the OVID Clinic Berlin. EPIsoDE investigated the efficacy and safety of psilocybin in treatment-resistant depression [1]. The study, funded by the German Federal Ministry of Education and Research (BMBF), addressed the much-discussed challenges of psychedelic research with scientific rigor and clinical inventiveness. This was done, for example, by using two control conditions (an active placebo with nicotinamide and a low 5 mg dose of psilocybin versus a high dose of 25 mg psilocybin). While all patients underwent at least one so-called “dosing sessions” in which they received the high dose at least once, part of the sample was treated with the high dose twice. All patients received the psychedelic as part of a minimal psychotherapeutic program [2, 3]. The aim of the study, which included 144 patients, was to develop innovative treatment approaches for people who do not respond to classic antidepressants. The results, presented at the symposium, show the potential of psilocybin as part of a comprehensive psychotherapeutic approach.

Treatment-resistant depression affects millions of people worldwide for whom previous therapeutic approaches are often insufficient. The EPIsoDE study investigated whether **psilocybin** could be effective as

an adjunctive treatment. The study results suggest significant symptom relief, accompanied by improved emotional resilience and quality of life for those affected. At the symposium, leading researchers reported on the clinical results and discussed how this research could shape the **implementation of psychedelic therapies** in practice. This is of central importance to ensure long-term, sustainable therapeutic effects.

Andreas Meyer-Lindenberg, Chairman of the Board of the Central Institute of Mental Health and current president of the German Association for Psychiatry, Psychotherapy and Psychosomatics (DGPPN), opened the "Scientific Symposium EPIsoDE - Efficacy and Safety of Psilocybin in Therapy-Resistant Depression" on September 6, 2024. Gerd Gründer, Lea Mertens and Michael Koslowski then reported the first data on efficacy and safety. After the lunch break, many of the people who had benefited from the study not only had the floor, but also contributed their own positions, criticism and constructive suggestions for the development of the new form of therapy. This was followed by a series of scientific and psychological studies on topics such as psilocin plasma levels and their correlation with acute psychedelic effects (Moritz Spangemacher), the neuropsychological effects of psilocybin therapy (Laura Kärnter) and initial MRI findings (Christian Schmitz).

We will also report on the specific results of the main and sub-studies in this blog as soon as they are published. The embargo policy of the scientific journals asks for a little patience here.

On September 7, 2024, the MIND Foundation, together with the German Society for Psychedelic Research and Therapy (DGPFT), hosted a follow-up symposium on the implementation of psychedelics entitled "The Future of Psychedelics in Psychiatry and Psychotherapy – Implementation, Medical care, Further Training". The second day focused on conclusions: that is, on the integration of new scientific findings into clinical practice. The focus here was on ethical guidelines, standardization processes, and training programs to optimally design psychotherapeutic support during and after treatment (presented by Uwe Herwig, Henrik Jungaberle, Andrea Jungaberle und Max Wolff). The implementation of such procedures is intended to ensure that patients are cared for by experienced therapists in a safe environment. It became clear here that the therapeutic use of psilocybin must take place in a structured setting in order not only to alleviate acute symptoms but also to ensure long-term integration and processing. The new paradigm of "pharmacologically-augmented salutogenesis" was also discussed in this context. Many of the ex-patients in attendance also reported that the therapy had given them important, sometimes life-changing impulses for many months after completion.

At both symposia, the importance of close collaboration between researchers, therapists and policy makers was emphasized to ensure the development of safe and effective therapeutic options. It was also emphasized that psychedelic experiences must be integrated within a clearly structured, therapeutic aftercare program. Only with this support can patients process what they have experienced and achieve long-term progress. Such aftercare must be personalized and differentiated: some patients benefit from guided integration groups. Others reported that the self-organized meetings among patients after completion of therapy were a particularly positive factor.

Overall, the two days of the event represented not only a milestone in research on psychedelic therapy, but also a significant step towards the further development of treatment approaches for depression. The symposium was accompanied by lively scientific discussions and networking opportunities.

At the end of the second day, Gerd Gründer gave an outlook on concrete steps towards the introduction of psilocybin-augmented psychotherapy. He and the MIND Foundation have been working for some time on a study that is unprecedented to date on the possible implementation of therapy with psilocybin in public health care (with reimbursement by the statutory health insurance system). Its preparation through the relevant scientific consultations at the Federal Institute for Drugs and Medical Devices (BfArM), the European Medicines Agency (EMA) and the Federal Joint Committee (G-BA) has already been supported over the last

two years by Germany's Federal Agency for Breakthrough Innovations (SPRIND). The name of the study is also the scientific program: **Di**sease **M**odification with Psilocybin-Assisted Psychotherapy versus Standard Treatm**en**t in Major Depres**sion** (DiMension). Whether therapy with psychedelics has this potential and can thus prove an additional benefit over guideline therapy: that remains to be demonstrated.

Sources:

1. Mertens, L. J., Koslowski, M., Betzler, F., Evens, R., Gilles, M., Jungaberle, A., Jungaberle, H., Maji , T., Ströhle, A., Wolff, M., Wellek, S., & Gründer, G. (2022). Methodological challenges in psychedelic drug trials: Efficacy and safety of psilocybin in treatment-resistant major depression (EPIsoDE) – Rationale and study design. Neuroscience Applied, 1, 100104.

2. Gründer, G., Brand, M., Mertens, L. J., Jungaberle, H., Kärtner, L., Scharf, D. J., Spangemacher, M., & Wolff, M. (2024). Treatment with psychedelics is psychotherapy: Beyond reductionism. The Lancet. Psychiatry, 11(3), 231–236. https://doi.org/10.1016/S2215-0366(23)00363-2

3. Gründer, G., & Jungaberle, H. (2021). The Potential Role of Psychedelic Drugs in Mental Health Care of the Future. *Pharmacopsychiatry*, *54*(04), 191–199.