

Winter 2018

Re: MAPP1 - A Randomized, Double-Blind, Placebo-Controlled, Multi-Site Phase 3 Study of the Efficacy and Safety of Manualized MDMA-Assisted Psychotherapy for the Treatment of Severe Posttraumatic Stress Disorder

Dear Treatment Provider:

We are recruiting participants for a clinical trial who have significant symptoms of PTSD which have lasted for at least six months. We would appreciate your referring or calling to discuss any potential participants you think might be suitable.

We created this message out of a reflection on and commitment to making MDMA-assisted psychotherapy accessible, inclusive, and relevant to people and communities suffering from trauma. As many of you know, there has been a lack of inclusion of people of color in clinical research generally, and psychedelic research specifically. Marginalized communities face disproportionate rates of trauma exposure and PTSD and deserve access to effective treatment options.

This multi-site, randomized, double-blind study assesses the efficacy and safety of MDMA assisted psychotherapy versus psychotherapy with placebo control in participants diagnosed with at least severe PTSD. Previous Phase 2 clinical trials support MDMA-assisted psychotherapy as a beneficial treatment for PTSD; over 60% of participants did not qualify for a PTSD diagnosis 1 year after three treatments and associated therapy. MDMA is expected to assist participants in processing trauma-related memories and emotions in a safer setting.

In this study, a flexible dose of study drug (MDMA or placebo), followed by a supplemental half-dose unless contraindicated, is administered on three occasions during day-long Experimental Sessions about a month apart. Following each Experimental Session, the participant spends the night with an attendant on duty and study staff then follows up with participants on four occasions in the following week. The ~12-week Treatment Period is preceded by three Preparatory Sessions. During the Treatment Period, each Experimental Session is followed by three Integrative Sessions of non-drug psychotherapy. All therapy sessions will follow the MDMA-assisted psychotherapy manual. The Primary Outcome measure is the change in CAPS-5 (Clinician-Administered PTSD Scale for DSM-5) from Baseline.

The minimum time a participant who completes all study visits from screening will be in the clinical trial is 19 weeks, and the maximum is 38 weeks. The average time expected for a participant to complete the study in 27 weeks.



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If you would like a copy of the protocol synopsis, the informed consent form, the sponsor's review of the MDMA literature or any other information, please do not hesitate to contact me. We look forward to considering any potential referrals as candidates for this study. Please let us know if there are any other therapists or service providers who should receive this information.

Please request that potential participants contact the following sites directly, noting in the subject line that they were referred by you, and if they feel comfortable sharing their racial background. This helps us prioritize people of color for participation in the study.

Contact information for sites in the US, Canada, and Israel is available on ClinicalTrials.gov, under Identifier number: NCT03537014.