Studying Psychedelics to Treat Psychiatric Distress in Late-Stage Cancer

Federally funded research aims to understand the effects of psilocybin on depression and anxiety in people with cancer.

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The effects of cancer are not just physical, especially in advanced stages of the disease. People living with a cancer diagnosis may experience depression, anxiety, and fear, or feel demoralized by the weight of new and unanticipated burdens.

While the majority of cancer interventions focus on treating or preventing the physical aspects of the disease, a growing body of research is studying behavioral and therapeutic interventions to address the psychiatric and existential distress that can result from a cancer diagnosis.

One such intervention is therapy combined with controlled-dose psilocybin, a naturally occurring psychedelic found in some varieties of mushrooms.

University of Colorado Cancer Center co-leader of Cancer Prevention and Control Stacy Fischer, MD, an associate professor of internal medicine in the CU School of Medicine, and research partner Jim Grigsby, PhD, a professor of psychology at CU Denver, along with researchers at New York University, will begin recruiting participants early next year to a groundbreaking study focused on psilocybin-assisted psychotherapy in advanced cancer.

The randomized, double-blind study, which will be regulated by the U.S. Food and Drug Administration (FDA) and U.S. Drug Enforcement Administration (DEA), is one of the first of its kind to receive funding support from the National Cancer Institute (NCI). It will evaluate the efficacy and psychological mechanisms of single-dose psilocybin-assisted therapy (PAP) to treat psychiatric and existential distress in people with late-stage cancer.

“There’s a lot of interest out there in the therapeutic use of psilocybin to treat disease,” Fischer explains. “We’re benefitting from our larger research community who have paved the way and gone through the FDA approval process, and from government bodies like the NCI funding good, peer-reviewed science.”

Understanding Psilocybin

If the term “psilocybin” is unfamiliar, the term “magic mushroom” probably isn’t. There’s fraught cultural baggage associated with a psychedelic drug more commonly stereotyped with the counterculture and summer music festivals.

Both Fischer and Grigsby acknowledge that studying psilocybin as a cancer intervention can mean treading lightly through potential minefields that have nothing to do with science. However, “we’re not talking about taking a handful of mushrooms and heading to a Phish concert,” Fischer says. “We’re talking about a very controlled intervention that includes a guided dosing session where patients who are participating are encouraged to look inward to examine what comes up for them.”

Grigsby adds that research studying the use of psychedelic drugs as an intervention for advanced disease has been taking place for decades. A foundational study was conducted 60 years ago in Chicago, in which LSD was studied as a psychological intervention for people with terminal illnesses, most of whom had cancer.

Their research is happening at a watershed time, when a lot of cultural conversation is happening around psychedelic drugs. In November, Colorado voters will decide whether to pass the Natural Medicine Health Act, which would decriminalize possessing, growing, and gifting mushrooms containing psilocybin and psilocin statewide.

While psilocybin is currently illegal in Colorado and the United States, in 2019 the FDA gave psilocybin a breakthrough therapy designation as a treatment for major depressive disorder and treatment-resistant depression.

Fischer emphasizes the importance of a rigorous scientific approach to studying psilocybin as a treatment for people with late-stage cancer and the need for peer-reviewed evidence to validate its use as a clinician-monitored therapy.

Addressing a Gap in Research

The upcoming study, which is anticipated to open for participant recruitment in January, went through four rounds of peer review before receiving NCI funding.

“What we took from the comments was a recognition that this is addressing an important gap in research,” Fischer says. “A lot of the questions and comments were really drilling down on very detailed pieces of the science, questions about how we’re going to preserve blinding, for example. Going through that process improved the methodology and ultimately improved the science.”

Participants will be randomized into study drug and placebo groups, with participants in the study drug group receiving one 25 mg dose of psilocybin delivered in conjunction with psychotherapy.

Participants in the placebo group will receive a 1 mg dose of psilocybin, which is clinically non-therapeutic, in addition to a psychotherapy intervention.

In both groups participants will receive six hours of preparatory psychotherapy prior to the single medication session and eight hours of follow-up integration psychotherapy after the guided dosing session. During the individual dosing session, each participant will be in the presence of two trained facilitators.

Each person participating will be evaluated using a number of validated scales at various points in time, including the GRID-Hamilton Depression Rating Scale, the Demoralization Scale, and the Mystical Experience Questionnaire, among many others.

The study is designed for people with stage 3 or stage 4 advanced solid tumors who are able to meet with a therapist and complete a guided dosing session on-site, and who have experienced anxiety, depression, demoralization, or other psychiatric or existential distress relating to their cancer diagnosis and treatment.

Hypothesizing Improved Quality of Life

Fischer says that while some people may feel intimidated by the idea of taking a dose of psychedelic drug, “there’s going to be a lot of preparation before the guided dosing session, when they can talk through it — not just concerns they might be having about the treatment, but their anxiety or depression or anything else they’ve been experiencing.”

The immediate or acute hallucinogenic and mystical effects of the psilocybin, “what in layman’s terms we would describe as the ‘trip,’ generally last four to eight hours,” Grigsby explains. “However, we are hypothesizing that the benefits to anxiety and depression, that improved quality of life, a perception of peace and meaning, will persist. It’s really fascinating to look at some of the previous research, with some of the follow-up as much as four years later, and participants are still saying it was one of the most profound, enduring things they’ve ever experienced.”

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