Ask MAPS Anything

Grace Cepe

*Since its inception in 1997, AskMAPS (**maps.org/askmaps**) has answered thousands of inquiries about psychedelics, therapy, and research each year. MAPS' Communications Associate Grace Cepe connects with the psychedelic community and provides educational resources through AskMAPS.*

Hello-

As I understand it, placebos are typically used as part of single and double-blind studies. Given the nature of the MDMA experience, can you help me understand how anyone participating wouldn't immediately know whether they had taken a placebo versus MDMA?

More to the point — what purpose is being served by this? I do not understand a medical community that would ask people suffering so terribly to go through what they will immediately know is a sham process.

Placebos are necessary tools for single and double-blind studies, no question. But here, they feel like a needlessly cruel requirement imposed by those who have never experienced the pain of mental illness themselves.

My son is slowly dying from the impacts of PTSD. I believe MDMA and/or other psychedelic treatments are his best, last hope. He has tried everything else. What he needs is an awakening beyond all the talk. An experience that offers a new "knowing" that will allow him to begin to move beyond his trauma, his grief and his overwhelming shame and loss, in a way that no other therapy ever has or could. Like I said, he's dying. Even so, I would never subject him to the risk of being selected (HOPE!) only to discover he is the guinea pig on placebo. "Give us your time, son. Your pain. Your dark thoughts. In return, we'll give you nothing you haven't been through before. You exist for the benefit of our experiment. You'll be made to suffer for the good of those who get 'the real thing'."

I would love nothing more than for you to tell me why I am wrong. I would be thrilled to see the evidence that says this is something other than inhumane.

I don't expect a response. I know I am writing to an organization. And I am grateful for what MAPS is trying to accomplish, but the process?

I want my son to be free from this torture.

So I wish you success. But please, don't hurt someone else's sons in the process.

Grace Cepe serves as the Communications Associate for MAPS. She has a B.A. in psychology from the University of California, Santa Cruz (UCSC). At UCSC, Grace was a research assistant for the social psychology department's Sexual and Gender Diversity Laboratory, instructor's assistant for the Introduction to Psychology course, and residential counselor intern for at-risk youth. Before joining MAPS as Communications Associate, Grace volunteered with MAPS and the San Francisco Psychedelic Society and has been an activist with Decriminalize Santa Cruz. Since attending MAPS' Psychedelic Science Conference in 2017, Grace's interests in psychedelics evolved from a primary focus on the clinical applications of psychedelics and into Indigenous ways of life and ceremonial uses, human rights, social justice, and increasing inclusivity and diversity in the field of psychedelics. Outside of her psychedelic work, Grace loves getting involved with her community, spending time in nature, hip-hop and salsa dancing, and getting lost in a good book.

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You're correct: placebos are used in blinded studies, and in this case the study was double-blinded (neither the therapists of participants were told what they received) and independent raters measured the PTSD symptoms to increase objectivity. We were grateful and relieved to see that, even among the participants who received placebo, many experienced clinically significant improvements after the therapy. We pay careful and close attention to all participants' mental health during the trials.

I'll try to get to each of your questions.

The placebo itself is selected to mimic some of the physical effects of MDMA. While the nature of the experience is quite unmistakable under many circumstances, it is the case that there were participants and therapists who didn't know which group they were in until after the study was unblinded.

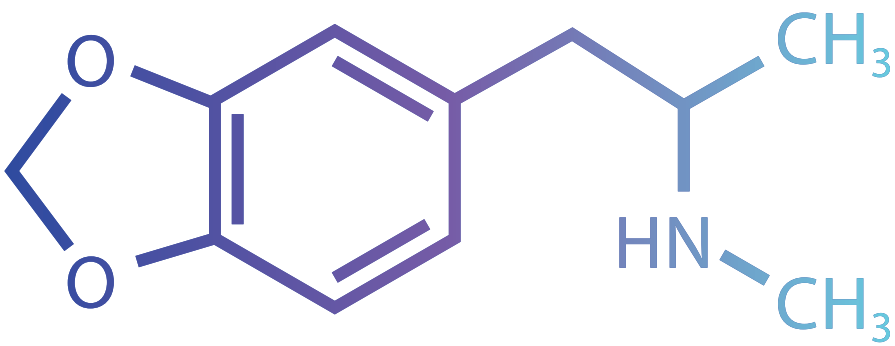
The study was designed to measure outcomes specific to the FDA's requirements, and in this case the biggest question (or primary outcome) was: is MDMA-assisted therapy more efficacious than therapy alone? For that, the FDA required that we split participants into a control group and a placebo group. While we design many elements of the study, we also are required to meet the FDA standards for drug development trials. Please understand that we are not the ones that set up these standards, we are simply abiding by what regulatory and medical authorities request.

Thankfully, we did receive breakthrough therapy status, which means we were able to work directly with the FDA to design a study that would meet the scientific standard. We also applied for and were granted permission to run an expanded access trial with 50 participants prior to approval. I know 50 seems like a tiny number when the need is so great — but that's 50 people who will be able to receive treatment without the study blind (they'll all receive MDMA). Perhaps he lives within the FDA-mandated distance from an expanded access site? Those will be announced soon.

I wish so much that I had more satisfying answers for you than "this is the system we're working in, and these are the choices we have to make." I don't. We have to do the best scientifically rigorous work we can. And we know that millions and millions have suffered since MDMA was made illegal in 1985 despite it's obvious potential even then. We're right there with you: not a single person should have to suffer an extra day because of it. We do this work for your son -- and our own families and communities. It will never be fast enough for us, either.

To healing for all,

Grace



Molecular compound of MDMA