



# REVOLUTIONARY TREATMENT OF PATIENTS WITH DEPRESSION AND EXISTENTIAL DISTRESS



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PEOPLE SUFFERING FROM FREQUENT DEPRESSIVE STATES OR THOSE TERMINALLY ILL ARE VERY OFTEN DISTRESSED BY UNPLEASANT EMOTIONS WHICH ARE VERY OFTEN DIFFICULT TO EASE. IN MANY CASES, STANDARD PROCEDURES DO NOT WORK, AND ESPECIALLY IN CASES WHEN THE PATIENT IS AWARE THAT THE INEVITABLE END OF THEIR LIFE IS APPROACHING. IN THESE CIRCUMSTANCES, TIME-DEMANDING THERAPIES ARE NOT ADEQUATE. TRADITIONAL ANTIDEPRESSANTS TAKE EFFECT AFTER MANY WEEKS AND THEIR EFFECTIVENESS IS NOT ALWAYS DESIRABLE.

Current clinical studies offer proof that psychedelic-assisted psychotherapy can bring a major relief for depressed patients, and those in palliative care. Distress in the form of deep depression brought by the approaching end of life can be seen among 40 % of patients diagnosed with cancer.

The therapeutic effect of psychedelics is based on setting a particular state of consciousness which is assumed to initiate long-term changes in learned ways of thinking and behaving. Available scientific evidence shows that utilising psilocybin in a safe (clinical) environment leads to a very fast and long-term improvement of depressive moods and distresses, through the rediscovery of life harmony and a decrease of existential crisis. With the help of psychedelic-assisted therapy, patients can discover a new way of looking at their life, very often finding new deeply hidden emotions, and experiencing changes in thinking about the importance of interpersonal relationships. The therapy is fascinating, not only for its rapid effect, but also for the minimum of unwanted side-effects and the atypical transpersonal factor.



Psilocybin, a substance which can be found in psychedelic mushrooms, and ketamine, a dissociative anaesthetic, both offer quick results after the first and only administration. Two currently active Czech scientific studies have a goal to answer the question about psilocybin, its mechanism of drug action, rapidity of its effect and also a comparison of the two named drugs. What is globally unique about this study is the fact that two psychedelics are being compared. Researchers will study the mechanism of these substances taking antidepressant effect using EEG for modern brain activity monitoring and magnetic resonance on patients with diagnosis of depression.

Furthermore, both studies are focused on patients who are faced with consequences which do not allow any different type of treatment to be successful, nor do they reduce symptoms of depression. The state of some oncological patients is so severe that they do not have enough time to wait for classic treatment to take effect.

Study focused on oncological patients also bring an existential dimension to palliative medicine, which has been only slightly touched on by the available procedures.

Study named PSIKETO01 reviews the effect of psychedelics on patients with depressive disorders. PSIKETO02 is focused on the effect of psychedelic-assisted psychotherapy in patients diagnosed with cancer and suffering from depression.

Given the importance of both areas, we can assume that the results of the studies will dramatically contribute to increasing the portfolio of available treatment procedures for depressed patients, and will allow for an overall psychological improvement of depressed and terminally ill patients' lives.

## THE PSIKET001: PROMISE TO THE PATIENTS DIAGNOSED WITH TREATMENT-RESIST- ANT DEPRESSION.

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### GUARANTOR AND DIRECTOR OF THE PROJECT

Dr. Tomáš Páleníček, PhD and his team from the National Institute of Mental Health (NIMH)

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### CURRENT SITUATION

The project was approved by the Ethics Committee in the summer of 2021, and subsequently supported by a grant from the Czech Academy of Sciences (AZV ČR), which does not sufficiently cover it financially. Patients who meet the strict criteria necessary for inclusion in the research (diagnosis, age over 18, resistance to several types of common antidepressants, etc.) are being recruited.

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### PLAN

A total of 60 patients will be included in the study if they meet the inclusion criteria. All substances are administered by trained personnel in a safe environment in combination with psychotherapy. The duration of the project is estimated at 4 years.

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### OUTPUT

It is expected that the psychedelics used will have a very rapid effect and minimum side effects after the one-time infusion. The project will help with the collection of information on the substances' direct influence on the brain and their effects. Based on the data, the discussion with medical associations about the possible therapeutical uses of these substances will take place.

## THE PSIKET 002: RELIEF FOR DYING ONCOLOGICAL PATIENTS.

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### GUARANTOR AND DIRECTOR OF THE PROJECT

Prof. Dr. Jiří Horáček, PhD and his team from the National Institute of Mental Health (MINH)

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### CURRENT SITUATION

In 2021 research was approved by the State Institute for Drug Control (SÚKL) and the Ethics Committee. A network of co-operating oncological and palliative establishments was put in place to receive recommendations of patients appropriate for the study. Insurance was handled and currently the practical part of the research is in progress. The project's initiation was supported by the Abakus Foundation.

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### PLAN

Preparations for the project started in autumn of 2021. The first patient involved in the study is scheduled for February of 2022. Gradually, the study should involve a total of 60 patients with the data collection ending at the end of 2024. The study's results will be published in 2025. All substances are administered by trained staff in a safe environment in combination with psychotherapy.

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### OUTPUT

A clinical review focused on antidepressive effects of psilocybin on terminally ill patients diagnosed with depression. The effects of psilocybin will be compared to an antidepressant control substance (ketamine) and a substance with no antidepressant effect (placebo).



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