ATMA JOURNEY CENTERS

Clinical Trial Team
March 18, 2023

Clinical Trial Eligibility Criteria for Participants

This eligibility criteria is based on Health Canada requirements, and serves to protect the health and safety of the participants and ensures that the study objectives are met.

Inclusion Criteria

- Be 18 – 65 years of age.
- Meet with their physician before enrollment in the trial to ensure that they are medically fit to participate. As this trial seeks to examine data on "physically healthy individuals," participants must have no significant medical issues. Some medical issues may currently be undiagnosed, and thus, a thorough medical screening is necessary as part of the enrollment process. This screening will include a personal interview, review of concomitant medications, a physical examination, an ECG, routine bloodwork, and a urinalysis. After receiving this documentation, our trial physician will review each applicant's medical information to determine his or her eligibility in the trial. As described in the exclusion criteria below, applicants' physicians will also assess for specific medical disorders that are contraindicated in this trial. Note: if applicants wish to taper off certain medications in order to be eligible for this study, the tapering process must be supervised by their own physicians and must be fully completed before the experimental session of this study occurs. ***(Based on recent trials, we are discussing with Health Canada the possibility that individuals on any class of anti-depressants, other than Monoamine Oxidase Inhibitors, be permitted into the trial).***
- Be a practicing frontline healthcare worker with professional accreditation. For the purpose of this study, frontline healthcare workers are defined as any licensed medical or mental healthcare professional who has direct contact with patients and provides them with treatment, including but not limited to physicians, psychiatrists, psychiatric nurses, registered nurses, nurse practitioners, pharmacists, EMTs, respiratory therapists, psychologists, social workers, counsellors, or psychotherapists.
- Be diagnosed with Major Depressive Disorder, Generalized Anxiety Disorder, and/or are experiencing occupational burnout, as determined by their physician, psychologist, or psychiatrist. The diagnosis must be attributable to/exacerbated by COVID-19, as determined by the COVID Exposure Index; this questionnaire will be filled out as part of the application process.

- Complete the following questionnaires as part of the application process, as well as on days 2 and 7, 4-6 weeks, and 8 weeks after the experimental session: GAD-7 (Generalized Anxiety Disorder 7-item questionnaire), QIDS-SR16 (Quick Inventory of Depressive Symptomatology Self-report 16-item), and the BAT (Burnout Assessment Tool).
- Agree to have a medical follow-up with their physician 8 weeks after the experimental session.
- Agree to have an adverse event assessment by the study physician on days 2 and 7 following the experimental session, as well as 8 weeks following the experimental session.
- Sign the Research Informed Consent Form.
- Be learning to conduct psilocybin-assisted psychotherapy or psilocybin research.
- Be willing to commit to medication dosing (including swallowing pills), attending study sessions, and submit to vital signs monitoring during the experimental session.
- Agree that for approximately one week preceding the experimental session, will refrain from:
    - Taking any herbal or dietary supplements, except with prior approval from the research team
    - Taking any non-prescription medications (with the exception of non-steroidal anti-inflammatory drugs or acetaminophen), unless with prior approval from the research team
    - Taking any prescription medications (with the exception of prescribed contraception, thyroid hormones, or other medications approved by the research team)
- Agree to take nothing by mouth after 12:00am (midnight) before the experimental session, except alcohol-free liquids and approved medications.
- Agree to not use caffeine or nicotine for two hours before and six hours after initial drug administration.
- Agree to not operate a vehicle for at least 24 hours after initial drug administration.
- If of childbearing potential, must provide a negative pregnancy test at study entry and prior to the experimental session, and must agree to use adequate birth control from the time of enrollment through 10 days after the experiential session.
- Adequate forms of birth control include double barrier methods, such as:
    - Male condom with diaphragm
    - Male condom with cervical cap
- If possible, highly effective forms of birth control should be used, including:
    - Oral contraceptives
    - Intrauterine device (IUD)
    - Patch
    - Vaginal Ring
    - Injectables
    - Implants
- Provide a contact (relative, spouse, friend, or other caregiver) who is willing and able to be reached by the Principal Investigator in the event of an emergency or if the participant is unreachable.
- Agree to travel to the clinic site and will be responsible for arranging his/her own transportation and accommodation.

- Agree to be delivered to the care of a responsible individual who can observe the participant for the remainder of the 24 hours following initial psilocybin administration.
- Be available for three full days for the trial (dates TBD)
- Be proficient in speaking and reading the predominately used or recognized language of the study site (English).
- Agree to inform the Principal Investigator with 48 hours if any medical conditions occur or medical procedures are planned.
- Agree not to participate in any other interventional clinical trials for the duration of this study.
- Have completed the didactic portion of an approved psilocybin-assisted therapy training program (examples of approved programs include the ATMA Advanced Psychedelic-assisted Therapy Certification Program, CIIS Psychedelic Therapy Training Certificate, and MAPS).

Exclusion Criteria

Applicants will be excluded if they:

- Have active psychotic symptoms (or a history of psychotic symptoms), a diagnosis of bipolar disorder or schizophrenia, or first- or second-degree relatives with a diagnosis or history of the same.
- Present with suicide risk.
- Are on any psychotropic medications including SSRIs, SNRIs, tricyclic anti-depressants, monoamine oxidase inhibitors, anti-psychotics, or lithium. ***(Based on recent trials, we are discussing with Health Canada the possibility that individuals on any class of anti-depressants, other than Monoamine Oxidase Inhibitors, be permitted in the trial).***
- Are on any known uridine diphosphate glucuronosyltransferase enzyme modulators. Inhibitors of UGT1A9 and 1A10 (such as desloratadine, lapatinib, pazopanib, regorafenib, and sorafenib) must be discontinued at least five half-lives prior to psilocybin administration.
- Note: if applicants wish to taper off certain medications in order to be eligible for this study, the tapering process must be supervised by their own physicians and must be fully completed before the experimental session of this study occurs.
- Have any significant medical disorder, including but not limited to dementia/delirium, uncontrolled cardiopulmonary disease, cardiovascular disease, hypertension, aneurysm, history of intracerebral hemorrhage, a high risk for coronary artery disease, hepatic cirrhosis, or hepatorenal disease.
- Have uncontrolled hypertension using the standard criteria of the American Heart Association (≥=140/90 mmHg assessed on three separate occasions by a physician).
- Have a history of ventricular arrhythmia at any time, other than occasional premature ventricular contractions in the absence of ischemic heart disease.
- Have QT prolongation, a history of QT prolongation, or are on medications that carry a risk of QT prolongation.
- Have Wolff-Parkinson-White syndrome or any other accessory pathway that has not been successfully eliminated by ablation.

- Are pregnant, nursing, or not willing to practice an effective means of birth control if they are of childbearing potential.
- Have previous experience with psilocybin demonstrating that it is not well tolerated or have otherwise experienced a significant adverse event after hallucinogen use.
- Have a known sensitivity to psilocybin or its metabolites.

Note: after assessing an applicant's medical data, the Principal Investigator reserves the right to decline enrollment in the trial based on his expert opinion that the applicant is not an appropriate candidate. This is in the best interest of the applicant due to safety reasons.

ATMA Journey Centers Inc, with or without consultation with the Principal Investigator (PI) of the trial, reserves the right to refuse admission of any persons enrolled in the ATMA Advanced Psychedelic-Assisted Therapy Certification Program to participate in the In-person Coaching Intensive and Clinical Trial Experiential Training. If ATMA chooses to disqualify a person from participating, a refund for that portion of the training will be given to that person and they will not receive a certificate of completion of that portion of the Certification Program. If a person chooses to not participate on a voluntary basis for any reason, no refund will be given.