Canada

MDMA trials under review in Canada over alleged abuse of study participants

Health Canada confirms reviews into trials following complaint of 'alleged investigator misconduct'

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All clinical trials into the psychoactive drug MDMA are being reviewed by Canadian regulators after complaints about abuse of study participants by a trailblazing American psychedelic research organization.

The California-based Multidisciplinary Association for Psychedelic Studies (Maps) has led the way in conducting trials into the medicinal qualities of the drug. In May 2021, it released results from a phase-three trial in the journal Nature on the benefits of the drug - commonly sold illegally as a powder or within ecstasy tablets - as a breakthrough treatment for PTSD, for which there is currently no effective pharmaceutical treatment.

But the government regulator Health Canada confirmed it had announced a review into the MDMA clinical trials sponsored by Maps that have in part been conducted in Canada, following a complaint that detailed “alleged investigator misconduct”.

The complaint was lodged by the producers of the New York magazine podcast Cover Story: Power Trip, who heard testimony from several former trial participants complaining about their treatment sessions with MDMA and psychotherapy.

In one 2015 incident, a video obtained and shared by Meaghan Buisson, a patient suffering from PTSD, shows two therapists guiding her through an MDMA session in Vancouver while spooning and restraining her in a professed attempt to help her relive her sexual assaults as a way to heal.

One of the therapists, Richard Yensen, whose psychology license had lapsed years earlier, said he had consensual sex with Buisson after the experimental therapy sessions had ended but while she was still part of the trial. Buisson accused him of sexual assault constituting battery. Canadian police passed the file to prosecutors, who chose not to take the case forward.

Buisson had initially pursued the therapy further by moving to live close to Yensen and his wife, Donna Dryer, the other therapist in the case in question, who did have a psychology license. Maps only required that one person per team be a licensed therapist.

At first Buisson spoke positively about it, and is quoted on the Maps website: “Therapeutic breakthroughs occur on the edge of consent. They pushed me hard, my toes curling in protest. But each time I fell they were there … I was literally loved back to life.”

Buisson later began to criticize her treatment and seek action, starting with a 2018 civil claim that went to the supreme court of British Columbia the following year before being settled out of court.

The complaint submitted by the podcast creators also alleged that three other patients across the trials expressed worsening suicidal thoughts and that these were incorrectly not logged as adverse events. Participants were required to stop taking antidepressant medication, and one tried to admit himself to a hospital psychiatric ward after his mental health worsened, though it is understood this patient quit their medication cold turkey, contrary to the agreement required to participate in the trial.

Maps was criticised in the podcast for taking until 2021 to watch the videos, though it said ties were cut with the therapists in 2018 due to “ethical misconduct”. Its protective measures at the time included having two therapists present - though only one needed to be licensed - and the recording of all visits, as well as the monitoring of study records. But mandatory viewing of all videos was not in place, and Buisson obtained the video years later, after asking Maps for it.

“The loving and trusting feelings that can be induced by MDMA can make patients more vulnerable to sexual pressure,” Maps’ founder, Rick Doblin, wrote in his 2000 doctoral thesis.

Maps, which has a detailed study safety protocol, first publicly acknowledged the episode in May 2019 after Buisson spoke out. The organization said its code of ethics policy that forbade sexual relationships between therapists and patients had been breached, though it said it had not seen anything at the time to suggest the code was being violated. It gave Buisson $15,000 to obtain therapy while her legal action was ongoing, and announced it had cut ties with both therapists.

Betty Aldworth, director of communications at Maps, said: “Any treatment that involves processing trauma might lead to worsening symptoms. Knowing all of that, we have worked to develop a treatment protocol that is supportive for most participants within the constraints of clinical trials, but look forward to a day when MDMA-assisted therapy may be approved and clinicians can collaborate with patients to individualize the timing of treatments and integration approaches.”

Despite multimillion-dollar companies such as US-based Atai Life Sciences and Compass Pathways going public on the Nasdaq as authorities loosen controls over psychedelic drug research, some psychedelic advocates are growing concerned that drugs such as MDMA, psilocybin and LSD are being cast as panaceas before research into the best ways to treat vulnerable patients is complete.

“Maps is trying to be too many things,” said one psychotherapist who worked on Maps MDMA trials and does not wish to be named for fear of professional backlash. “They need to slow down and focus on the research that’s actually being done, and doing quality long-term follow-ups while listening to and providing for their trial participants when they’re saying, ‘I need extra support.’”

David Nickles, an expert on the nascent psychedelic industry and co-creator of the podcast, has called on the US Food and Drug Administration to also review all MDMA trials.

“I’m concerned that the regulatory agencies involved in overseeing this research are not attending to the psychotherapy aspect of MDMA clinical trials,” he said. “A full audit of all video footage and trial data is necessary, with particular attention to the psychotherapy.”

The podcast team said Maps provided them with “more than five conflicting answers about who had watched the videos and when”.

Aldworth said: “Based on the information available to me at the time, I did inaccurately state that no one at MAPS had reviewed the participant videos. When I became aware of the error, I sent a correction updating our response. During the course of the trial, a portion of one video was reviewed but did not signal concerns of an ethical violation. I regret the error and any distress our lack of clarity has caused for the participant.”

She added that Maps provides unlimited additional integration sessions in the months between the final session and the final study visit.

A Health Canada spokesperson confirmed the complaint had spurred it to review all previously authorized clinical trial applications involving MDMA. It says it has requested additional information from Maps specifically regarding adverse events, efficacy data and participant complaints.

“The department will take appropriate action as necessary if any deficiencies or non-compliance are found,” the spokesperson said, adding that complaints have been rare and reiterating the government’s commitment to reducing mental illness across the country.

The government review is scheduled to be completed next month. Potential actions could include the suspension or cancellation of trials should Health Canada determine an immediate safety risk to participants. It can also refer contraventions of the Food and Drugs Act to public prosecutors.

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