

# Cultural Daily

Independent Voices, New Perspectives

## Numinus Submits Psilocybin Therapy Trial to Health Canada

Our Friends · Friday, July 26th, 2024

Psilocybin is now gaining the recognition it deserves due to advocacy from Canadian mental health providers like Numinus. Health Canada has already granted access to this compound through their Special Access Program (SAP). More institutions and small businesses must continue pushing for easier access to psilocybin, whether allowing people to [buy shrooms online](#) or in physical stores.

Numinus is advancing the movement by applying for a clinical trial to train its practitioners in Psilocybin-Assisted Therapy. This trial will use a whole mushroom psilocybe tea for dosing.

### Key Takeaways

- Psychedelics have garnered attention for their promising roles in managing conditions like depression, PTSD, and addiction.
- The clinical trial will use the whole mushroom in tea form, and the first trial to use a natural option.
- The Numinus trial can increase access to Psilocybin-Assisted Therapy by training more professionals and promoting natural options.

### What are Psilocybe Mushrooms?

Psilocybe mushrooms, commonly called magic mushrooms or shrooms, are fungi that contain psychoactive compounds such as psilocybin and psilocin. Psilocybin converts to psilocin in the body and acts on serotonin receptors to alter perception, mood, and sometimes profound spiritual experiences.

Psilocybin's interaction with brain receptors has prompted many researchers to investigate its effects. The active compound helps manage depression, anxiety, and other mental health conditions.

### Psychedelic Properties

Psilocin acts agonistically with 5-HT<sub>2A</sub> receptors to produce a “mystical-like” hallucinatory effect, which mediates its anti-depressant and anti-anxiety effects. One possible anti-depressant mechanism is the normalization of the hyperactivity of the [medial prefrontal cortex](#) (mPFC). In depression, this part of the brain is hyperactive.

Its anti-depressant properties occur through the modulation of the prefrontal and limbic brain regions that manage emotional response. In depression, individuals lose responsiveness to

emotional stimuli.

Evidence also suggests that the compound interacts with the mesolimbic dopaminergic pathway, which plays a role in the brain's reward system. This indirect interaction contributes to its low potential for addiction and abuse.

## Numinus Clinical Trial Application for PAT

Numinus, a Vancouver-based healthcare company, develops and supports safe, evidence-based, and accessible psychedelic-assisted therapies. It dedicates itself to delivering treatments that enhance and supplement existing options for people seeking lasting physical, mental, and emotional health.

In 2022, the company applied to Health Canada for a clinical trial to train practitioners in Psilocybin-Assisted Therapy (PAT). This trial will allow practitioners to experience and observe sessions to understand and educate themselves better.

## What is Psilocybin-Assisted Therapy?

Psilocybin-Assisted Therapy (PAT) describes the professionally supervised use of psychedelic drugs. Patients remain in extended psychotherapy sessions during which the activity of the drug takes effect. Here are existing studies supporting its effect:

- **2011:** A Harbour-UCLA Medical Center study has demonstrated that psilocybin can be administered safely without reported clinically significant effects.
- **2016:** An open-label, non-controlled study of 12 patients that investigated the benefits of psilocybin in treatment-resistant depression demonstrated that 67% of patients received clinical remission

PAT is a significant innovation for several reasons. It produces long-lasting effects after a short treatment course, with improvements continuing well after active treatment ends.

PAT represents a new treatment model where drugs and psychotherapy work synergistically. It also shifts the approach to mental illness from daily neurochemical correction of brain dysfunction to the modification and meaningful interpretation of conscious experiences. PAT may alleviate the following disorders:

- Addiction
- Eating Disorders
- Major Depressive Disorder (MDD)
- Obsessive-Compulsive Disorder (OCD)
- Depression & Anxiety in patients at the end of their life
- Post-Traumatic Stress Disorder (PTSD)

## What Will Happen During the PAT Trial of Numinus?

The clinical trial, formally titled “A Phase 1, Open-Label, Single-Arm Study to Evaluate Psilocybin Experiential Training in Healthy Volunteers and Expand Knowledge and Qualifications of Therapists Planning to Conduct Psilocybin-Assisted Therapy” (NUMT2), will take place at Numinus' Vancouver clinic. The company expects to expand their trial to additional clinic

locations in the future.

The NUMT2 protocol allows each participating practitioner to engage in experiential and observational roles. They will receive PAT and observe another participant undergoing the therapy under the supervision of an experienced and trained provider.

They will recruit volunteers from those who have expressed interest through the company's practitioner training program. The trial will also be open to other practitioners interested in expanding their knowledge of PAT practices.

Each participant will undergo three sessions: one preparatory session, one dosing session, and one integration session. There will be an observation period with interviews and questionnaires.

## **Whole Mushroom Product for Trial**

The clinical trial will use the company's own mushroom concoction, a whole mushroom tea product, for trial dosing. This is one of the first clinical trials globally to be conducted with whole psilocybe mushrooms to assess their safety.

The Psilocybe tea product delivers 25mg of psilocybin. Numinus produces it using their validated strain of Psilocybe cubensis BP-Star. It is uniquely shelf-stable, consistently dosed, and economical to produce.

## **What Does This Application Mean to Canadians?**

As Canada's federal health department, Health Canada safeguards public health through rigorous regulatory oversight and policy implementation. One of its essential mechanisms, the Special Access Program (SAP), serves as a pathway for accessing medications and treatments that are not currently for sale in Canada.

Under the SAP, healthcare professionals can request access to these substances for patients with severe or life-threatening conditions when conventional treatments have proven inadequate.

Health Canada has rejected many doctors' applications to access the substance for their patients, even in life-saving situations. Allowing other institutions to conduct assisted therapy would enable more Canadians to access the substance when needed.

## **A Move Towards Natural Options**

Another impact of this trial is the movement towards a more natural option. Dennis McKenna, a renowned ethnopharmacologist, said that while synthetic version has its place in clinical practice, well-characterized and standardized natural extracts represent the future – Malabar Coast, for example.

Many people would prefer the natural substance, as mushrooms have been part of traditional practices for thousands of years. The whole version connects them to ancient practices. Natural extracts are likely to be more affordable than synthetic. This ensures access to this beneficial medicine. McKenna added, *"Cost should not hinder access to these treatments, and using extracts can help ensure that those who need psilocybin therapies most can benefit from them."*

## Buy Shrooms Online: A Natural Option for Your Therapy Session

The natural version of Psilocybe is gaining attention as many institutions explore the use of whole Psilocybe mushrooms in their therapy processes. This development will also make it easier for Canadians to access affordable options. Consider exploring these products for your psychedelic sessions.

Product	Type	Potency/ Dosage	Effects/ Experience
Golden Teacher	Whole, Dried	Mild to moderate	Introspective and insightful visuals
Blue Meanies	Whole, Dried	High	Visual, physical, euphoric, energetic, and introspective.
Malabar	Whole, Dried	Moderate	Controlled and introspective experience
Bright Future – Nootropic Matcha	Tea	100mg	Supercharge you with focus, energy, cognitive function and boosted mood
Euphoria Psychedelics – Green Tea	Tea	1000mg	Euphoria and enhanced senses

## Use Psilocybe For Psilocybin-Assisted Therapy

Numinus is taking a significant step by providing PAT trials. These trials aim to explore the use of psychedelics and help professionals understand their importance. Increasing the number of trained professionals will improve access for Canadians seeking help. The trial request also emphasizes the need for natural options.

Psilocybe can facilitate deep introspection and emotional healing by enhancing patients' ability to explore and process unresolved issues. The overall outcome includes relief from conditions like depression, anxiety, and PTSD. Zoomies Canada dispensary offers natural whole, dried varieties, and tea options.

## Frequently Asked Questions

### Is buying psychedelics online worth it?

Yes. It provides access to multiple products that may not be locally available. You can find specific strains or types that suit your therapeutic or recreational needs. Online platforms offer detailed product information and reviews, which can help consumers make informed decisions.

### Can higher doses help in managing mental health disorders?

Although Numinus will use a 25mg tea formulation, some studies also explore using higher doses of the psychoactive compound. A 2023 systematic review examined multiple studies that used high and low doses, with the low dose as a placebo. The findings show that this treatment for depression is a promising approach in psychology and psychiatry.

### What makes natural psilocybin better than synthetic?

Natural contains all the important substances that can interact with one another to create an overall

---

effect that can better manage certain mental health conditions. Synthetic compounds solve the problem of varying potency between different natural psychedelic growth.

---

**[CLICK HERE TO DONATE IN SUPPORT OF OUR NONPROFIT COVERAGE OF ARTS AND CULTURE](#)**

This entry was posted on Friday, July 26th, 2024 at 7:03 pm and is filed under [Check This Out](#). You can follow any responses to this entry through the [Comments \(RSS\)](#) feed. You can leave a response, or [trackback](#) from your own site.