



ATMA

PHASE II PSILOCYBIN CLINICAL TRIAL



Inclusion and Exclusion Criteria (Eligibility)

Inclusion and exclusion criteria are utilized in clinical trials to ensure participant safety and scientific validity by selecting individuals who meet specific eligibility requirements and minimizing confounding factors, thus generating reliable and meaningful data.

Inclusion Criteria

- 18-65 years old
- Pass the medical screening. A trial physician will conduct a personal interview, a physical examination, psychiatric exam, ensure a negative pregnancy test if of child-bearing potential, bloodwork, urinalysis, and an ECG.
- Must be a current, licensed, practicing frontline mental healthcare provider with professional accreditation (psychiatrist, psychologist, psychiatric nurse, social worker, counselling therapist, or psychotherapist, counsellor, or therapist), who was practicing during the COVID-19 pandemic (December 2019-August 2022).
- Must be previously diagnosed with Major Depressive Disorder by a physician, psychiatrist, or psychologist, and must provide documentation outlining this diagnosis to the trial team during screening.
- Participants must have completed an approved (listed on the Psychedelic Association of Canada website) psilocybin-assisted therapy training program. Applicants will upload evidence of their completion as part of the initial application form.
- Are able to swallow pills.
- Are proficient in speaking and reading English.
- Agree to not participate in any other interventional clinical trials for the duration of this study.
- Must provide a contact (relative, spouse, close friend, or other caregiver) who is willing and able to be reached by the investigator in the event of an emergency or if the participant is unreachable.
- Participants must agree to arrange a responsible caregiver that can observe the participant for the 24 hours following psilocybin administration.

- Agree to not operate a vehicle for at least 24 hours after initial drug administration. Participants must have transportation available after the Experiential Session and for traveling back for the Integrative Session, if the Integrative Session is within 24 hours of the initial dose.

Exclusion Criteria

- Presence or history of active psychotic symptoms, a diagnosis of bipolar disorder or schizophrenia, or first-degree relatives with history of same.
- Are prescribed certain psychotropic medications including tricyclic antidepressants, MAOIs, or lithium.
- Diagnosis of dementia/delirium, high risk for coronary artery disease, uncontrolled cardiopulmonary disease/cardiovascular disease/hypertension, aneurysm, history of intracerebral hemorrhage, hepatic cirrhosis, hepatorenal disease.
- Are pregnant, nursing, or are of child-bearing potential and are not willing to practice an effective means of birth control.
- Present with suicide risk, as determined through clinical interview.
- Have uncontrolled hypertension.
- Have previous experience with psilocybin demonstrating it is not well tolerated, or otherwise experienced a significant adverse event after prior hallucinogen use.
- Have a known sensitivity to psilocybin and/or its metabolites.
- Deemed not suitable for the treatment program by the qualified investigator.

There are additional inclusion/exclusion criteria.

