ATMA JOURNEY CENTERS

Clinical Trial Team
March 18, 2023

Clinical Trial Enrolment Information

All students in the Advanced Psychedelic-Assisted Therapy course will be given the opportunity to participate in ATMA's 7 day in-person training program, which includes 3 days of clinical trial participation. Below is an example timeline for the first clinical trial cohort. Please note, the dates listed are tentative and are dependent on final ethics approval, which we expect to be close to the dates provided and will be confirmed as soon as possible. The first cohort will be subject to more logistics than subsequent cohorts because the dates for the first cohort are contingent on when the research ethics board provides approval. Subsequent cohorts will proceed with increased efficiency and information will be available earlier. The remaining 2023 trial dates and locations for the subsequent 2-3 cohorts will be provided in April.

ATMA acknowledges that there is a large amount of information to digest, as well as preparatory work to complete in order to participate in this clinical trial. We will do our best to assist participants with the process, so you will not feel overwhelmed trying to carry out the requirements.

Step 1: Pre-enrolment

April 15 - You must receive a diagnosis of Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), or Occupational Burnout from a General Practitioner (family doctor), psychiatrist, or psychologist in order to be considered for this trial. Mild, moderate, or severe presentations of these disorders are acceptable for admission. Therefore, you should schedule your appointment with one of these medical professionals to receive a diagnosis before enrolment begins on May 22; this will increase the efficiency of the enrolment process. We will need documentation from your doctor, psychiatrist, or psychologist confirming your diagnosis. This documentation is acceptable for up to 6 months after it has been completed, so it will likely cover you for the first and second trial cohort dates. This diagnosis must be attributable to COVID-19, as determined by the COVID Exposure Index, which will be filled out during the enrolment process.

You can also book an appointment in advance with your family physician. Your physician will need to fill out your medical form, and you will also require laboratory tests. The actual appointment must be scheduled for after May 22, but it can be booked in advance to ensure you are able to get an appointment during the required timeframe.

May 15 – We will likely receive approval for the clinical trial protocol and the application form from the research ethics board by May 15.

Step 2: Enrolment

May 22 - The application webpage will open for enrolment on the ATMA website. You must fill out the enrolment application form on this webpage, as well as upload your documentation from your doctor, psychiatrist, or psychologist with your mental health diagnosis. After your application is reviewed, ATMA will provide you with six forms/questionnaires that will help assess your eligibility in the trial, as described below.

After your application is received, we will send you the Physician Form to be completed by your doctor. You must have approval from a family physician before you are accepted in the trial, to ensure you are physically fit to proceed. Your family physician will conduct a personal interview and a physical exam, as well as order laboratory tests including an ECG, routine bloodwork, and urinalysis. Your family physician will fill out the form we provide, indicating any medical conditions that you may have. Before participants are selected for the study, the trial physician will review the medical forms to ensure the applicants are physically healthy. This form is acceptable for up to 6 months after it has been completed by your physician.

- As part of the clinical trial application approved by Health Canada and the research ethics board, you must meet the inclusion/exclusion criteria, which can be viewed here: https://www.atmajourney.com/n500- eligibility-criteria/

After your application form is received, we will provide you with three self-assessment questionnaires to complete. You must meet the cut-off score on at least one of these self-assessments in order to be accepted into the trial:

1. Generalized Anxiety Disorder – 7 (GAD-7): This is a seven item, self-report scale that is a valid and efficient screening tool for generalized anxiety disorder and assessing its severity in clinical practice and research.

2. Quick Inventory of Depressive Symptomatology – Self-Report 16 (QIDS-SR16): This is a 16-item, self-report screening tool for depression, which has been utilized extensively following validation in a number of clinical populations.

3. Burnout Assessment Tool (BAT): This is a 33-item questionnaire that analyzes core and secondary dimensions of occupational burnout, including exhaustion, mental distance, and psychological complaints.

After your application form is submitted, we will provide you with the COVID Exposure Index, which is a short questionnaire designed to determine the impact COVID-19 as had on you as a frontline healthcare worker. This will help us determine if your MDD, GAD, or burnout is attributable to the stresses faced during COVID-19.

After your application form is submitted, we will send you the Informed Consent Form that you must sign in order to be accepted into the trial. This form explains the purpose of the trial, as well as the potential benefits, risks, and procedure, and is required in order to conduct the trial in an ethical manner.

June 22 – All enrolment documents must be submitted at the very latest one month after enrolment opens. This includes the Physician Form, the GAD-7, the QIDS-SR16, the BAT, the COVID Exposure Index, and the Informed Consent Form. Acceptance is based on a first come first serve basis.

June 30 – You must have completed ATMA's Advanced PaT Training Course (or an approved equivalent), as this is a prerequisite for acceptance into the trial.

July 22 – The Principal Investigator will finish reviewing all application forms and will begin compiling the list of approved participants. Only 21 participants will be accepted into this first cohort, but a waitlist will be compiled in case approved participants decide to withdraw.

July 31 – We will have confirmation of the final list of participants.

Step 3: In-person Training & Trial

August 11 – Participants will be emailed the Welcome Package, which will include information regarding data collection commitments, physician follow-up appointments, in-person training overview and schedule, as well as the ATMA Manual that contains details regarding the trial.

August 15 – An email reminder will go out to participants one week prior to the start of the in-person training.

August 22 – 28 – The 7 day in-person training course and orientation will begin on Aug. 22, and the training course and trial will both take place during this 7 day period.

The trial has two outcomes: to demonstrate the efficacy and the utility of psilocybin treatment. In order to gather data that will evaluate these outcomes, several questionnaires will be administered to all participants. It is important that all questionnaires are completed, as this data will help move psilocybin-assisted therapy towards legalization. The psilocybin treatment sessions will take place over 3 days, beginning on Aug. 25; therefore, the precise date each participant will fill out the questionnaires will vary depending on what day the psilocybin is consumed. Below is a

general list detailing the schedule for each questionnaire:

-Fill out the GAD-7: 1-2 days before the psilocybin session, 2 days after the psilocybin session, 7 days after, 4-6 weeks after, and 8 weeks after.

-Fill out the QIDS-SR16: 1-2 days before the psilocybin session, 2 days after the psilocybin session, 7 days after, 4-6 weeks after, and 8 weeks after.

-Fill out the BAT: 1-2 days before the psilocybin session, 2 days after the psilocybin session, 7 days after, 4-6 weeks after, and 8 weeks after.

-Fill out the ATMA Questionnaire for Treatment Satisfaction with Psilocybin: 2 and 7 days after the psilocybin session.

The Principal Investigator will also assess any adverse events both 2 days and 7 days after the psilocybin sessions.

Of note, while not everyone may qualify to ingest psilocybin as part of the clinical trial, everyone is still able to participate as a "guide/facilitator" in the 7 day in-person training program. In this role, you will learn how to facilitate a psilocybin experience by providing unobtrusive support for trial participants who are ingesting psilocybin.

Step 4: Follow-up

October 22-28 – Two months after the psilocybin session, participants will be required to meet with their family doctor to have a final assessment of vital signs. The Follow-up Physician Form will be submitted to ATMA following your appointment. Participants will also have a final phone follow-up with the Principal Investigator of this study to conduct a final assessment of adverse events.